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► B **COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011**
of 25 May 2011
implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as
regards the list of approved active substances
(Text with EEA relevance)
(OJ L 153, 11.6.2011, p. 1)

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► <u>M203</u>	Commission Implementing Regulation (EU) 2017/359 of 28 February 2017	L 54	8	1.3.2017
► <u>M204</u>	Commission Implementing Regulation (EU) 2017/360 of 28 February 2017	L 54	11	1.3.2017
► <u>M205</u>	Commission Implementing Regulation (EU) 2017/375 of 2 March 2017	L 58	3	4.3.2017
► <u>M206</u>	Commission Implementing Regulation (EU) 2017/406 of 8 March 2017	L 63	83	9.3.2017
► <u>M207</u>	Commission Implementing Regulation (EU) 2017/407 of 8 March 2017	L 63	87	9.3.2017
► <u>M208</u>	Commission Implementing Regulation (EU) 2017/408 of 8 March 2017	L 63	91	9.3.2017
► <u>M209</u>	Commission Implementing Regulation (EU) 2017/409 of 8 March 2017	L 63	95	9.3.2017
► <u>M210</u>	Commission Implementing Regulation (EU) 2017/419 of 9 March 2017	L 64	4	10.3.2017
► <u>M211</u>	Commission Implementing Regulation (EU) 2017/428 of 10 March 2017	L 66	1	11.3.2017
► <u>M212</u>	Commission Implementing Regulation (EU) 2017/438 of 13 March 2017	L 67	67	14.3.2017
► <u>M213</u>	Commission Implementing Regulation (EU) 2017/555 of 24 March 2017	L 80	1	25.3.2017
► <u>M214</u>	Commission Implementing Regulation (EU) 2017/725 of 24 April 2017	L 107	24	25.4.2017
► <u>M215</u>	Commission Implementing Regulation (EU) 2017/753 of 28 April 2017	L 113	24	29.4.2017
► <u>M216</u>	Commission Implementing Regulation (EU) 2017/755 of 28 April 2017	L 113	35	29.4.2017
► <u>M217</u>	Commission Implementing Regulation (EU) 2017/781 of 5 May 2017	L 118	1	6.5.2017

► <u>M218</u>	Commission Implementing Regulation (EU) 2017/805 of 11 May 2017	L 121	26	12.5.2017
► <u>M219</u>	Commission Implementing Regulation (EU) 2017/806 of 11 May 2017	L 121	31	12.5.2017
► <u>M220</u>	Commission Implementing Regulation (EU) 2017/831 of 16 May 2017	L 124	27	17.5.2017
► <u>M221</u>	Commission Implementing Regulation (EU) 2017/841 of 17 May 2017	L 125	12	18.5.2017
► <u>M222</u>	Commission Implementing Regulation (EU) 2017/842 of 17 May 2017	L 125	16	18.5.2017
► <u>M223</u>	Commission Implementing Regulation (EU) 2017/843 of 17 May 2017	L 125	21	18.5.2017
► <u>M224</u>	Commission Implementing Regulation (EU) 2017/855 of 18 May 2017	L 128	10	19.5.2017
► <u>M225</u>	Commission Implementing Regulation (EU) 2017/856 of 18 May 2017	L 128	14	19.5.2017
► <u>M226</u>	Commission Implementing Regulation (EU) 2017/1113 of 22 June 2017	L 162	27	23.6.2017
► <u>M227</u>	Commission Implementing Regulation (EU) 2017/1114 of 22 June 2017	L 162	32	23.6.2017
► <u>M228</u>	Commission Implementing Regulation (EU) 2017/1115 of 22 June 2017	L 162	38	23.6.2017
► <u>M229</u>	Commission Implementing Regulation (EU) 2017/1125 of 22 June 2017	L 163	10	24.6.2017
► <u>M230</u>	Commission Implementing Regulation (EU) 2017/1186 of 3 July 2017	L 171	131	4.7.2017
► <u>M231</u>	Commission Implementing Regulation (EU) 2017/1455 of 10 August 2017	L 208	28	11.8.2017
► <u>M232</u>	Commission Implementing Regulation (EU) 2017/1491 of 21 August 2017	L 216	15	22.8.2017
► <u>M233</u>	Commission Implementing Regulation (EU) 2017/1496 of 23 August 2017	L 218	7	24.8.2017
► <u>M234</u>	Commission Implementing Regulation (EU) 2017/1506 of 28 August 2017	L 222	21	29.8.2017
► <u>M235</u>	Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017	L 224	115	31.8.2017
► <u>M236</u>	Commission Implementing Regulation (EU) 2017/1527 of 6 September 2017	L 231	3	7.9.2017
► <u>M237</u>	Commission Implementing Regulation (EU) 2017/1529 of 7 September 2017	L 232	1	8.9.2017
► <u>M238</u>	Commission Implementing Regulation (EU) 2017/1530 of 7 September 2017	L 232	4	8.9.2017
► <u>M239</u>	Commission Implementing Regulation (EU) 2017/1531 of 7 September 2017	L 232	6	8.9.2017
► <u>M240</u>	Commission Implementing Regulation (EU) 2017/2066 of 13 November 2017	L 295	43	14.11.2017
► <u>M241</u>	Commission Implementing Regulation (EU) 2017/2069 of 13 November 2017	L 295	51	14.11.2017
► <u>M242</u>	Commission Implementing Regulation (EU) 2017/2090 of 14 November 2017	L 297	22	15.11.2017
► <u>M243</u>	Commission Implementing Regulation (EU) 2017/2091 of 14 November 2017	L 297	25	15.11.2017
► <u>M244</u>	Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017	L 333	10	15.12.2017

► <u>M245</u>	Commission Implementing Regulation (EU) 2018/84 of 19 January 2018	L 16	8	20.1.2018
► <u>M246</u>	Commission Implementing Regulation (EU) 2018/112 of 24 January 2018	L 20	3	25.1.2018
► <u>M247</u>	Commission Implementing Regulation (EU) 2018/113 of 24 January 2018	L 20	7	25.1.2018
► <u>M248</u>	Commission Implementing Regulation (EU) 2018/184 of 7 February 2018	L 34	10	8.2.2018
► <u>M249</u>	Commission Implementing Regulation (EU) 2018/185 of 7 February 2018	L 34	13	8.2.2018
► <u>M250</u>	Commission Implementing Regulation (EU) 2018/291 of 26 February 2018	L 55	30	27.2.2018
► <u>M251</u>	Commission Implementing Regulation (EU) 2018/309 of 1 March 2018	L 60	16	2.3.2018
► <u>M252</u>	Commission Implementing Regulation (EU) 2018/524 of 28 March 2018	L 88	4	4.4.2018
► <u>M253</u>	Commission Implementing Regulation (EU) 2018/660 of 26 April 2018	L 110	122	30.4.2018
► <u>M254</u>	Commission Implementing Regulation (EU) 2018/670 of 30 April 2018	L 113	1	3.5.2018
► <u>M255</u>	Commission Implementing Regulation (EU) 2018/679 of 3 May 2018	L 114	18	4.5.2018
► <u>M256</u>	Commission Implementing Regulation (EU) 2018/690 of 7 May 2018	L 117	3	8.5.2018
► <u>M257</u>	Commission Implementing Regulation (EU) 2018/691 of 7 May 2018	L 117	6	8.5.2018
► <u>M258</u>	Commission Implementing Regulation (EU) 2018/692 of 7 May 2018	L 117	9	8.5.2018
► <u>M259</u>	Commission Implementing Regulation (EU) 2018/710 of 14 May 2018	L 119	31	15.5.2018
► <u>M260</u>	Commission Implementing Regulation (EU) 2018/755 of 23 May 2018	L 128	4	24.5.2018
► <u>M261</u>	Commission Implementing Regulation (EU) 2018/783 of 29 May 2018	L 132	31	30.5.2018
► <u>M262</u>	Commission Implementing Regulation (EU) 2018/784 of 29 May 2018	L 132	35	30.5.2018
► <u>M263</u>	Commission Implementing Regulation (EU) 2018/785 of 29 May 2018	L 132	40	30.5.2018
► <u>M264</u>	Commission Implementing Regulation (EU) 2018/917 of 27 June 2018	L 163	13	28.6.2018
► <u>M265</u>	Commission Implementing Regulation (EU) 2018/1019 of 18 July 2018	L 183	14	19.7.2018
► <u>M266</u>	Commission Implementing Regulation (EU) 2018/1043 of 24 July 2018	L 188	9	25.7.2018
► <u>M267</u>	Commission Implementing Regulation (EU) 2018/1060 of 26 July 2018	L 190	3	27.7.2018
► <u>M268</u>	Commission Implementing Regulation (EU) 2018/1061 of 26 July 2018	L 190	8	27.7.2018
► <u>M269</u>	Commission Implementing Regulation (EU) 2018/1075 of 27 July 2018	L 194	36	31.7.2018
► <u>M270</u>	Commission Implementing Regulation (EU) 2018/1260 of 20 September 2018	L 238	30	21.9.2018
► <u>M271</u>	Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018	L 238	62	21.9.2018
► <u>M272</u>	Commission Implementing Regulation (EU) 2018/1264 of 20 September 2018	L 238	71	21.9.2018
► <u>M273</u>	Commission Implementing Regulation (EU) 2018/1265 of 20 September 2018	L 238	77	21.9.2018

► <u>M274</u>	Commission Implementing Regulation (EU) 2018/1266 of L 238	81	21.9.2018
► <u>M275</u>	Commission Implementing Regulation (EU) 2018/1278 of L 239	4	24.9.2018
► <u>M276</u>	Commission Implementing Regulation (EU) 2018/1295 of L 243	7	27.9.2018
► <u>M277</u>	Commission Implementing Regulation (EU) 2018/1495 of 8 October 2018	L 253	1 9.10.2018
► <u>M278</u>	Commission Implementing Regulation (EU) 2018/1500 of 9 October 2018	L 254	1 10.10.2018
► <u>M279</u>	Commission Implementing Regulation (EU) 2018/1501 of 9 October 2018	L 254	4 10.10.2018
► <u>M280</u>	Commission Implementing Regulation (EU) 2018/1532 of 12 October 2018	L 257	10 15.10.2018
► <u>M281</u>	Commission Implementing Regulation (EU) 2018/1796 of L 294	15	21.11.2018
► <u>M282</u>	Commission Implementing Regulation (EU) 2018/1865 of L 304	6	29.11.2018
► <u>M283</u>	Commission Implementing Regulation (EU) 2018/1913 of L 311	13	7.12.2018
► <u>M284</u>	Commission Implementing Regulation (EU) 2018/1914 of L 311	17	7.12.2018
► <u>M285</u>	Commission Implementing Regulation (EU) 2018/1915 of L 311	20	7.12.2018
► <u>M286</u>	Commission Implementing Regulation (EU) 2018/1916 of L 311	24	7.12.2018
► <u>M287</u>	Commission Implementing Regulation (EU) 2018/1917 of L 311	27	7.12.2018
► <u>M288</u>	Commission Implementing Regulation (EU) 2018/1981 of L 317	16	14.12.2018
► <u>M289</u>	Commission Implementing Regulation (EU) 2019/139 of 29 January 2019	L 26	4 30.1.2019
► <u>M290</u>	Commission Implementing Regulation (EU) 2019/147 of 30 January 2019	L 27	14 31.1.2019
► <u>M291</u>	Commission Implementing Regulation (EU) 2019/149 of 30 January 2019	L 27	20 31.1.2019
► <u>M292</u>	Commission Implementing Regulation (EU) 2019/151 of 30 January 2019	L 27	26 31.1.2019
► <u>M293</u>	Commission Implementing Regulation (EU) 2019/158 of 31 January 2019	L 31	21 1.2.2019
► <u>M294</u>	Commission Implementing Regulation (EU) 2019/168 of 31 January 2019	L 33	1 5.2.2019
► <u>M295</u>	Commission Implementing Regulation (EU) 2019/291 of 19 February 2019	L 48	17 20.2.2019
► <u>M296</u>	Commission Implementing Regulation (EU) 2019/324 of 25 February 2019	L 57	1 26.2.2019
► <u>M297</u>	Commission Implementing Regulation (EU) 2019/337 of 27 February 2019	L 60	12 28.2.2019
► <u>M298</u>	Commission Implementing Regulation (EU) 2019/344 of 28 February 2019	L 62	7 1.3.2019
► <u>M299</u>	Commission Implementing Regulation (EU) 2019/481 of 22 March 2019	L 82	19 25.3.2019
► <u>M300</u>	Commission Implementing Regulation (EU) 2019/676 of 29 April 2019	L 114	12 30.4.2019

► <u>M301</u>	Commission Implementing Regulation (EU) 2019/677 of 29 April 2019	L 114	15	30.4.2019
► <u>M302</u>	Commission Implementing Regulation (EU) 2019/706 of 7 May 2019	L 120	11	8.5.2019
► <u>M303</u>	Commission Implementing Regulation (EU) 2019/707 of 7 May 2019	L 120	16	8.5.2019
► <u>M304</u>	Commission Implementing Regulation (EU) 2019/716 of 30 April 2019	L 122	39	10.5.2019
► <u>M305</u>	Commission Implementing Regulation (EU) 2019/717 of 8 May 2019	L 122	44	10.5.2019
► <u>M306</u>	Commission Implementing Regulation (EU) 2019/989 of 17 June 2019	L 160	11	18.6.2019
► <u>M307</u>	Commission Implementing Regulation (EU) 2019/1085 of 25 June 2019	L 171	110	26.6.2019
► <u>M308</u>	Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019	L 173	39	27.6.2019
► <u>M309</u>	Commission Implementing Regulation (EU) 2019/1100 of 27 June 2019	L 175	17	28.6.2019
► <u>M310</u>	Commission Implementing Regulation (EU) 2019/1101 of 27 June 2019	L 175	20	28.6.2019
► <u>M311</u>	Commission Implementing Regulation (EU) 2019/1137 of 3 July 2019	L 180	3	4.7.2019
► <u>M312</u>	Commission Implementing Regulation (EU) 2019/1138 of 3 July 2019	L 180	8	4.7.2019
► <u>M313</u>	Commission Implementing Regulation (EU) 2019/1589 of 26 September 2019	L 248	24	27.9.2019
► <u>M314</u>	Commission Implementing Regulation (EU) 2019/1605 of 27 September 2019	L 250	49	30.9.2019
► <u>M315</u>	Commission Implementing Regulation (EU) 2019/1606 of 27 September 2019	L 250	53	30.9.2019
► <u>M316</u>	Commission Implementing Regulation (EU) 2019/1675 of 4 October 2019	L 257	6	8.10.2019
► <u>M317</u>	Commission Implementing Regulation (EU) 2019/1690 of 9 October 2019	L 259	2	10.10.2019
► <u>M318</u>	Commission Implementing Regulation (EU) 2019/2094 of 29 November 2019	L 317	102	9.12.2019
► <u>M319</u>	Commission Implementing Regulation (EU) 2020/17 of 10 January 2020	L 7	11	13.1.2020
► <u>M320</u>	Commission Implementing Regulation (EU) 2020/18 of 10 January 2020	L 7	14	13.1.2020
► <u>M321</u>	Commission Implementing Regulation (EU) 2020/23 of 13 January 2020	L 8	8	14.1.2020
► <u>M322</u>	Commission Implementing Regulation (EU) 2020/421 of 18 March 2020	L 84	7	20.3.2020
► <u>M323</u>	Commission Implementing Regulation (EU) 2020/616 of 5 May 2020	L 143	1	6.5.2020
► <u>M324</u>	Commission Implementing Regulation (EU) 2020/617 of 5 May 2020	L 143	6	6.5.2020
► <u>M325</u>	Commission Implementing Regulation (EU) 2020/642 of 12 May 2020	L 150	134	13.5.2020
► <u>M326</u>	Commission Implementing Regulation (EU) 2020/646 of 13 May 2020	L 151	3	14.5.2020

► <u>M327</u>	Commission Implementing Regulation (EU) 2020/653 of 14 May 2020	L 152	1	15.5.2020
► <u>M328</u>	Commission Implementing Regulation (EU) 2020/869 of 24 June 2020	L 201	7	25.6.2020
► <u>M329</u>	Commission Implementing Regulation (EU) 2020/892 of 29 June 2020	L 206	5	30.6.2020
► <u>M330</u>	Commission Implementing Regulation (EU) 2020/968 of 3 July 2020	L 213	7	6.7.2020
► <u>M331</u>	Commission Implementing Regulation (EU) 2020/1003 of 9 July 2020	L 221	127	10.7.2020
► <u>M332</u>	Commission Implementing Regulation (EU) 2020/1004 of 9 July 2020	L 221	133	10.7.2020
► <u>M333</u>	Commission Implementing Regulation (EU) 2020/1018 of 13 July 2020	L 225	9	14.7.2020
► <u>M334</u>	Commission Implementing Regulation (EU) 2020/1160 of 5 August 2020	L 257	29	6.8.2020
► <u>M335</u>	Commission Implementing Regulation (EU) 2020/1246 of 2 September 2020	L 288	18	3.9.2020
► <u>M336</u>	Commission Implementing Regulation (EU) 2020/1263 of 10 September 2020	L 297	1	11.9.2020
► <u>M337</u>	Commission Implementing Regulation (EU) 2020/1276 of 11 September 2020	L 300	32	14.9.2020
► <u>M338</u>	Commission Implementing Regulation (EU) 2020/1280 of 14 September 2020	L 301	4	15.9.2020
► <u>M339</u>	Commission Implementing Regulation (EU) 2020/1293 of 15 September 2020	L 302	24	16.9.2020
► <u>M340</u>	Commission Implementing Regulation (EU) 2020/1498 of 15 October 2020	L 342	5	16.10.2020
► <u>M341</u>	Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020	L 344	18	19.10.2020
► <u>M342</u>	Commission Implementing Regulation (EU) 2020/1643 of 5 November 2020	L 370	18	6.11.2020
► <u>M343</u>	Commission Implementing Regulation (EU) 2020/2007 of 8 December 2020	L 414	10	9.12.2020
► <u>M344</u>	Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020	L 423	50	15.12.2020
► <u>M345</u>	Commission Implementing Regulation (EU) 2020/2101 of 15 December 2020	L 425	79	16.12.2020
► <u>M346</u>	Commission Implementing Regulation (EU) 2020/2104 of 15 December 2020	L 425	93	16.12.2020
► <u>M347</u>	Commission Implementing Regulation (EU) 2020/2105 of 15 December 2020	L 425	96	16.12.2020
► <u>M348</u>	Commission Implementing Regulation (EU) 2021/52 of 22 January 2021	L 23	13	25.1.2021
► <u>M349</u>	Commission Implementing Regulation (EU) 2021/81 of 27 January 2021	L 29	12	28.1.2021

► <u>M350</u>	Commission Implementing Regulation (EU) 2021/129 of 3 February 2021	L 40	11	4.2.2021
► <u>M351</u>	Commission Implementing Regulation (EU) 2021/134 of 4 February 2021	L 42	4	5.2.2021
► <u>M352</u>	Commission Implementing Regulation (EU) 2021/413 of 8 March 2021	L 81	32	9.3.2021
► <u>M353</u>	Commission Implementing Regulation (EU) 2021/427 of 10 March 2021	L 84	21	11.3.2021
► <u>M354</u>	Commission Implementing Regulation (EU) 2021/459 of 16 March 2021	L 91	4	17.3.2021
► <u>M355</u>	Commission Implementing Regulation (EU) 2021/556 of 31 March 2021	L 115	26	6.4.2021
► <u>M356</u>	Commission Implementing Regulation (EU) 2021/566 of 30 March 2021	L 118	1	7.4.2021
► <u>M357</u>	Commission Implementing Regulation (EU) 2021/567 of 6 April 2021	L 118	6	7.4.2021
► <u>M358</u>	Commission Implementing Regulation (EU) 2021/574 of 30 March 2021	L 120	9	8.4.2021
► <u>M359</u>	Commission Implementing Regulation (EU) 2021/726 of 4 May 2021	L 155	20	5.5.2021
► <u>M360</u>	Commission Implementing Regulation (EU) 2021/745 of 6 May 2021	L 160	89	7.5.2021
► <u>M361</u>	Commission Implementing Regulation (EU) 2021/795 of 17 May 2021	L 174	2	18.5.2021
► <u>M362</u>	Commission Implementing Regulation (EU) 2021/824 of 21 May 2021	L 183	35	25.5.2021
► <u>M363</u>	Commission Implementing Regulation (EU) 2021/843 of 26 May 2021	L 186	20	27.5.2021
► <u>M364</u>	Commission Implementing Regulation (EU) 2021/853 of 27 May 2021	L 188	56	28.5.2021
► <u>M365</u>	Commission Implementing Regulation (EU) 2021/917 of 7 June 2021	L 201	19	8.6.2021
► <u>M366</u>	Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021	L 258	37	20.7.2021
► <u>M367</u>	Commission Implementing Regulation (EU) 2021/1379 of 19 August 2021	L 297	32	20.8.2021
► <u>M368</u>	Commission Implementing Regulation (EU) 2021/1446 of 3 September 2021	L 313	9	6.9.2021
► <u>M369</u>	Commission Implementing Regulation (EU) 2021/1448 of 3 September 2021	L 313	15	6.9.2021
► <u>M370</u>	Commission Implementing Regulation (EU) 2021/1449 of 3 September 2021	L 313	20	6.9.2021
► <u>M371</u>	Commission Implementing Regulation (EU) 2021/1450 of 3 September 2021	L 313	25	6.9.2021
► <u>M372</u>	Commission Implementing Regulation (EU) 2021/1452 of 3 September 2021	L 313	30	6.9.2021
► <u>M373</u>	Commission Implementing Regulation (EU) 2021/1455 of 6 September 2021	L 315	1	7.9.2021
► <u>M374</u>	Commission Implementing Regulation (EU) 2021/2049 of 24 November 2021	L 420	6	25.11.2021
► <u>M375</u>	Commission Implementing Regulation (EU) 2021/2068 of 25 November 2021	L 421	25	26.11.2021
► <u>M376</u>	Commission Implementing Regulation (EU) 2021/2081 of 26 November 2021	L 426	28	29.11.2021

► <u>M377</u>	Commission Implementing Regulation (EU) 2022/4 of 4 January 2022	L 1	5	5.1.2022
► <u>M378</u>	Commission Implementing Regulation (EU) 2022/19 of 7 January 2022	L 5	9	10.1.2022
► <u>M379</u>	Commission Implementing Regulation (EU) 2022/43 of 13 January 2022	L 9	7	14.1.2022
► <u>M380</u>	Commission Implementing Regulation (EU) 2022/94 of 24 January 2022	L 16	33	25.1.2022
► <u>M381</u>	Commission Implementing Regulation (EU) 2022/159 of 4 February 2022	L 26	7	7.2.2022
► <u>M382</u>	Commission Implementing Regulation (EU) 2022/378 of 4 March 2022	L 72	2	7.3.2022
► <u>M383</u>	Commission Implementing Regulation (EU) 2022/383 of 4 March 2022	L 76	1	7.3.2022
► <u>M384</u>	Commission Implementing Regulation (EU) 2022/437 of 16 March 2022	L 89	3	17.3.2022
► <u>M385</u>	Commission Implementing Regulation (EU) 2022/456 of 21 March 2022	L 93	138	22.3.2022
► <u>M386</u>	Commission Implementing Regulation (EU) 2022/489 of 25 March 2022	L 100	7	28.3.2022
► <u>M387</u>	Commission Implementing Regulation (EU) 2022/496 of 28 March 2022	L 101	1	29.3.2022
► <u>M388</u>	Commission Implementing Regulation (EU) 2022/501 of 25 March 2022	L 102	1	30.3.2022
► <u>M389</u>	Commission Implementing Regulation (EU) 2022/686 of 28 April 2022	L 126	18	29.4.2022
► <u>M390</u>	Commission Implementing Regulation (EU) 2022/698 of 3 May 2022	L 130	3	4.5.2022
► <u>M391</u>	Commission Implementing Regulation (EU) 2022/708 of 5 May 2022	L 133	1	10.5.2022
► <u>M392</u>	Commission Implementing Regulation (EU) 2022/782 of 18 May 2022	L 140	3	19.5.2022
► <u>M393</u>	Commission Implementing Regulation (EU) 2022/800 of 20 May 2022	L 143	4	23.5.2022
► <u>M394</u>	Commission Implementing Regulation (EU) 2022/801 of 20 May 2022	L 143	7	23.5.2022
► <u>M395</u>	Commission Implementing Regulation (EU) 2022/808 of 23 May 2022	L 145	37	24.5.2022
► <u>M396</u>	Commission Implementing Regulation (EU) 2022/814 of 20 May 2022	L 146	6	25.5.2022
► <u>M397</u>	Commission Implementing Regulation (EU) 2022/1251 of 19 July 2022	L 191	35	20.7.2022
► <u>M398</u>	Commission Implementing Regulation (EU) 2022/1468 of 5 September 2022	L 231	101	6.9.2022
► <u>M399</u>	Commission Implementing Regulation (EU) 2022/1474 of 6 September 2022	L 232	3	7.9.2022

► <u>M400</u>	Commission Implementing Regulation (EU) 2022/1480 of L 233	43	8.9.2022	
► <u>M401</u>	Commission Implementing Regulation (EU) 2022/2305 of L 305	53	25.11.2022	
► <u>M402</u>	Commission Implementing Regulation (EU) 2022/2314 of L 307	47	28.11.2022	
► <u>M403</u>	Commission Implementing Regulation (EU) 2022/2315 of L 307	52	28.11.2022	
► <u>M404</u>	Commission Implementing Regulation (EU) 2022/2364 of L 312	99	5.12.2022	
► <u>M405</u>	Commission Implementing Regulation (EU) 2023/114 of 16 January 2023	L 15	9	17.1.2023
► <u>M406</u>	Commission Implementing Regulation (EU) 2023/115 of 16 January 2023	L 15	13	17.1.2023
► <u>M407</u>	Commission Implementing Regulation (EU) 2023/116 of 16 January 2023	L 15	15	17.1.2023
► <u>M408</u>	Commission Implementing Regulation (EU) 2023/149 of 20 January 2023	L 20	30	23.1.2023
► <u>M409</u>	Commission Implementing Regulation (EU) 2023/199 of 30 January 2023	L 27	22	31.1.2023
► <u>M410</u>	Commission Implementing Regulation (EU) 2023/216 of 1 February 2023	L 30	7	2.2.2023
► <u>M411</u>	Commission Implementing Regulation (EU) 2023/223 of 27 January 2023	L 32	5	3.2.2023
► <u>M412</u>	Commission Implementing Regulation (EU) 2023/515 of 8 March 2023	L 71	22	9.3.2023
► <u>M413</u>	Commission Implementing Regulation (EU) 2023/689 of 20 March 2023	L 91	1	29.3.2023
► <u>M414</u>	Commission Implementing Regulation (EU) 2023/741 of 5 April 2023	L 98	1	11.4.2023
► <u>M415</u>	Commission Implementing Regulation (EU) 2023/918 of 4 May 2023	L 119	160	5.5.2023
► <u>M416</u>	Commission Implementing Regulation (EU) 2023/932 of 8 May 2023	L 124	4	10.5.2023
► <u>M417</u>	Commission Implementing Regulation (EU) 2023/939 of 10 May 2023	L 125	19	11.5.2023
► <u>M418</u>	Commission Implementing Regulation (EU) 2023/962 of 15 May 2023	L 129	8	16.5.2023
► <u>M419</u>	Commission Implementing Regulation (EU) 2023/998 of 23 May 2023	L 136	4	24.5.2023
► <u>M420</u>	Commission Implementing Regulation (EU) 2023/999 of 23 May 2023	L 136	11	24.5.2023
► <u>M421</u>	Commission Implementing Regulation (EU) 2023/1000 of 23 May 2023	L 136	16	24.5.2023
► <u>M422</u>	Commission Implementing Regulation (EU) 2023/1001 of 23 May 2023	L 136	23	24.5.2023

► <u>M423</u>	Commission Implementing Regulation (EU) 2023/1002 of 23 May 2023	L 136	28	24.5.2023
► <u>M424</u>	Commission Implementing Regulation (EU) 2023/1003 of 23 May 2023	L 136	35	24.5.2023
► <u>M425</u>	Commission Implementing Regulation (EU) 2023/1004 of 23 May 2023	L 136	42	24.5.2023
► <u>M426</u>	Commission Implementing Regulation (EU) 2023/1005 of 23 May 2023	L 136	49	24.5.2023
► <u>M427</u>	Commission Implementing Regulation (EU) 2023/1021 of 24 May 2023	L 137	16	25.5.2023
► <u>M428</u>	Commission Implementing Regulation (EU) 2023/1436 of 10 July 2023	L 176	10	11.7.2023
► <u>M429</u>	Commission Implementing Regulation (EU) 2023/1446 of 12 July 2023	L 178	1	13.7.2023
► <u>M430</u>	Commission Implementing Regulation (EU) 2023/1447 of 12 July 2023	L 178	7	13.7.2023
► <u>M431</u>	Commission Implementing Regulation (EU) 2023/1488 of 6 July 2023	L 183	1	20.7.2023
► <u>M432</u>	Commission Implementing Regulation (EU) 2023/1755 of 11 September 2023	L 224	18	12.9.2023
► <u>M433</u>	Commission Implementing Regulation (EU) 2023/1756 of 11 September 2023	L 224	23	12.9.2023
► <u>M434</u>	Commission Implementing Regulation (EU) 2023/1757 of 11 September 2023	L 224	28	12.9.2023
► <u>M435</u>	Commission Implementing Regulation (EU) 2023/2455 of 7 November 2023	L 2455	1	8.11.2023
► <u>M436</u>	Commission Implementing Regulation (EU) 2023/2456 of 7 November 2023	L 2456	1	8.11.2023
► <u>M437</u>	Commission Implementing Regulation (EU) 2023/2513 of 16 November 2023	L 2513	1	17.11.2023
► <u>M438</u>	Commission Implementing Regulation (EU) 2023/2589 of 21 November 2023	L 2589	1	22.11.2023
► <u>M439</u>	Commission Implementing Regulation (EU) 2023/2591 of 21 November 2023	L 2591	1	22.11.2023
► <u>M440</u>	Commission Implementing Regulation (EU) 2023/2592 of 21 November 2023	L 2592	1	22.11.2023
► <u>M441</u>	Commission Implementing Regulation (EU) 2023/2657 of 6 November 2023	L 2657	1	23.11.2023
► <u>M442</u>	Commission Implementing Regulation (EU) 2023/2660 of 28 November 2023	L 2660	1	29.11.2023
► <u>M443</u>	Commission Implementing Regulation (EU) 2024/20 of 12 December 2023	L 20	1	3.1.2024

► <u>M444</u>	Commission Implementing Regulation (EU) 2024/324 of 19 January 2024	L 324	1	22.1.2024
► <u>M445</u>	Commission Implementing Regulation (EU) 2024/821 of 8 March 2024	L 821	1	11.3.2024
► <u>M446</u>	Commission Implementing Regulation (EU) 2024/839 of 8 March 2024	L 839	1	11.3.2024
► <u>M447</u>	Commission Implementing Regulation (EU) 2024/835 of 12 March 2024	L 835	1	13.3.2024
► <u>M448</u>	Commission Implementing Regulation (EU) 2024/836 of 12 March 2024	L 836	1	13.3.2024
► <u>M449</u>	Commission Implementing Regulation (EU) 2024/1206 of 29 April 2024	L 1206	1	30.4.2024
► <u>M450</u>	Commission Implementing Regulation (EU) 2024/1207 of 29 April 2024	L 1207	1	30.4.2024
► <u>M451</u>	Commission Implementing Regulation (EU) 2024/1217 of 29 April 2024	L 1217	1	30.4.2024
► <u>M452</u>	Commission Implementing Regulation (EU) 2024/1280 of 30 April 2024	L 1280	1	3.5.2024
► <u>M453</u>	Commission Implementing Regulation (EU) 2024/1696 of 19 June 2024	L 1696	1	20.6.2024
► <u>M454</u>	Commission Implementing Regulation (EU) 2024/1718 of 19 June 2024	L 1718	1	20.6.2024
► <u>M455</u>	Commission Implementing Regulation (EU) 2024/1749 of 24 June 2024	L 1749	1	25.6.2024
► <u>M456</u>	Commission Implementing Regulation (EU) 2024/1768 of 26 June 2024	L 1768	1	27.6.2024
► <u>M457</u>	Commission Implementing Regulation (EU) 2024/1892 of 10 July 2024	L 1892	1	11.7.2024
► <u>M458</u>	Commission Implementing Regulation (EU) 2024/2186 of 3 September 2024	L 2186	1	4.9.2024
► <u>M459</u>	Commission Implementing Regulation (EU) 2024/2198 of 4 September 2024	L 2198	1	5.9.2024
► <u>M460</u>	Commission Implementing Regulation (EU) 2024/2221 of 6 September 2024	L 2221	1	9.9.2024
► <u>M461</u>	Commission Implementing Regulation (EU) 2024/2390 of 6 September 2024	L 2390	1	9.9.2024
► <u>M462</u>	Commission Implementing Regulation (EU) 2024/2777 of 31 October 2024	L 2777	1	4.11.2024
► <u>M463</u>	Commission Implementing Regulation (EU) 2024/2781 of 31 October 2024	L 2781	1	4.11.2024
► <u>M464</u>	Commission Implementing Regulation (EU) 2024/2806 of 31 October 2024	L 2806	1	4.11.2024
► <u>M465</u>	Commission Implementing Regulation (EU) 2024/2878 of 8 November 2024	L 2878	1	11.11.2024
► <u>M466</u>	Commission Implementing Regulation (EU) 2024/2848 of 11 November 2024	L 2848	1	12.11.2024
► <u>M467</u>	Commission Implementing Regulation (EU) 2025/96 of 21 January 2025	L 96	1	22.1.2025
► <u>M468</u>	Commission Implementing Regulation (EU) 2025/99 of 21 January 2025	L 99	1	22.1.2025

► <u>M469</u>	Commission Implementing Regulation (EU) 2025/102 of 21 January 2025	L 102	1	22.1.2025
► <u>M470</u>	Commission Implementing Regulation (EU) 2025/103 of 22 January 2025	L 103	1	23.1.2025
► <u>M471</u>	Commission Implementing Regulation (EU) 2025/106 of 22 January 2025	L 106	1	23.1.2025
► <u>M472</u>	Commission Implementing Regulation (EU) 2025/109 of 22 January 2025	L 109	1	23.1.2025
► <u>M473</u>	Commission Implementing Regulation (EU) 2025/119 of 24 January 2025	L 119	1	27.1.2025
► <u>M474</u>	Commission Implementing Regulation (EU) 2025/150 of 29 January 2025	L 150	1	30.1.2025
► <u>M475</u>	Commission Implementing Regulation (EU) 2025/787 of 24 April 2025	L 787	1	25.4.2025

Corrected by:

- **C1** Corrigendum, OJ L 26, 28.1.2012, p. 38 (540/2011)
- **C2** Corrigendum, OJ L 235, 4.9.2013, p. 12 (200/2013)
- **C3** Corrigendum, OJ L 277, 22.10.2015, p. 60 (140/2014)
- **C4** Corrigendum, OJ L 2, 5.1.2018, p. 15 (2017/842)
- **C5** Corrigendum, OJ L 18, 27.1.2022, p. 128 (1330/2014)

▼B**COMMISSION IMPLEMENTING REGULATION (EU) No
540/2011****of 25 May 2011****implementing Regulation (EC) No 1107/2009 of the European
Parliament and of the Council as regards the list of approved
active substances****(Text with EEA relevance)****▼M1***Article 1*

The active substances, as set out in Part A of the Annex, shall be deemed to have been approved under Regulation (EC) No 1107/2009.

▼M166

The active substances approved under Regulation (EC) No 1107/2009 are as set out in Part B of the Annex to this Regulation. The basic substances approved under Regulation (EC) No 1107/2009 are as set out in Part C of the Annex to this Regulation. The low-risk active substances approved under Regulation (EC) No 1107/2009 are as set out in Part D of the Annex to this Regulation. The candidates for substitution approved under Regulation (EC) No 1107/2009 are as set out in Part E of the Annex to this Regulation.

▼B*Article 2*

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 14 June 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼ M110

ANNEX ACTIVE SUBSTANCES

▼ M1

PART A

Active substances deemed to have been approved under Regulation (EC) No 1107/2009

General provisions applying to all substances listed in this Part:

▼ B

- for the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009 in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, shall be taken into account;
- Member States shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make it available to them on specific request.

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M6</u> _____						
▼ <u>M4</u> _____						
▼ <u>M18</u> _____						
▼ <u>M13</u> _____						
▼ <u>M5</u> _____						
▼ <u>M8</u> _____						
▼ <u>M169</u> _____						
▼ <u>M3</u> _____						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M181</u> _____						
▼ <u>M162</u> _____						
▼ <u>M253</u> _____						
▼ <u>M170</u> _____						
▼ <u>M155</u> _____						
▼ <u>M182</u> _____						
▼ <u>M280</u> _____						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M148</u> _____						
▼ <u>M198</u> _____						
▼ <u>M136</u> _____						
▼ <u>M233</u> _____						
▼ <u>M175</u> _____						
▼ <u>M394</u> _____						
▼ <u>M152</u> _____						
▼ <u>M279</u> _____						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M173</u> _____						
▼ <u>M244</u> _____						
▼ <u>M191</u> _____						
▼ <u>M161</u> _____						
▼ <u>M183</u> _____						
▼ <u>M193</u> _____						
▼ <u>M171</u> _____						
▼ <u>M205</u> _____						
▼ <u>M150</u> _____						

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M394</u> _____						
▼ <u>M215</u> _____						
▼ <u>M367</u> _____						
▼ <u>M159</u> _____						
▼ <u>M324</u> _____						
▼ <u>M190</u> _____						
▼ <u>M379</u> _____						
▼ <u>B</u> 40	Deltamethrin CAS No 52918-63-5 CIPAC No 333	(S)- α -cyano-3-phen-oxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclo-propane carboxylate	980 g/kg	1 November 2003	► <u>M434</u> 15 August 2026 ◀	Only uses as insecticide may be authorised For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on deltamethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 18 October 2002 shall be taken into account. In this overall assessment Member States:

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						— must pay particular attention to the operator safety and must ensure that the conditions of authorisation include appropriate protective measures, — should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels, — must pay particular attention to the protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate.
▼ <u>M239</u> _____						
▼ <u>M265</u> _____						
▼ <u>M394</u> _____						
▼ <u>M323</u> _____						
▼ <u>M394</u> _____						
▼ <u>M363</u> _____						
▼ <u>M232</u> _____						
▼ <u>M329</u> _____						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ M394 _____						
▼ M243 _____						
▼ M201 _____						
▼ M234 _____						
▼ M227 _____						
▼ M251 _____						
▼ M260 _____						
▼ M394 _____						
▼ B 57	Mecoprop-P CAS No 16484-77-8 CIPAC No 475	(R)-2-(4-chloro-o-tolyloxy)-propionic acid	860 g/kg	1 June 2004	► M475 15 October 2027 ◀	Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mecoprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M282</u> _____						
▼ <u>M267</u> _____						
▼ <u>M268</u> _____						
▼ <u>M214</u> _____						
▼ <u>M266</u> _____						
▼ <u>M305</u> _____						

▼ B▼ M287▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
65	Flufenacet CAS No 142459-58-3 CIPAC No 588	4'-fluoro-N-isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yloxy]acetanilide	950 g/kg	1 January 2004	► <u>M434</u> 15 June 2025 ◀	Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flufenacet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of algae and aquatic plants, — should pay particular attention to the protection of operators. Risk mitigation measures should be applied where appropriate.
▼ <u>M207</u>						
▼ <u>M311</u>						
▼ <u>M231</u>						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
69	Fosthiazate CAS No 98886-44-3 CIPAC No 585	(RS)-S-sec-butyl O-ethyl 2-oxo-1,3-thiazolidin-3-ylphosphothioate	930 g/kg	1 January 2004	► M434 31 January 2027 ◀	Only uses as insecticide or nematicide may be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fosthiazate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions; — should pay particular attention to the protection of birds and wild mammals in particular if the substance is applied during the breeding season; — should pay particular attention to the protection of non-target soil organisms. Risk mitigation measures should be applied where appropriate. In order to mitigate the potential risk to small birds, product authorisations must require that a very high level of incorporation of granules into soil is achieved. The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.
▼ M259 _____						
▼ M222 _____						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ M394						
▼ M278						
▼ B						
74	Ziram CAS No 137-30-4 CIPAC No 31	Zinc bis (dimethyl-dithiocarbamate)	950 g/kg (FAO-specification) Arsenic: maximum 250 mg/kg Water: maximum 1,5 %	1 August 2004	► M468 31 January 2027 ◀	Only uses as fungicide or as repellent may be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ziram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of non-target arthropods and aquatic organisms. Risk mitigation measures should be applied, where appropriate, — Member States should observe the acute dietary exposure situation of consumers in view of future revisions of Maximum Residue Levels.
▼ M216						
▼ M228						
▼ M258						
▼ M306						
▼ M226						

▼ **B**▼ **M218**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
81	Pyraclostrobin CAS No 175013-18-0 CIPAC No 657	methyl N-(2-{{1-(4-chlorophenyl)-1H-pyrazol-3-yl}oxymethyl}phenyl) N-methoxy carbamate	975 g/kg The manufacturing impurity dimethyl sulfate (DMS) is considered to be of toxicological concern and must not exceed a concentration of 0,0001 % in the technical product.	1 June 2004	► M444 15 September 2025 ◀	Only uses as fungicide or plant growth regulator may be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyraclostrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 November 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of aquatic organisms, especially fish, — should pay particular attention to the protection of terrestrial arthropods and earthworms. Risk mitigation measures should be applied where appropriate. The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

▼ **M284**▼ **M317**

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ M338						
▼ M337						
▼ M309						
▼ M394						
▼ B	88 Phenmedipham CAS No 13684-63-4 CIPAC No 77	methyl 3-(3-methyl-carbaniloxyloxy)carb-anilate; 3-methoxycarbony-laminophenyl 3'-methylcarbanilate	Min. 970 g/kg	1 March 2005	► M468 30 September 2026 ◀	Only uses as herbicide may be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on phenmedipham, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 February 2004 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.
▼ M411						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M451</u> _____						
▼ <u>M247</u> _____						
▼ <u>M321</u> _____						
▼ <u>M269</u> _____						
▼ <u>M394</u> _____						
▼ <u>M246</u> _____						

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M293</u> _____						
▼ <u>M443</u> _____						
▼ <u>M292</u> _____						
▼ <u>M347</u> _____						
▼ <u>M394</u> _____						

▼ B▼ M301▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
102	Chlorotoluron (unstated stereochemistry) CAS No 15545-48-9 CIPAC No 217	3-(3-chloro-p-tolyl)-1,1-dimethylurea	975 g/kg	1 March 2006	► <u>M434</u> 15 August 2026 ◀	PART A Only uses as herbicide may be authorised PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorotoluron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of ground-water, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Conditions of authorisation should include risk mitigation measures, where appropriate
104	Daminozide CAS No 1596-84-5 CIPAC No 330	N-dimethylaminosuccinamic acid	990 g/kg Impurities: — N-nitrosodimethylamine: not more than 2,0 mg/kg — 1,1-dimethylhydrazide: not more than 30 mg/kg	1 March 2006	► <u>M434</u> 15 September 2025 ◀	PART A Only uses as growth regulator in non-edible crops may be authorised

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on daminozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the safety of operators and workers after re-entry. Conditions of authorisation should include protective measures, where appropriate
▼ <u>M340</u>						
▼ <u>M283</u>						
▼ <u>B</u>						
107	MCPA CAS No 94-74-6 CIPAC No 2	4-chloro-o-tolyloxyacetic acid	≥ 930 g/kg	1 May 2006	► <u>M434</u> 15 August 2026 ◀	PART A Only uses as herbicide may be authorised PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on MCPA, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2005 shall be taken into account

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones
108	MCPB CAS No 94-81-5 CIPAC No 50	4-(4-chloro-o-tolyloxy)butyric acid	≥ 920 g/kg	1 May 2006	► M434 15 August 2026 ◀	PART A Only uses as herbicide may be authorised PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on MCPB, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2005 shall be taken into account Member States should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones

▼ **M390**

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
110	Milbemectin Milbemectin is a mixture of M.A3 and M.A4 CAS No M.A3: 51596-10-2 M.A4: 51596-11-3 CIPAC No 660	M.A3: (10E,14E,16E,22Z)- (1R,4S,5'S,6R,6' R,8R,13R,20R,21R,2- 4S)-21,24-dihydroxy- 5',6',11,13,22-penta- methyl-3,7,19-trioxa- tetracyclo [15.6.1.14,8.020,24] pentacosa- 10,14,16,22-tetraene- 6-spiro-2'-tetrahy- dropyran-2-one M.A4: (10E,14E,16E,22Z)- (1R,4S,5'S,6R,6' R,8R,13R,20R,21R,2- 4S)-6'-ethyl-21,24- dihydroxy- 5',11,13,22-tetra- methyl-3,7,19-trioxa- tetracyclo[15.6.1. 14,8020,24] pentacosa- 10,14,16,22-tetraene- 6-spiro-2'-tetrahy- dropyran-2-one	≥ 950 g/kg	1 December 2005	► M468 31 May 2026 ◀	PART A Only uses as acaricide or insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on milbemectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account. In this overall assessment Member States should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
▼ M320						
▼ M319						
▼ M394						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M344</u> _____						
▼ <u>M435</u> _____						
▼ <u>M414</u> _____						
▼ <u>M307</u> _____						
▼ <u>M255</u> _____						
▼ <u>M376</u> _____						

▼ B▼ M394▼ M272▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
123	Clodinafop CAS No 114420-56-3 CIPAC No 683	(R)-2-[4-(5-chloro-3-fluoro- 2 pyridyloxy)-phenoxy]-propionic acid	≥ 950 g/kg (expressed as clodinafop-propargyl)	1 February 2007	► <u>M413</u> 15 December 2025 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clodinafop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account.
124	Pirimicarb CAS No 23103-98-2 CIPAC No 231	2-dimethylamino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate	≥ 950 g/kg	1 February 2007	► <u>M468</u> 31 October 2026 ◀	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pirimicarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Member States must pay particular attention to the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment. Member States must pay particular attention to the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate, such as buffer zones. The concerned Member States shall request the submission of further studies to confirm the long term risk assessment for birds and for potential groundwater contamination, in particular concerning metabolite R35140. They shall ensure that the notifiers at whose request pirimicarb has been included in this Annex provide such studies to the Commission within two years from the approval.
125	Rimsulfuron CAS No 122931-48-0 (rimsulfuron) CIPAC No 716	1-(4-6 dimethoxy-pyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl) urea	≥ 960 g/kg (expressed as rimsulfuron)	1 February 2007	► M475 15 August 2028 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rimsulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. Member States must pay particular attention to the protection of non target plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.
▼ M310						

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
127	Triticonazole CAS No 131983-72-7 CIPAC No 652	(±)-(E)-5-(4-chloro-benzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	≥ 950 g/kg	1 February 2007	► M468 31 January 2027 ◀	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing triticonazole for uses other than seed treatment, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triticonazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate, — must pay particular attention to the potential for groundwater contamination, in particular from the highly persistent active substance and its metabolite RPA 406341, in vulnerable zones, — must pay particular attention to the protection of granivorous birds (long term risk). Conditions of authorisation should include risk mitigation measures, where appropriate.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						The concerned Member States shall request the submission of further studies to confirm the risk assessment for granivorous birds. They shall ensure that the notifier at whose request triticonazole has been included in this Annex provide such studies to the Commission within two years from the approval.
▼ <u>M428</u>						
▼ <u>M366</u>						
▼ <u>B</u>	130	Cyprodinil CAS No 121522-61-2 CIPAC No 511	(4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenyl-amine	≥ 980 g/kg	1 May 2007	► <u>M468</u> 31 October 2026 ◀ PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyprodinil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment,

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— must pay particular attention to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones. The concerned Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for possible presence of residues of metabolite CGA 304075 in food of animal origin. They shall ensure that the notifiers at whose request cyprodinil has been included in this Annex provide such studies to the Commission within two years from the approval.
131	Fosetyl CAS No 15845-66-6 CIPAC No 384	Ethyl hydrogen phosphonate	≥ 960 g/kg (expressed as fosetyl-Al)	1 May 2007	► M468 31 October 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fosetyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones. The concerned Member States shall request the submission of further studies to confirm the risk assessment for non-target arthropods, in particular with regard to in-field recovery, and for herbivorous mammals. They shall ensure that the notifier at whose request fosetyl has been included in this Annex provide such studies to the Commission within two years from the approval.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M447</u>						
▼ <u>B</u>	133	Dichlorprop-P CAS No 15165-67-0 CIPAC No 476	(R)-2-(2,4-dichlorop-henoxy) propanoic acid	≥ 900 g/kg	1 June 2007	► <u>M468</u> 31 October 2026 ◀ ► <u>M89</u> PART A Only uses as herbicide may be authorised. As regards cereals, only application in spring may be authorised, at rates not exceeding 800 g active substance per hectare per application. Use on grassland shall not be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dichlorprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of birds, mammals, aquatic organisms and non-target plants. Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀
▼ <u>M455</u>						

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
135	Pyrimethanil CAS No 53112-28-0 CIPAC No not allocated	N-(4,6-dimethylpyrimidin-2-yl) aniline	≥ 975 g/kg (the manufacturing impurity cyanamide is considered to be of toxicological concern and must not exceed 0,5 g/kg in the technical material)	1 June 2007	► M468 30 June 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyrimethanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones, — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment. The Member States concerned shall request the submission of further studies to confirm the risk assessment to fish. They shall ensure that the notifiers at whose request pyrimethanil has been included in this Annex provide such studies to the Commission within two years from the approval.
136	Triclopyr CAS No 055335-06-3 CIPAC No 376	3,5,6-trichloro-2-pyridyloxyacetic acid	≥ 960 g/kg (as Triclopyr butoxyethyl ester)	1 June 2007	► M460 31 March 2026 ◀	► M137 PART A Only uses as herbicide may be authorised. Only uses with a total application per year of maximum 480 g active substance per hectare shall be authorised.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triclopyr, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014 shall be taken into account. In this overall assessment Member States: — shall pay particular attention to the protection of groundwater under vulnerable conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated in vulnerable zones, where appropriate, — shall pay particular attention to the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment, — shall pay particular attention to the protection of birds, mammals, aquatic organisms and non-target plants. Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀
▼ M461						
▼ M422						

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
139	Spinosad CAS No 131929-60-7 (Spinosyn A) 131929-63-0 (Spinosyn D) CIPAC No 636	Spinosyn A: (2R,3aS,5aR,5bS,9S,-13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-D-erythro-pyr-anosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10-,11,12,13,14,15,16a,-16b-hexadecahydro-14-methyl-1H-8-oxacyclododeca[b]as-indacene-7,15-dione Spinosyn D: (2S,3aR,5aS,5bS,9S,-13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetra-deoxy-β-D-erythro-pyr-anosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10-,11,12,13,14,15,16a,-16b-hexadecahydro-4,14-dimethyl-1H-8-oxacyclododeca[b]as-indacene-7,15-dione Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D	≥ 850 g/kg	1 February 2007	► M468 31 October 2026 ◀	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spinosad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 shall be taken into account. In this overall assessment Member States — must pay particular attention to the protection of aquatic organisms; — must pay particular attention to the risk to earthworms when the substance is used in glasshouses. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M394</u> _____						
▼ <u>M335</u> _____						
▼ <u>M439</u> _____						
▼ <u>M394</u> _____ _____						

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
▼ <u>M458</u>						
▼ <u>M459</u>						
▼ <u>B</u>						
147	Formetanate CAS No 23422-53-9 CIPAC No 697	3-dimethylamino-methyleneaminophenyl methylcarbamate	≥ 910 g/kg	1 October 2007	► <u>M468</u> 30 September 2026 ◀	PART A Only uses as insecticide and acaricide may be authorised. PART B In assessing applications to authorise plant protection products containing formetanate for uses other than in field tomatoes and ornamental shrubs Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on formetanate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, non-target arthropods and bees and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — must pay particular attention to the dietary exposure of consumers in view of future revisions of Maximum Residue Levels.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and non-target arthropods. They shall ensure that the notifier at whose request formetanate has been included in this Annex provide such studies to the Commission within two years from the approval.
▼ <u>M315</u> _____						
▼ <u>M308</u> _____						
▼ <u>M450</u> _____						
▼ <u>M394</u> _____						
▼ <u>M464</u> _____						

▼ B▼ M380▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
154	Propamocarb CAS No 24579-73-5 CIPAC No 399	Propyl 3-(dimethyl-amino) propylcarbamate	≥ 920 g/kg	1 October 2007	► <u>M475</u> 31 January 2027 ◀	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing propamocarb for uses other than foliar applications, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, as regards worker exposure and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on propamocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators and workers safety. Conditions of authorisation should include protective measures, where appropriate; — the transfer of soil residues for rotating or succeeding crops; — the protection of surface and groundwater in vulnerable zones; — the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

▼ B▼ M298▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
156	Pirimiphos-methyl CAS No 29232-93-7 CIPAC No 239	O-2-diethylamino-6-methylpyrimidin-4-yl O,O-dimethylphosphorothioate	> 880 g/kg	1 October 2007	► <u>M475</u> 31 January 2027 ◀	PART A Only uses as insecticide for post harvest storage can be authorised. Hand-held applications shall not be authorised. PART B In assessing applications to authorise plant protection products containing pirimiphos-methyl for uses other than applications with automated systems in empty cereals storehouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pirimiphos-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment including respiratory protective equipment and risk mitigation measures to reduce the exposure; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels.

▼ B▼ M394▼ B▼ M387▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
158	Beflubutamid CAS No 113614-08-7 CIPAC No 662	(RS)-N-benzyl-2-(4-fluoro-3-trifluoromethylphenoxy) butanamide	≥ 970 g/kg	1 December 2007	► <u>M415</u> 31 October 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on beflubutamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 May 2007 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.
160	Prosulfocarb CAS No 52888-80-9 CIPAC No 539	S-benzyl dipropyl (thiocarbamat)	970 g/kg	1 November 2008	► <u>M434</u> 31 January 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account.

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no spray buffer zone.
161	Fludioxonil CAS No 131341-86-1 CIPAC No 522	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile	950 g/kg	1 November 2008	►M475 30 September 2026 ◀	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing fludioxonil for uses other than seed treatment, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted and: — must pay particular attention to the potential for groundwater contamination, in particular from the soil photolysis metabolites CGA 339833 and CGA 192155, in vulnerable zones, — must pay particular attention to the protection of fish and aquatic invertebrates. Conditions of authorisation should include risk mitigation measures, where appropriate.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fludioxonil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account.
162	Clomazone CAS No 81777-89-1 CIPAC No 509	2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	960 g/kg	1 November 2008	► M475 30 September 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clomazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones.
164	Boscalid CAS No 188425-85-6 CIPAC No 673	2-Chloro-N-(4'-chlorobiphenyl-2-yl) nicotinamide	≥ 960 g/kg	1 August 2008	► M415 15 April 2026 ◀	PART A Only uses as fungicide may be authorised.

▼ **M441**▼ **B**

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on boscalid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention — to the operator safety, — to the long term risk to birds and soil organisms, — to the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include adequate risk mitigation measures, where appropriate.
▼ <u>M302</u>						
▼ <u>B</u>						
166	Fluoxastrobin CAS No 361377-29-9 CIPAC No 746	(E)-{2-[6-(2-chloro-phenoxy)-5-fluor-opyrimidin-4-yloxy] phenyl}(5,6-dihydro-1,4,2-dioxazin-3-yl) methanone O-methyloxime	≥ 940 g/kg	1 August 2008	► <u>M475</u> 31 January 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluoxastrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States must pay particular attention to: — the operator safety, in particular when handling the undiluted concentrate. Conditions of use shall include adequate protective measures, such as wearing a face shield, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the levels of residues of the metabolites of fluoxastrobin, when straw from treated areas is used as animal feeding stuff. Conditions of use shall include restrictions for feeding to animals, where appropriate, — the risk of accumulation in the soil surface, if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — data to allow a comprehensive aquatic risk assessment to be made taking into account spray drift, run-off, drainage and the effectiveness of potential risk mitigation measures, — data on toxicity of non-rat metabolites if straw from treated areas is to be used as feedstuff. They shall ensure that the notifier at whose request fluoxastrobin has been included in this Annex provide such studies to the Commission within two years from the approval.
▼ M378						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
168	Prothioconazole CAS No 178928-70-6 CIPAC No 745	(RS)-2-[2-(1-chloro-cyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione	≥ 970 g/kg The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material:	1 August 2008	► M475 31 March 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety in spray applications. Conditions of use shall include adequate protective measures, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin, — a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds, — information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment.

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			— Toluene: < 5 g/kg — Prothioconazole-desthio (2-(1-chloro-cyclopropyl)1-(2-chloro-phenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0,5 g/kg (LOD)			They shall ensure that the notifier at whose request prothioconazole has been included in this Annex provide such studies to the Commission within two years from the approval.
169	Amidosulfuron CAS No 120923-37-7 CIPAC No 515	3-(4,6-dimethoxypyrimidin-2-yl)-1-(N-methyl-N-methylsulfonyl-aminosulfonyl) urea or 1-(4,6-dimethoxypyrimidin-2-yl)-3-mesyl (methyl) sulfa-moylurea	≥ 970 g/kg	1 January 2009	►M475 30 November 2026 ◀	PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing amidosulfuron for uses other than meadows and pasture, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on amidosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of groundwater due to a potential for groundwater contamination by some of the degradation products when it is applied in regions with vulnerable soil and/or climatic conditions,

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the protection of aquatic plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate.
170	Nicosulfuron CAS No 111991-09-4 CIPAC No 709	2-[(4,6-dimethoxy-pyrimidin-2-ylcarbamoyl)sulfamoyl]-N,N-dimethylnicotinamide or 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-dimethylcarbamoyl-2-pyridylsulfonyl)urea	≥ 910 g/kg	1 January 2009	► M440 31 March 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions, — the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone, — the protection of groundwater and surface water under vulnerable soil and climatic conditions.

▼ **B**▼ **M436**▼ **M23**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
172	Dicamba CAS No 1918-00-9 CIPAC No 85	3,6-dichloro-2-methoxybenzoic acid	≥ 850 g/kg	1 January 2009	► M440 31 March 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of non-target plants. Conditions of use shall include adequate risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the identification and quantification of a group of soil transformation products formed in a soil incubation study; (b) the potential for long range transport through the atmosphere. The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013.
173	Difenoconazole CAS No 119446-68-3 CIPAC No 687	3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether	≥ 940g/kg Toluene maximum content: 5 g/kg	1 January 2009	► M440 15 March 2026 ◀	PART A Only uses as fungicide may be authorised.

▼ **M23**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on difenoconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms. Conditions of use shall include adequate risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) further data on the specification of the technical material; (b) residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops, processed commodities and products of animal origin; (c) the potential for endocrine disrupting effects on fish (fish full life cycle study) and the chronic risk to earthworms from the active substance and the metabolite CGA 205375 ⁽¹⁶⁾; (d) the possible impact of the variable isomer-ratio in the technical material and of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and on the environment. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by 31 May 2012, the information set out in points (b) and (c) by 30 November 2013 and the information set out in point (d) within 2 years from the adoption of specific guidance.

▼ **M23**▼ **M394**▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
176	Lenacil CAS No 2164-08-1 CIPAC No 163	3-cyclohexyl-1,5,6,7-tetrahydrocyclopentapyrimidine-2,4(3H)-dione	≥ 975 g/kg	1 January 2009	► M440 15 August 2025 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lenacil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the risk to aquatic organisms, especially algae and aquatic plants. Conditions of authorisation shall include risk mitigation measures, such as bufferzones between treated areas and surface water bodies; — the protection of the groundwater, where the active substance is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites IN-KF 313, M1, M2 and M3 in vulnerable zones, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission confirmatory information on the identity and characterisation of soil metabolites Polar B and Polars and metabolites M1, M2 and M3 which

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						occurred in lysimeter studies and confirmatory data on rotational crops, including possible phytotoxic effects. They shall ensure that the notifier provides such information to the Commission by 30 June 2012. If a decision on the classification of lenacil under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾ identifies the need for further information on the relevance of the metabolites IN-KE 121, IN-KF 313, M1; M2, M3, Polar B and Polars, the Member States concerned shall request the submission of such information. They shall ensure that the notifier provides that information to the Commission within six months from the notification of such a classification decision.
▼ <u>M394</u>						
▼ <u>B</u>						
178	Picloram CAS No 1918-02-1 CIPAC No 174	4-amino-3,5,6-trichloropyridine-2-carboxylic acid	≥ 920 g/kg	1 January 2009	► <u>M440</u> 15 February 2028 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on picloram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account. In the overall assessment Member States must pay particular attention to: — the potential for ground water contamination where picloram is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate; The Member States concerned shall ensure that the notifier submits to the Commission:

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						— further information to confirm that the monitoring analytical method applied in residue trials correctly quantifies the residues of picloram and its conjugates; — a soil photolysis study to confirm the evaluation of picloram degradation. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.
▼ M330						
▼ B						
180	Bifenox CAS No 42576-02-3 CIPAC No 413	Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate	≥ 970 g/kg impurities: max. 3 g/kg 2,4-dichlorophenol max. 6 g/kg 2,4-dichloroanisole	1 January 2009	► M440 31 March 2027 ◀	► M85 PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; (b) the dietary exposure of consumers to bifenox residues in products of animal origin and in succeeding rotational crops; (c) the environmental conditions leading to the potential formation of nitrofen. Member States shall impose restrictions as regards the conditions of use, where appropriate in view of point (c). ◀
181	Diflufenican CAS No 83164-33-4 CIPAC No 462	2',4'-difluoro-2-(α,α , α -trifluoro-m-tolyloxy) nicotin-anilide	≥ 970 g/kg	1 January 2009	► M440 15 January 2026 ◀	PART A Only uses as herbicide may be authorised.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diflufenican, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones shall be applied, where appropriate.
182	Fenoxaprop-P CAS No 113158-40-0 CIPAC No 484	(R)-2[4-[(6-chloro-2-benzoxazolyl)oxy]-phenoxy]-propanoic acid	≥ 920 g/kg	1 January 2009	► M475 30 November 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenoxaprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non target plants, — the presence of the safener mefenpyr-diethyl in formulated products as regards operator, worker and bystander exposure,

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the persistence of the substance and of some of its degradation products in colder zones and areas where anaerobic conditions may occur. Conditions of authorisation should include risk mitigation measures, where appropriate.
183	Fenpropidin CAS No 67306-00-7 CIPAC No 520	(R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]-piperidine	≥ 960 g/kg (racemate)	1 January 2009	►M440 15 May 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpropidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zone. The Member States concerned shall request the submission of: — information to further address the long-term risk to herbivorous and insectivorous birds arising from the use of fenpropidin. They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval.

▼ B▼ M394▼ M462▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
187	Flutolanil CAS No 66332-96-5 CIPAC No 524	α,α,α -trifluoro-3'-isopropoxy-o-toluanilide	≥ 975 g/kg	1 March 2009	► <u>M475</u> 15 June 2026 ◀	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing flutolanil for uses other than potato tuber treatment, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flutolanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate.
▼ <u>M408</u>						
▼ <u>B</u>	189	Fluazinam CAS No 79622-59-6 CIPAC No 521	3-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2, 6-dinitro-p-toluidine ≥ 960 g/kg Impurities: 5-chloro-N-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-4,6-dinitro-o-toluidine — not more than 2 g/kg	1 March 2009	► <u>M444</u> 15 April 2026 ◀	PART A Only uses as fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing fluazinam for uses other than potatoes, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluazinam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 shall be taken into account.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States must pay particular attention to: — the protection of the operators' and workers' safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in food of plant and animal origin and evaluate the dietary exposure of consumers, — the protection of aquatic organisms. In relation to this identified risk, risk mitigation measures, such as buffer zones, should be applied where appropriate. The Member States concerned shall request the submission of further studies to confirm the risk assessment for aquatic organisms and soil macro-organisms. They shall ensure that the notifiers at whose request fluazinam has been included in this Annex provide such studies to the Commission within two years from the approval.
▼ <u>M394</u> _____						
▼ <u>M474</u> _____						
▼ <u>M394</u> _____						
▼ <u>M423</u> ▼ <u>M421</u> _____						
▼ <u>M420</u> _____						

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M427</u>						
▼ <u>M426</u>						
▼ <u>M425</u>						
▼ <u>M424</u>						
▼ <u>M419</u>						

▼ <u>M394</u>						

▼ <u>B</u>						
197	Beauveria bassiana STRAIN: ATCC 74040 Culture collection: No ATCC 74040 STRAIN: GHA Culture collection: No ATCC 74250	Not applicable	Max level of beauvericin: 5 mg/kg	1 May 2009	► <u>M413</u> 30 September 2025 ◀	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Beauveria bassiana ATCC 74040 (SANCO/1546/2008) and GHA (SANCO/1547/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
▼ <u>M433</u>						

▼ <u>M351</u>						

▼ <u>M383</u>						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ M394						
▼ M402						
▼ M364						
▼ M452	204 <i>Trichoderma atroviride</i> (formerly <i>T. harzianum</i>)					
	STRAIN: T11 Culture collection: No Spanish type culture collection CECT 20498, identical with IMI 352941	Not applicable	No relevant impurities	1 May 2009	► M468 30 November 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on <i>Trichoderma harzianum</i> T-22 (SANCO/1839/2008) and ITEM 908 (SANCO/1840/208) respectively and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
	STRAIN: IMI 206040 – Culture collection No IMI 206040, ATCC 20476	Not applicable	No relevant impurities	1 May 2009	31 August 2024	Conditions of use shall include, where appropriate, risk mitigation measures.

▼ B▼ M394▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
206	Trichoderma harzianum Rifai STRAIN: Trichoderma harzianum T-22; Culture collection No ATCC 20847 STRAIN: Trichoderma harzianum ITEM 908; Culture collection No CBS 118749	Not applicable	No relevant impurities	1 May 2009	► <u>M468</u> 30 November 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on Trichoderma harzianum T-22 (SANCO/1839/2008) and ITEM 908 (SANCO/1840/2008) respectively and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
207	Trichoderma asperellum (formerly T. harzianum) STRAIN: ICC012 Culture collection No CABI CC IMI 392716 STRAIN: Trichoderma asperellum (formerly T. viride T25) T25 Culture collection No CECT 20178	Not applicable	No relevant impurities	1 May 2009	► <u>M468</u> 30 November 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review reports on Trichoderma asperellum (formerly T. harzianum) ICC012 (SANCO/1842/2008) and Trichoderma asperellum (formerly T. viride T25 and TV1) T25 and TV1 (SANCO/1868/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
	STRAIN: Trichoderma asperellum (formerly T. viride TV1) TV1 Culture collection No MUCL 43093					
208	Trichoderma gamsii (formerly T. viride) STRAINS: ICC080 Culture collection No IMI CC number 392151 CABI	Not applicable	No relevant impurities	1 May 2009	► M468 30 November 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Trichoderma viride (SANCO/1868/2008), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
▼ M316						
▼ M412						

▼ B▼ M394▼ B

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
213	Fenpyroximate CAS No 134098-61-6 CIPAC No 695	tert-butyl (E)-alpha-(1,3-dimethyl-5-phenoxypyrazol-4-ylmethyleneamino-oxy)-p-toluate	> 960 g/kg	1 May 2009	► M413 15 June 2026 ◀	PART A Only uses as acaricide may be authorised. The following uses must not be authorised: — applications in high crops with a high risk of spray drift, for example tractor mounted air-blast sprayer and hand-held applications. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpyroximate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the impact on aquatic organisms and non-target arthropods and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. The Member States concerned shall request the submission of information to further address: — the risk to aquatic organisms from metabolites containing the benzyl moiety, — the risk of biomagnification in aquatic food chains. They shall ensure that the notifiers at whose request fenpyroximate has been included in this Annex provide such information to the Commission within two years from the approval.

▼ B▼ M394▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
215	Aclonifen CAS No 74070-46-5 CIPAC No 498	2-chloro-6-nitro-3-phenoxyaniline	≥ 970 g/kg The impurity phenol is of toxicological concern and a maximum level of 5 g/kg is established.	1 August 2009	► <u>M415</u> 31 October 2026 ◀	PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing aclonifen for uses other than sunflower, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aclonifen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the residues in rotational crops and evaluate the dietary exposure of consumers,

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						— the protection of birds, mammals, aquatic organisms and non-target plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate. The Member States concerned shall request the submission of further studies on rotational crops residues and relevant information to confirm the risk assessment for birds, mammals, aquatic organisms and non-target plants. They shall ensure that the notifier provides such confirmatory data and information to the Commission within two years from the approval.
▼ <u>M394</u>						
▼ <u>B</u>	217	Metazachlor CAS No 67129-08-2 CIPAC No 411	2-chloro-N-(pyrazol-1-ylmethyl)acet-2',6'-xylidide ≥ 940 g/kg The manufacturing impurity toluene is considered to be of toxicological concern and a maximum level of 0,05 % is established.	1 August 2009	► <u>M415</u> 31 October 2026 ◀	► <u>M28</u> PART A Only uses as herbicide may be authorised. Applications shall be limited to a total dose of not more than 1,0 kg metazachlor/ha in a three-year period on the same field. ◀ PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metazachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate. If metazachlor is classified under Regulation (EC) No 1272/2008 as ‘suspected of causing cancer’, the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer. They shall ensure that the notifiers provide that information to the Commission within six months from the notification of such a classification decision.
218	Acetic acid CAS No 64-19-7 CIPAC 838	acetic acid	≥ 980 g/kg	1 September 2009	► M429 30 November 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acetic acid (SANCO/2602/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013, shall be taken into account.

▼ **M74**

▼ **M74**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to the protection of operators, the protection of groundwater and the protection of aquatic organisms. Conditions of use shall include, where appropriate, risk mitigation measures. The notifier shall submit confirmatory information as regards: — the acute and long-term risk to birds and mammals, — the risk to honeybees, — the risk to non-target arthropods. The notifier shall submit that information to the Commission, the Member States and the Authority by 31 December 2015.

▼ **M438**

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▼ **M32**

220	Aluminium silicate CAS No 1332-58-7 CIPAC No 841	Not available Chemical name: Aluminium silicate	≥ 999,8 g/kg	1 September 2009	► M460 31 March 2026 ◀	PART A Only uses as repellent may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium silicate (SANCO/2603/08) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to the operator safety; conditions of use shall include the application of adequate personal and respiratory protective equipment, where appropriate. Conditions of use shall include, where appropriate, risk mitigation measures.
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▼ **M32**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall ensure that the applicant submits to the Commission confirmatory information as regards: (a) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data; (b) the relevance of the test material used in the toxicity dossier in view of the specification of the technical material. The Member States concerned shall ensure that the applicant submits such information to the Commission by 1 May 2013.
▼ M394						
▼ M352						
▼ M31	223	Calcium carbide CAS No: 75-20-7 CIPAC No: 910	Calcium acetylide ≥ 765 g/kg Containing 0,08 – 0,9 g/kg Calcium Phosphide	1 September 2009	► M429 30 November 2026 ◀	PART A Only uses as repellent may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on calcium carbide (SANCO/2605/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
▼ M369						
▼ M384						
▼ M394						

▼ **B**▼ **M49**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
227	Ethylene CAS No 74-85-1 CIPAC No 839	Ethylene	≥ 90 % Relevant impurity: ethylene oxide, max content 1 mg/kg	1 September 2009	► M429 30 November 2026 ◀	PART A Only indoor uses as plant growth regulator by professional users may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ethylene (SANCO/2608/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the compliance of ethylene with the required specifications, irrespective of the form in which it is supplied to the user; (b) the protection of operators, workers and bystanders. Conditions of authorisation shall include, where appropriate, risk mitigation measures.
228	Extract from tea tree CAS No Tea Tree Oil 68647-73-4 Main components: terpinen-4-ol 562-74-3 γ-terpinene 99-85-4 α-terpinene 99-86-5 1,8-cineole 470-82-6 CIPAC No 914	Tea Tree Oil is a complex mixture of chemical substances.	Main components: terpinen-4-ol ≥ 300 g/kg γ-terpinene ≥ 100 g/kg α-terpinene ≥ 50 g/kg 1,8-cineole ≥ 1 g/kg Relevant impurity:	1 September 2009	► M429 31 January 2026 ◀	PART A Only uses as fungicide in greenhouse may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on extract from tea tree (SANCO/2609/2008 final) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;

▼ **M106**

▼ **M106**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			Methyl eugenol: maximum 1 g/kg of the technical material			— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of surface water and aquatic organisms; — the protection of honey bees, non-target arthropods, earthworms and non-target micro- and macro-organisms. Conditions of use shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the plant metabolism and consumer exposure; (b) the toxicity of the compounds that constitute the extract and the relevance of possible impurities other than methyl eugenol; (c) the groundwater exposure for the less strongly absorbed components that constitute the extract and for potential soil transformation products; (d) the effects on biological methods of sewage treatment. The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016 at latest.

▼ **M432**

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▼ **M460**

230	Fatty acids C7 to C20					
	CAS No 112-05-0 (Pelargonic Acid) 67701-09-1 (Fatty acids C7-C18 and C18 unsaturated potassium salts) 124-07-2 (Caprylic Acid) 334-48-5 (Capric Acid)	Nonanoic acid Caprylic Acid, Pelargonic Acid, Capric Acid, Lauric Acid, Oleic Acid (ISO in each case)	≥ 889 g/kg (Pelargonic Acid) ≥ 838 g/kg fatty acids ≥ 99 % fatty acid methyl esters	1 September 2009	1 December 2026	PART A Only uses as insecticide, acaricide, and herbicide and plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fatty acids (SANCO/2610/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

▼ **M460**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
		Octanoic Acid, Nonanoic Acid, Decanoic Acid, Dodecanoic Acid, cis-9-Octadecenoic Acid (IUPAC in each case) Fatty acids, C7-C10, Me esters				Conditions of use shall include, where appropriate, risk mitigation measures.
	143-07-7 (Lauric Acid) 112-80-1 (Oleic Acid) 85566-26-3 (Fatty acids C8-C10 Me esters) 111-11-5 (Methyl octanoate) 110-42-9 (Methyl decanoate) CIPAC No not allocated	Nonanoic acid Caprylic Acid, Pelargonic Acid, Capric Acid, Lauric Acid, Oleic Acid (ISO in each case) Octanoic Acid, Nonanoic Acid, Decanoic Acid, Dodecanoic Acid, cis-9-Octadecenoic Acid (IUPAC in each case) Fatty acids, C7-C10, Me esters	≥ 889 g/kg (Pelargonic Acid) ≥ 838 g/kg fatty acids ≥ 99 % fatty acid methyl esters	1 September 2009	31 August 2024	
▼ M350						

▼ **B**

232	Gibberellic acid CAS No 77-06-5 CIPAC No 307	(3S,3aS,4S,4aS,7S,9-aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenol(1,2-b)furan-4-carboxylic acid	≥ 850 g/kg	1 September 2009	► M475 31 October 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on gibberellic acid (SANCO/2613/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.
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▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
		Alt: (3S,3aR,4S,4aS,6S,8-aR,8bR,11S)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-methano-3,8b-prop-lenoperhydro-indenol (1,2-b) furan-4-carboxylic acid				Conditions of use shall include, where appropriate, risk mitigation measures.
233	Gibberellins CAS No GA4: 468-44-0 GA7: 510-75-8 GA4A7 mixture: 8030-53-3 CIPAC No not allocated	GA4: (3S,3aR,4S,4aR,7R,9-aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propenoazuleno [1,2-b]furan-4-carboxylic acid GA7: (3S,3aR,4S,4aR,7R,9-aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno [1,2-b]furan-4-carboxylic acid	Review report (SANCO/2614/2008).	1 September 2009	► M475 31 October 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on gibberellins (SANCO/2614/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
▼ M445						
▼ M38	235 <i>Iron sulphate:</i> Iron(II)sulfate anhydrous: CAS No 7720-78-7	Iron(II)sulphate or iron(2+) sulfate	Iron(II)sulfate anhydrous: ≥ 350 g/kg total iron.	1 September 2009	► M429 30 November 2026 ◀	PART A Only uses as herbicide may be authorised.

▼ **M38**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
	Iron(II)sulfate monohydrate: CAS No 17375-41-6 Iron(II)sulfate heptahydrate: CAS No 7782-63-0 CIPAC No 837		Relevant impurities: arsenic, 18 mg/kg cadmium, 1,8 mg/kg chromium, 90 mg/kg lead, 36 mg/kg mercury, 1,8 mg/kg expressed on the basis of the anhydrous variant			PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on iron sulphate (SANCO/2616/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk for operator; — the risk to children/residents playing on treated turf; — the risk to surface waters and to aquatic organisms. Conditions of use shall include, where appropriate, risk mitigation measures and the application of adequate personal protective equipment. The notifier shall submit to the Member States, the Commission and the Authority, confirmatory information as regards the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicity dossiers. The Member States concerned shall ensure that the notifier submits to the Commission such information by 1 May 2013.
▼ M345						
▼ M394						
▼ M217						
▼ M394						

▼ **B**▼ **M115**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
240	Plant oils/citronella oil CAS No 8000-29-1 CIPAC No 905	Citronella Oil is a complex mixture of chemical substances. The main components are: Citronellal (3,7-dimethyl-6-octenal). Geraniol ((E)-3,7-dimethyl-2,6-octadien-1-ol). Citronellol (3,7-dimethyl-6-octan-2-ol). Geranyl acetate (3,7-dimethyl-6-octen-1-yl acetate).	The sum of the following impurities must not exceed 0,1 % of technical material: methyl eugenol and methyl-isoeugenol.	1 September 2009	► M199 31 August 2022 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on citronella oil (SANCO/2621/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures. In this overall assessment Member States shall pay particular attention to: — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; — the protection of groundwater, when the substance is applied in regions with vulnerable soil; — the risk to non-target organisms. The notifier shall submit confirmatory information as regards: (a) the technical specification; (b) data comparing natural background exposure situations of plant oils/ citronella oil and methyl eugenol and methyl isoeugenol in relation to exposure from the use of plant oils/citronella oil as a plant protection product. This data shall cover human exposure as well as exposure of non-target organisms; (c) the groundwater exposure assessment for potential metabolites of plant oils/citronella oil, in particular for methyl eugenol and methyl isoeugenol. The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016.

▼ **B**▼ **M100**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
241	Plant oils/clove oil CAS No 84961-50-2 (clove oil) 97-53-0 (Eugenol — main component) CIPAC No 906	Clove Oil is a complex mixture of chemical substances. The main component is eugenol.	≥ 800 g/kg Relevant impurity: methyl eugenol maximum 0,1 % of the technical material	1 September 2009	► M429 31 January 2026 ◀	PART A Only indoor uses as post-harvest fungicide and bactericide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clove oil (SANCO/2622/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate. The notifier shall submit confirmatory information as regards (a) the technical specification; (b) data comparing natural background exposure situations of plant oils/ clove oil, eugenol and methyl eugenol in relation to exposure from the use of plant oils/clove oil as a plant protection product. This data shall cover human exposure. The notifier shall submit to the Commission, the Member States and the Authority that information by 30 April 2016.
242	Plant oils/rape seed oil CAS No: 8002-13-9 CIPAC No: not allocated	Rape seed oil	Rape seed oil is a complex mixture of fatty acids Relevant impurity: Maximum 2 % of erucic acid	1 September 2009	► M460 31 March 2026 ◀	PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rape seed oil (SANCO/2623/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account.

▼ **M87**

▼ M87

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Conditions of use shall include, where appropriate, risk mitigation measures.

▼ M37

243	Plant oils/spear mint oil CAS No 8008-79-5 CIPAC No 908	Spearmint oil	≥ 550 g/kg as (R)-Carvone	1 September 2009	► <u>M429</u> 31 January 2026 ◀	PART A Only uses as plant growth regulator for postharvest treatment of potatoes may be authorised. Member States shall ensure that authorisations provide that hot fogging is performed exclusively in professional storage facilities and that the best available techniques are applied to exclude the release into the environment of the product (fogging mist) during storage, transport, waste disposal and application. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the amended review report on plant oils/spearmint oil (SANCO/2624/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
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▼ M372

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▼ M394

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▼ **B**▼ **M75**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
246	Pyrethrins: 8003-34-7 CIPAC No 32 Extract A: extractives of Chrysanthemum cinerariaefolium: 89997- 63-7 Pyrethrin 1: CAS 121-21-1 Pyrethrin 2: CAS 121-29-9 Cinerin 1: CAS 25402-06-6 Cinerin 2: CAS 121-20-0 Jasmolin 1: CAS 4466-14-2 Jasmolin 2: CAS 1172-63-0 Extract B: Pyrethrin 1: CAS 121-21-1 Pyrethrin 2: CAS 121-29-9 Cinerin 1: CAS 25402-06-6 Cinerin 2: CAS 121-20-0 Jasmolin 1: CAS 4466-14-2 Jasmolin 2: CAS 1172-63-0	Pyrethrins are a complex mixture of chemical substances.	Extract A: ≥ 500 g/kg Pyrethrins Extract B: ≥ 480 g/kg Pyrethrins	1 September 2009	► M429 15 June 2026 ◀	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyrethrins (SANCO/2627/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators and workers; (b) the risk to non-target organisms. Conditions of use shall, where appropriate, include the application of adequate personal protective equipment and other risk mitigation measures. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured including information on any relevant impurities and its equivalence with the specifications of the test material used in the toxicity studies; (2) the risk from inhalation; (3) the residue definition; (4) the representativeness of the major component ‘pyrethrin 1’ as regards the fate and behaviour in soil and water. The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) by 31 March 2014 and the information set out in points (2), (3) and (4) by 31 December 2015.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M431</u> _____						
▼ <u>M401</u> _____						
▼ <u>M399</u> _____						
▼ <u>M230</u> _____						
▼ <u>M229</u> _____						
▼ <u>M394</u> _____						

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ <u>M394</u>						
▼ <u>M397</u>						
▼ <u>M394</u>						
▼ <u>M446</u>						
▼ <u>M180</u>						
▼ <u>M179</u>						

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
260	Aluminium phosphide CAS No 20859-73-8 CIPAC No 227	Aluminium phosphide	≥ 830 g/kg	1 September 2009	► M429 30 November 2026 ◀	PART A Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use aluminium phosphide containing products may be authorised. As rodenticide, talpicide and leporicide only outdoor uses may be authorised. Authorisations should be limited to professional users. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of consumers and ensure that the spent ready-to-use aluminium phosphide containing products are removed from the food commodity in uses against storage pests and subsequently an adequate additional withholding period is applied; — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment; — the protection of operators and workers during fumigation for indoor uses; — the protection of workers at re-entry (after fumigation period) for indoor uses; — the protection of bystanders against leaking of gas for indoor uses; — the protection of birds and mammals. Conditions of authorisation should include risk mitigation measures, such as the closure of the burrows and the achievement of complete incorporation of granules in the soil, where appropriate;

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones between treated areas and surface water bodies, where appropriate.
▼ M394						
▼ B	262 Magnesium phosphide CAS No 12057-74-8 CIPAC No 228	Magnesium phosphide	≥ 880 g/kg	1 September 2009	► M429 30 November 2026 ◀	PART A Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use magnesium phosphide containing products may be authorised. As rodenticide, talpicide and leporicide only outdoor uses may be authorised. Authorisations should be limited to professional users. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on magnesium phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of consumers and ensure that the spent ready-to-use magnesium phosphide containing products are removed from the food commodity in uses against storage pests and subsequently an adequate additional withholding period is applied; — the operator safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment;

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the protection of operators and workers during fumigation for indoor uses; — the protection of workers at re-entry (after fumigation period) for indoor uses; — the protection of bystanders against leaking of gas for indoor uses; — the protection of birds and mammals. Conditions of authorisation should include risk mitigation measures, such as the closure of the burrows and the achievement of complete incorporation of granules in the soil, where appropriate; — the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones between treated areas and surface water bodies, where appropriate.
263	Cymoxanil CAS No 57966-95-7 CIPAC No 419	1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea	≥ 970 g/kg	1 September 2009	►M429 15 August 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
264	Dodemorph CAS No 1593-77-7 CIPAC No 300	cis/trans-[4-cyclo-dodecyl]-2,6-dimethylmorpholine	≥ 950 g/kg	1 September 2009	► M452 31 August 2024 ◀	PART A Only uses as fungicide on ornamentals in glasshouse may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dodemorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil conditions; — conditions of authorisation should include risk mitigation measures, where appropriate.
265	2,5-Dichlorobenzoic acid methylester CAS No 2905-69-3 CIPAC No 686	methyl-2,5-dichlorobenzoate	≥ 995 g/kg	1 September 2009	► M429 30 November 2026 ◀	PART A Only indoor uses as plant growth regulator and fungicide for grafting of grapevines may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,5-Dichlorobenzoic acid methylester, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
266	Metamitron CAS No 41394-05-2 CIPAC No 381	4-amino-4,5-dihydro-3-methyl-6-phenyl-1,2,4-triazin-5-one	≥ 960 g/kg	1 September 2009	► M429 30 November 2026 ◀	PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing metamitron for uses other than on root crops, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metamitron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of personal protective equipment where appropriate; — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to birds and mammals, and non-target terrestrial plants. Conditions of authorisation shall include risk mitigation measures, where appropriate.

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request the submission of further information on the impact of soil metabolite M3 on groundwater, on residues in rotational crops, on the long-term risk to insectivorous birds and the specific risk to birds and mammals that may be contaminated by the intake of water in field. They shall ensure that the notifiers at whose request metamitron has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.
267	Sulcotrione CAS No 99105-77-8 CIPAC No 723	2-(2-chloro-4-mesyl-benzoyl)cyclohexane-1,3-dione	≥ 950 g/kg Impurities: — hydrogen cyanide: not more than 80 mg/kg — toluene: not more than 4 g/kg	1 September 2009	►M429 30 November 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulcotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; — the risk to insectivorous birds, aquatic and terrestrial non-target plants, and non-target arthropods.

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the degradation in soil and water of the cyclohexadione moiety and the long-term risk to insectivorous birds. They shall ensure that the notifier at whose request sulcotrione has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.
268	Tebuconazole CAS No 107534-96-3 CIPAC No 494	(RS)-1-p-chloro-phenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol	≥ 905 g/kg	1 September 2009	► M429 15 August 2026 ◀	► M128 PART A Only uses as fungicide and plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers to the tebuconazole (triazole) metabolites; — the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil or climatic conditions, in particular as regards the occurrence in groundwater of the metabolite 1,2,4-triazole; — the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; — the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines. ◀
▼ <u>M394</u>						
▼ <u>B</u>						
271	Bensulfuron CAS No 83055-99-6 CIPAC No 502.201	α-[(4,6-dimethoxy-pyrimidin-2-ylcarbamo-yl)sulfamoyl]-o-toluic acid (bensulfuron) methyl α-[(4,6-dimethoxy-pyrimidin-2-ylcarbamo-yl)sulfamoyl]-o-toluate (bensulfuron-methyl)	≥ 975 g/kg	1 November 2009	► <u>M434</u> 15 August 2026 ◀	PART A Only uses as a herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bensulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 8 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to the following: — the protection of aquatic organisms; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, where the active substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall ensure that the notifier submits to the Commission: — further studies on the specification, — information to further address the route and rate of degradation of bensulfuron-methyl under aerobic flooded soil conditions, — information to address the relevance of metabolites for the consumer risk assessment. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
272	Sodium 5-nitroguaiacolate CAS No 67233-85-6 CIPAC number not allocated	Sodium 2-methoxy-5-nitrophenolate	≥ 980 g/kg	1 November 2009	► M434 31 January 2027 ◀	PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
273	Sodium o-nitrophenolate CAS No 824-39-5 CIPAC number not allocated	Sodium 2-nitrophenolate; sodium o-nitrophenolate	≥ 980 g/kg The following impurities are of toxicological concern: Phenol Max content: 0,1 g/kg 2,4 dinitrophenol max content: 0,14 g/kg 2,6 dinitrophenol max content: 0,32 g/kg	1 November 2009	► M434 31 January 2027 ◀	PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
274	Sodium p-nitrophenolate CAS No 824-78-2 CIPAC number not allocated	Sodium 4-nitrophenolate; sodium p-nitrophenolate	≥ 998 g/kg The following impurities are of toxicological concern: Phenol max content: 0,1 g/kg 2,4 dinitrophenol max content: 0,07 g/kg 2,6 dinitrophenol max content: 0,09 g/kg	1 November 2009	► M434 31 January 2027 ◀	PART A Only use as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the protection of the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further studies to address the risk to groundwater. They shall ensure that the notifiers provide such studies to the Commission by 31 October 2011.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
275	Tebufenpyrad CAS No 119168-77-3 CIPAC No 725	N-(4-tert-butylbenzyl)-4-chloro-3-ethyl-1-methylpyrazole-5-carboxamide	≥ 980 g/kg	1 November 2009	► M434 31 January 2027 ◀	PART A Only uses as acaricide and insecticide may be authorised. PART B In assessing applications to authorise plant protection products containing tebufenpyrad in formulations other than water soluble bags Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebufenpyrad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 December 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and must ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the protection of insectivorous birds and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. The Member States concerned shall ensure that the notifier submits to the Commission: — further information confirming that no relevant impurities are present, — information to further address the risk to insectivorous birds. They shall ensure that the notifier provides such information to the Commission by 31 October 2011.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
276	Chlormequat CAS No 7003-89-6 (chlormequat) CAS No 999-81-5 (chlormequat chloride) CIPAC No 143 (chlormequat) CIPAC No 143.302 (chlormequat chloride)	2-chloroethyltrimethylammonium (chlormequat) 2-chloroethyltrimethylammonium chloride (chlormequat chloride)	≥ 636 g/kg Impurities 1,2-dichloroethane: max 0,1 g/kg (on the dry chlormequat chloride content) Chloroethene (vinylchloride): max 0,0005 g/kg (on the dry chlormequat chloride content)	1 December 2009	► M434 28 February 2027 ◀	PART A Only uses as plant growth regulator on cereals and non edible crops may be authorised. PART B In assessing applications to authorise plant protection products containing chlormequat for uses other than in rye and triticale, notably as regards the exposure of consumers, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlormequat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — the protection of birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the fate and behaviour (adsorption studies to be performed at 20 °C, recalculation of the predicted concentrations in groundwater, surface water and sediment), the monitoring methods for determination of the substance in animal products and water, and the risk to aquatic organisms, birds and mammals. They shall ensure that the notifier at whose request chlormequat has been included in this Annex provide such information to the Commission by 30 November 2011 at the latest.

▼ B▼ M288▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
278	Propaquizafop CAS No 111479-05-1 CIPAC No 173	2-isopropylide-namino-oxyethyl (R)-2-[4-(6-chloro-quin-oxalin-2-yloxy)phenoxy]propionate	≥ 920 g/kg Toluene maximum content 5 g/kg	1 December 2009	► M434 28 February 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on propaquizafop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the protection of non-target arthropods and ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall ensure that the notifier submits to the Commission: — further information on the relevant impurity Ro 41-5259, — information to further address the risk to aquatic organisms and to non-target arthropods. They shall ensure that the notifier provides such information to the Commission by 30 November 2011.
279	Quizalofop-P					
	Quizalofop-P-tefuryl CAS No 119738-06-6 CIPAC No 641.226	(RS)-Tetrahydro-furfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy] propionate	≥ 795 g/kg	1 December 2009	► M434 28 February 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quizalofop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission further information on the risk to non-target arthropods.
	Quizalofop-P-ethyl CAS No 100646-51-3 CIPAC No 641.202	ethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy] propionate	≥ 950 g/kg	1 December 2009	► M434 28 February 2027 ◀	

▼ **M213**

▼ **M213**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						They shall ensure that the notifier provides such information to the Commission by 30 November 2011.

▼ **M394**

▼ **B**

284	Dimethachlor CAS No 50563-36-5 CIPAC No 688	2-chloro-N-(2-methoxyethyl)acet-2',6'-xylylidide	≥ 950 g/kg Impurity 2,6-dimethylaniline: Not more than 0,5 g/kg	1 January 2010	► M440 15 October 2026 ◀	PART A Only uses as herbicide in application max. of 1,0 kg/ha only every third year on the same field may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dimethachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from metabolites CGA 50266, CGA 354742, CGA 102935 and SYN 528702 in vulnerable zones, where appropriate.
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▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall: — ensure that the notifier submits to the Commission further studies on the specification by 1 January 2010. If dimethachlor is classified as carcinogenic category 2 in accordance with Regulation (EC) No 1272/2008, the Member States concerned shall request the submission of further information on the relevance of the metabolites CGA 50266, CGA 354742, CGA 102935 and SYN 528702 with respect to cancer and ensure that the notifier provides that information to the Commission within six months from the notification of the classification decision concerning that substance.
285	Etofenprox CAS No 80844-07-1 CIPAC No 471	2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether	≥ 980 g/kg	1 January 2010	►M440 31 March 2027 ◀	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on etofenprox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of bees and non-target arthropods; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall: — ensure that the notifier submits to the Commission further information on the risk to aquatic organisms including the risk to sediment dwellers and biomagnification, — the submission of further studies on the endocrine disruption potential in aquatic organisms (fish full life cycle study). They shall ensure that the notifiers provide such studies to the Commission by 31 December 2011.
▼ <u>M394</u>						
▼ <u>B</u>	287	Penconazole CAS No 66246-88-6 CIPAC No 446	(RS) 1-[2-(2,4-dichloro-phenyl)-pentyl]-1H-[1,2,4] triazole	≥ 950 g/kg	1 January 2010	► <u>M440</u> 15 October 2026 ◀ PART A Only uses as fungicides may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the fate and behaviour of the soil metabolite CGA179944 in acidic soils. They shall ensure that the notifier at whose request penconazole has been included in this Annex provide such information to the Commission by 31 December 2011 at the latest.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
288	Tri-allate CAS No 2303-17-5 CIPAC No 97	S-2,3,3-trichloroallyl di-isopropyl (thiocarbamate)	≥ 940 g/kg NDIPA (Nitroso-diisopropylamine) max. 0,02 mg/kg	1 January 2010	► M440 31 March 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tri-allate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the dietary exposure of consumers to residues of tri-allate in treated crops as well as in succeeding rotational crops and in products of animal origin — the protection of aquatic organisms and non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate, — the potential for ground water contamination by the degradation products TCPSA when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission: — further information to assess the primary plant metabolism,

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						— further information on the fate and behaviour of the soil metabolite diisopropylamine, — further information on the potential for biomagnification in aquatic food chains, — information to further address the risk to fish-eating mammals and the long-term risk to earthworms. They shall ensure that the notifier provides such information to the Commission by 31 December 2011.
▼ <u>M437</u>						
▼ <u>M394</u>						
▼ <u>M48</u>						
▼ <u>B</u>						
292	sulphur CAS No 7704-34-9 CIPAC No 18	sulphur	≥ 990 g/kg	1 January 2010	► <u>M468</u> 31 July 2026 ◀	PART A Only uses as fungicide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2009 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall ensure that the notifier submit to the Commission further information to confirm the risk assessment for birds, mammals, sediment dwelling organisms and non-target arthropods. They shall ensure that the notifier at whose request sulphur has been included in this Annex provide such data to the Commission at latest by 30 June 2011.
293	Tetraconazole CAS No 112281-77-3 CIPAC No 726	(RS)-2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propyl-1,1,2,2-tetrafluoroethyl ether	≥ 950 g/kg (racemic mixture) Impurity toluene: not more than 13 g/kg	1 January 2010	►M440 31 March 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tetraconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms and non-target plants; in relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall request: — the submission of further information on a refined consumer risk assessment, — further information on the specification regarding ecotoxicology,

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— further information on the fate and behaviour of potential metabolites in all relevant compartments, — the refined risk assessment of such metabolites to birds, mammals aquatic organisms and non-target arthropods, — further information on the potential for endocrine disrupting effects to birds, mammals and fish. They shall ensure that the notifier provides such information to the Commission by 31 December 2011.
294	Paraffin oils CAS No 64742-46-7 CAS No 72623-86-0 CAS No 97862-82-3 CIPAC No n.a.	paraffin oil	European Pharmacopoeia 6.0	1 January 2010	► M440 31 March 2027 ◀	► M393 Part A Only uses as insecticide, acaricide and fungicide may be authorised. Part B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3, including its addendum, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. ◀
295	Paraffin oil CAS No 8042-47-5 CIPAC No n.a.	paraffin oil	European Pharmacopoeia. 6,0	1 January 2010	► M475 30 November 2026 ◀	PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on paraffin oil 8042-47-5, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request: The submission of the specification of the technical material as commercially manufactured to verify the compliance with purity criteria of European Pharmacopoeia. 6,0 They shall ensure that the notifier provides such information to the Commission by 30 June 2010.
296	Cyflufenamid CAS No 180409-60-3 CIPAC No 759	(Z)-N-[α-(cyclopropylmethoxyimino) – 2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide	> 980 g/kg	1 April 2010	► M444 30 June 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyflufenamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 2 October 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate.
297	Fluopicolide CAS No 239110-15-7 CIPAC No 787	2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	≥ 970 g/kg The impurity toluene must not exceed 3 g/kg in the technical material.	1 June 2010	► M415 31 August 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluopicolide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009 shall be taken into account.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment, Member States must pay particular attention to: — the protection of aquatic organisms, — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — to the risk to operators during application, — the potential for long range transport via air. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential accumulation and exposure in vulnerable areas, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission further information on the relevance of the metabolite M15 for groundwater by 30 April 2012 at the latest.
▼ <u>M403</u>						
▼ <u>B</u>						
299	2-phenylphenol (including its salts such as the sodium salt) CAS No 90-43-7 CIPAC No 246	biphenyl-2-ol	≥ 998 g/kg	1 January 2010	► <u>M440</u> 15 November 2027 ◀	PART A Only uses as a post-harvest fungicide for indoor use may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2-phenylphenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009, as amended in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States must pay particular attention: — to the protection of operators and workers and ensure that conditions of use prescribe the application of adequate personal protective equipment, — to put in place appropriate waste management practices to handle the waste solution remaining after application, including the cleaning water of the drenching and other application systems. Member States permitting the release of wastewater into the sewage system, shall ensure that a local risk assessment is carried out. The Member States concerned shall ensure that the notifier submits to the Commission: — further information on the potential for skin depigmentation for workers and consumers due to possible exposure to the metabolite 2-phenylhydroquinone (PHQ) on citrus peel, — further information to confirm that the analytical method applied in residue trials correctly quantifies the residues of 2-phenylphenol, PHQ and their conjugates. They shall ensure that the notifier provides such information to the Commission by 31 December 2011. Furthermore, the Member States concerned shall ensure that the notifier submits to the Commission further information to confirm the residue levels occurring as a result of application techniques other than those in drench chambers. They shall ensure that the notifier provides such information to the Commission by 31 December 2012.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
300	Malathion CAS No 121-75-5 CIPAC No 12	diethyl (dimethoxyphosphinothioylthio) succinate or S-1,2-bis(ethoxycarbonyl)ethyl O,O-dimethyl phosphorodithioate racemate	≥ 950 g/kg Impurities: Isomalathion: not more than 2 g/kg	1 May 2010	► M413 31 July 2026 ◀	► M277 PART A Only uses as an insecticide in greenhouses with a permanent structure may be authorised. Authorisations shall be limited to professional users. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on malathion, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account. In this overall assessment, Member States must pay particular attention to: (a) releases from greenhouses, such as condensation water, drain water, soil or artificial substrate, in order to preclude risks to aquatic organisms; (b) the protection of pollinator colonies purposely placed in the greenhouse; (c) the protection of operators and workers, so as to ensure that the conditions of use prescribe the use of adequate personal protective equipment, where appropriate; (d) the protection of consumers in the case of processed commodities. Member States shall ensure that malathion-based formulations are accompanied by the necessary instructions to avoid any risk of formation of isomalathion in excess of the permitted maximum quantities during storage and transport.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						Conditions of authorisation shall include risk mitigation measures and provide for adequate labelling of plant protection products. ◀
301	Penoxsulam CAS No 219714-96-2 CIPAC No 758	3-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluorotoluene-2-sulfonamide	> 980 g/kg The impurity Bis-CHYMP 2-chloro-4-[2-(2-chloro-5-methoxy-4-pyrimidinyl)hydrazino]-5-methoxypyrimidine must not exceed 0,1 g/kg in the technical material	1 August 2010	► M415 15 May 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penoxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention to: — the protection of aquatic organisms, — the dietary exposure of consumers to residues of the metabolite BSCTA in succeeding rotational crops, — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission further information to address the off-field risk to higher aquatic plants. They shall ensure that the notifier provides such information to the Commission by 31 July 2012.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Rapporteur Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.
302	Proquinazid CAS No 189278-12-4 CIPAC No 764	6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one	> 950 g/kg	1 August 2010	► M415 15 May 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on proquinazid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010 shall be taken into account. In this overall assessment, Member States must pay particular attention: — to the long-term risk to earthworm-eating birds for uses in grapevine, — to the risk to aquatic organisms, — the dietary exposure of consumers to proquinazid residues in products of animal origin and in succeeding rotational crops, — to the operator safety. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Rapporteur Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

▼ **M394**

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
304	Metalaxyl CAS No 57837-19-1 CIPAC No 365	Methyl N-(methoxyacetyl)-N-(2,6-xylyl)-DL-alaninate	950 g/kg The impurity 2,6-dimethylaniline was considered of toxicological concern and a maximum level of 1 g/kg is established.	1 July 2010	► M415 30 September 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metalaxyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2010 shall be taken into account. Member States must pay particular attention to the potential contamination of groundwater by the active substance or its degradation products CGA 62826 and CGA 108906 when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Risk mitigation measures should be applied where appropriate.
305	Flonicamid (IKI-220) CAS No 158062-67-0 CIPAC No 763	N-cyanomethyl-4-(trifluoromethyl)nicotinamide	≥ 960 g/kg The impurity toluene must not exceed 3 g/kg in the technical material.	1 September 2010	► M429 30 November 2026 ◀	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flonicamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2010, shall be taken into account. In this overall assessment, Member States must pay particular attention to: — the risk to operators and re-entry workers, — the risk to bees. Conditions of authorisation shall include risk mitigation measures where appropriate. The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

▼ B▼ M394▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
307	Sulfuryl fluoride CAS No 002699-79-8 CIPAC No 757	Sulfuryl fluoride	> 994 g/kg	1 November 2010	► <u>M434</u> 31 January 2027 ◀	► <u>M202</u> PART A Only uses as insecticide/nematicide (fumigant) applied by professional users in sealable structures may be authorised insofar: (a) these structures are empty; or (b) where food or feed commodities are present in a fumigated facility, the users and the food business operators ensure that only the food or feed commodities compliant with the existing maximum residue levels for sulfuryl fluoride and fluoride ion set by Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽¹⁹⁾ may enter the food and feed chain; to this purpose, the users and the food business operators shall fully implement measures equivalent to the HACCP principles as laid down in Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽²⁰⁾; in particular, the users shall identify the critical control point at which control is essential to prevent maximum residue levels to be exceeded, and establish and implement effective monitoring procedures at that critical control point. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfuryl fluoride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 7 December 2016 shall be taken into account. In this overall assessment, Member States must pay particular attention to:

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the risk posed by inorganic fluoride through contaminated products, such as flour and bran that remained in the mill machinery during fumigation, or grain stored in silos in the mill. Measures are required to ensure that only products complying with the existing MRLs enter the food and feed chain; — the risk to operators and the risk to workers, such as when re-entering a fumigated structure after aeration. Measures are required to ensure that they wear self-containing breathing apparatus or other appropriate personal protective equipment; — the risk to bystanders by applying an appropriate exclusion zone around the fumigated structure. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit to the Commission, Member States and the Authority monitoring data on tropospheric concentrations of sulfuryl fluoride every fifth year, starting from 30 June 2017. The limit of detection for the analysis shall be at least 0,5 ppt (equivalent to 2,1 ng sulfuryl fluoride/m³ of tropospheric air). ◀
▼ <u>M394</u>						
▼ <u>B</u>						
310	Napropamide CAS No 15299-99-7	(RS)-N,N-diethyl-2-(1-naphthyloxy)propionamide	≥ 930 g/kg (Racemic mixture) Relevant impurity Toluene: not more than 1,4 g/kg	1 January 2011	► <u>M440</u> 31 March 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on napropamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account.

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Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — operator safety: conditions of use shall prescribe the use of adequate personal protective equipment, where necessary, — protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones, — consumer safety as regards the occurrence in groundwater of the metabolite 2-(1-naphthylloxy)propionic acid, hereinafter 'NOPA'. The Member States concerned shall ensure that the applicant presents to the Commission, by 31 December 2012 at the latest, information confirming the surface water exposure assessment as regards the photolysis metabolites and the metabolite NOPA and information for the risk assessment of aquatic plants.
311	Quinmerac CAS No 90717-03-6 CIPAC No 563	7-chloro-3-methylquinoline-8-carboxylic acid	≥ 980 g/kg	1 May 2011	►M449 31 December 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quinmerac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the dietary exposure of consumers to residues of quinmerac (and its metabolites) in succeeding rotational crops — the risk to aquatic organisms and the long term risk for earthworms. Conditions of use shall include risk mitigation measures, where appropriate.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request the submission of information as regards: — the potential of plant metabolism to result in an opening of the quinoline ring; — residues in rotational crops and the long term risk for earthworms due to the metabolite BH 518-5. They shall ensure that the applicant provides such confirmatory data and information to the Commission by 30 April 2013.
▼ <u>M394</u>						
▼ <u>B</u>	313	Pyridaben CAS No 96489-71-3 CIPAC No 583	2-tert-butyl-5-(4-tert-butylbenzylthio)-4-chloropyrididazin-3(2H)-one	>980 g/kg	1 May 2011	► <u>M413</u> 31 July 2026 ◀ PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyridaben, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the risk to aquatic organisms and mammals, — the risk to non target arthropods including honeybees. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify the real exposure of honeybees to pyridaben in areas extensively used by such bees for foraging or by beekeepers, where and as appropriate.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request the submission of confirmatory information as regards: — the risks for the water compartment resulting from the exposure to aqueous photolysis metabolites W-1 and B-3, — the potential long term risk for mammals, — the assessment of fat soluble residues. They shall ensure that the applicant provides such confirmatory information to the Commission by 30 April 2013.
314	Zinc phosphide CAS No 1314-84-7 CIPAC No 69	Trizinc diphosphide	≥ 800 g/kg	1 May 2011	► M449 31 December 2026 ◀	PART A Only uses as rodenticide in the form of ready-to-use baits placed in bait stations or target locations may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on zinc phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account. In this overall assessment Member States should pay particular attention to: — the protection of non target organisms. Risk mitigation measures should be applied as appropriate in particular to avoid the spread of baits where only part of the content has been consumed.

▼ **M394**

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
316	Cycloxydim CAS No 101205-02-1 CIPAC No 510	(5RS)-2-[(EZ)-1-(ethoxyimino)butyl]-3-hydroxy-5-[(3RS)-thian-3-yl]cyclohex-2-en-1-one	≥ 940 g/kg	1 June 2011	► M415 31 August 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cycloxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information concerning the methods for analysis of residues of cycloxydim in plant and animal products. The Member States concerned shall ensure that the applicant submits such methods of analysis to the Commission by 31 May 2013.
317	6-Benzyladenine CAS No 1214-39-7 CIPAC No 829	N6-benzyladenine	≥ 973 g/kg	1 June 2011	► M449 15 July 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 6-benzyladenine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
318	Bromuconazole CAS No 116255-48-2 CIPAC No 680	1-[(2RS,4RS:2RS,4SR)-4-bromo-2-(2,4-dichlorophenyl)tetrahydrofurfuryl]-1H-1,2,4-triazole	≥ 960 g/kg	1 February 2011	► M444 30 April 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bromuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — operator's safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; — protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones. The Member States concerned shall ensure that the applicant presents to the Commission: — further information on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; — information to further address the long term risk to herbivorous mammals. They shall ensure that the applicant at whose request bromuconazole has been included in this Annex provides such confirmatory information to the Commission by 31 January 2013 at the latest. The Member States concerned shall ensure that the applicant submits to the Commission further information addressing the potential endocrine disrupting properties of bromuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.

▼ B▼ M394▼ B▼ M394▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
320	Buprofezin CAS No 953030-84-7 CIPAC No 681	(Z)-2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one	≥ 985 g/kg	1 February 2011	► <u>M444</u> 15 December 2025 ◀	► <u>M204</u> PART A Only uses as insecticide and acaricide on non-edible crops may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on buprofezin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed shall be taken into account. In this overall assessment, Member States must pay particular attention to: — the operators' and workers' safety and ensure that conditions of use impose the use of adequate personal protective equipment where appropriate, — the application of an appropriate waiting period for rotational crops in greenhouses, — the risk to aquatic organisms and ensure that conditions of use impose adequate risk mitigation measures, where appropriate. Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀
322	Hymexazol CAS No 10004-44-1 CIPAC No 528	5-methylisoxazol-3-ol (or 5-methyl-1,2-oxazol-3-ol)	≥985 g/kg	1 June 2011	► <u>M415</u> 31 August 2026 ◀	PART A Only uses as fungicide for seed pelleting of sugar beets in professional seed treatment facilities may be authorised.

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Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on hymexazol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operators and workers safety. Conditions of authorisation shall include protective measures, where appropriate, — the risk to granivorous birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards the nature of residues in root crops and the risk for granivorous birds and mammals. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
323	Dodine CAS No 2439-10-3 CIPAC No 101	1-dodecylguanidinium acetate	≥ 950 g/kg	1 June 2011	► M449 15 July 2026 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dodine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the potential long-term risk to birds and mammals;

▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the risk to aquatic organisms and ensure that conditions of use impose adequate risk mitigation measures; — the risk to non-target plants in the off-field area and ensure that conditions of use impose adequate risk mitigation measures; — the monitoring of residue levels in pome fruit. The Member States concerned shall request the submission of confirmatory information as regards: — long-term risk assessment for birds and mammals, — risk assessment in natural surface water systems where major metabolites have potentially formed. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
▼ <u>M394</u>						
▼ <u>B</u>	326	Indolylbutyric acid CAS No 133-32-4 CIPAC No 830	4-(1H-indol-3-yl) butyric acid	≥ 994 g/kg	1 June 2011	► <u>M415</u> 15 March 2026 ◀ PART A Only uses as plant growth regulator in ornamentals may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on indolylbutyric acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the operators and workers safety. Conditions of authorisation shall include the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request the submission of further information to confirm: — the absence of clastogenicity potential of indolylbutyric acid; — the vapour pressure of indolylbutyric acid and, consequently, an inhalation toxicity study; — the natural background concentration of indolylbutyric acid in the soil. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
▼ <u>M394</u>						
▼ <u>B</u>	328	Tau-fluvalinate CAS No 102851-06-9 CIPAC No 786	(RS)- α -cyano-3-phen- oxybenzyl N-(2- chloro- α,α α - trifluoro-p-tolyl)-D- valinate (Isomer ratio 1:1)	≥ 920 g/kg (1:1 ratio of R- α - cyano and S- α - cyano isomers) Impurities: Toluene: not more than 5 g/kg	1 June 2011 ► <u>M449</u> 31 January 2027 ◀	PART A Only uses as insecticide and acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tau-fluvalinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms and ensure that conditions of use prescribe the application of adequate risk mitigation measures; — the risk to non-target arthropods and ensure that conditions of use prescribe the application of adequate risk mitigation measures; — the test material used in the toxicity dossiers shall be compared and verified against the specification of the technical material commercially manufactured.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request the submission of confirmatory information as regards: — the risk of bioaccumulation/biomagnification in the aquatic environment; — the risk to non-target arthropods; The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013. The Member States concerned shall ensure that the applicant submits confirmatory information, two years after the adoption of specific guidance, as regards: — the possible impact on the environment of the potential enantio-selective degradation in environmental matrices.
329	Clethodim CAS No 99129-21-2 CIPAC No 508	(5RS)-2-[(1EZ)-1-[(2E)-3-chloroallyloxyimino]propyl]-5-[(2RS)-2-(ethylthio)propyl]-3-hydroxy-cyclohex-2-en-1-one	≥ 930 g/kg Impurities: toluene max. 4 g/kg	1 June 2011	► M415 31 August 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clethodim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 December 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection to aquatic organisms, birds and mammals, and shall ensure that conditions of use include the application of adequate risk mitigation measures. The Member States concerned shall request the submission of confirmatory information, on the basis of most recent scientific knowledge, as regards: — the soil and groundwater exposure assessments, — the residue definition for risk assessment. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.

▼ **M27**

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
330	Bupirimate CAS No 41483-43-6 CIPAC No 261	5-butyl-2-ethylamino-6-methylpyrimidine-4-yl dimethylsulfamate	≥ 945 g/kg Impurities: Ethirimol: max. 2 g/kg Toluene: max. 3 g/kg	1 June 2011	► M449 31 January 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bupirimate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigations, where appropriate, — the in-field risk to non-target arthropods. The Member States concerned shall request the submission of confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured, by appropriate analytical data; including information on the relevance of the impurities, (2) the equivalence between the specifications of the technical material; as commercially manufactured, and those of the test material used in the toxicity dossiers, (3) the kinetic parameters, the soil degradation and the adsorption and desorption parameter for the major soil metabolite DE-B ⁽⁶⁾. The Member States concerned shall ensure that the applicant submits such confirmatory data and information to the Commission set out in point (1) and (2) by 30 November 2011 and the information set out in point (3) by 31 May 2013.

▼ B▼ M112▼ M394▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
333	1-decanol CAS No 112-30-1 CIPAC No 831	Decan-1-ol	≥ 960 g/kg	1 June 2011	► <u>M449</u> 15 July 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-decanol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers from residues in case of use on food or feed crops; — the risk for operator and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate; — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms; — the risk to non-target arthropods and bees that may be exposed to the active substance by visiting flowering weeds present in the crop at time of application. Risk mitigation measures shall be applied, where appropriate.

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Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall request the submission of confirmatory information, as regards the risk to aquatic organisms and of information confirming the groundwater, surface water and sediment exposure assessments. The Member States concerned shall ensure that the applicant submits such confirmatory information to the Commission by 31 May 2013.
334	Isoxaben CAS No 82558-50-7 CIPAC No 701	N-[3-(1-ethyl-1-methylpropyl)-1,2-oxazol-5-yl]-2,6-dimethoxybenzamide	≥ 910 g/kg Toluene: ≤ 3 g/kg	1 June 2011	►M449 31 January 2027 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on isoxaben, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 January 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, the risk to non-target terrestrial plants and the potential leaching of metabolites to groundwater. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the specification of the technical material, as commercially manufactured, (b) the relevance of the impurities; (c) the residues in rotational crops;

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Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						(d) the potential risk to aquatic organisms. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a) and (b) by 30 November 2011 and the information set out in points (c) and (d) by 31 May 2013.
335	Fluometuron CAS No: 2164-17-2 CIPAC No: 159	1,1-dimethyl-3-(α,α,α -trifluoro-m-tolyl)urea	≥ 940 g/kg	1 June 2011	►M449 15 July 2026 ◀	PART A Only uses as herbicide on cotton may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluometuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: — pay particular attention to the protection of the operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; — pay particular attention to the protection of the groundwater where the active substance is applied in regions with vulnerable soil and/or climatic conditions; they shall ensure that conditions of authorisation include risk mitigation measures and the obligation to carry out monitoring programmes to verify potential leaching of fluometuron and soil metabolites desmethyl-fluometuron and trifluoromethylaniline in vulnerable areas, where appropriate; — pay particular attention to the risk to non-target soil macro-organisms others than earthworms and non-target plants, and ensure that conditions of authorisation include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicants submit to the Commission confirmatory information as regards: (a) the toxicological properties of the plant metabolite trifluoroacetic acid; (b) the analytical methods for the monitoring of fluometuron in air; (c) the analytical methods for the monitoring of the soil metabolite trifluoromethylaniline in soil and water;

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						(d) the relevance for ground water of the soil metabolites desmethyl-fluometuron and trifluoromethylaniline, if fluometuron is classified under Regulation (EC) No 1272/2008 as 'suspected of causing cancer'. The Member States concerned shall ensure that the applicants submit to the Commission the information set out in points (a), (b) and (c) by 31 March 2013 and the information set out in point (d) within six months from the notification of the decision classifying fluometuron.
▼ M394						
▼ B	339	Dazomet CAS No 533-74-4 CIPAC No 146	3,5-dimethyl-1,3,5-thiadiazinane-2-thione or tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione	≥ 950 g/kg	1 June 2011	► M415 31 August 2026 ◀ PART A Only uses as nematocide, fungicide, herbicide and insecticide may be authorised. Only application as soil fumigant may be authorised. Use shall be limited to one application every third year. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dazomet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to operators, workers and bystanders; — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms.

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the potential groundwater contamination by methyl isothiocyanate; (b) the assessment of the long range atmospheric transport potential of methyl isothiocyanate and related environmental risks; (c) the acute risk to insectivorous birds; (d) the long term risk to birds and mammals. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b), (c) and (d) by 31 May 2013.
340	Metaldehyde CAS No 108-62-3 (tetramer) 9002-91-9 (homopolymer) CIPAC No 62	r-2, c-4, c-6, c-8-tetramethyl-1,3,5,7-tetroxocane	≥ 985 g/kg acetaldehyde max. 1,5 g/kg	1 June 2011	►M415 31 August 2026 ◀	PART A Only uses as molluscicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metaldehyde, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to operators and workers; — the dietary exposure situation of consumers in view of future revisions of maximum residue levels; — the acute risk and long term risk to birds and mammals.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Member States shall ensure that authorisations shall contain an effective dog repellent agent. Conditions of use shall include risk mitigation measures, where appropriate.
341	Sintofen CAS No 130561-48-7 CIPAC No 717	1-(4-chlorophenyl)- 1,4-dihydro-5-(2-methoxyethoxy)-4-oxocinnoline-3-carboxylic acid	≥ 980 g/kg Impurities: 2-methoxyethanol, not more than 0,25 g/kg N,N-dimethylformamide, not more than 1,5 g/kg	1 June 2011	► M449 15 July 2026 ◀	PART A Only uses as a plant growth regulator on wheat for hybrid seed production not intended for human consumption may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sintofen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate risk mitigation measures. They shall ensure that wheat treated with sintofen does not enter the food and feed chain. The Member States concerned shall request the submission of confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured, supported by appropriate analytical data; (2) the relevance of the impurities present in the technical specifications, except of the impurities 2-methoxyethanol and N,N-dimethylformamide; (3) the relevance of the test material used in the toxicity and ecotoxicity dossiers in view of the specification of the technical material;

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						(4) the metabolic profile of sintofen in rotational crops. The Member States concerned shall ensure that the applicant submits to the Commission: the information set out in points (1) (2) and (3) by 30 November 2011 and the information set out in point (4) by 31 May 2013.
342	Fenazaquin CAS No 120928-09-8 CIPAC No 693	4-tert-butylphenethyl quinazolin-4-yl ether	≥ 975 g/kg	1 June 2011	► M415 31 August 2026 ◀	► M256 PART A Only uses as acaricide in greenhouses may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenazaquin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, and of the addendum to the review report on fenazaquin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 22 March 2018, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of aquatic organisms; (b) the protection of operators, also ensuring that the conditions of the use include the application of adequate personal protective equipment; (c) the protection of bees; (d) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses; (e) the risk to consumers, in particular from the residues generated during processing;

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(f) the conditions of use to avoid exposure to residues of fenazaquin with respect to crops for human and animal consumption. Conditions of use shall include risk mitigation measures, where appropriate. ◀
343	Azadirachtin CAS No 11141-17-6 (azadirachtin A) CIPAC No 627 (azadirachtin A)	Azadirachtin A: dimethyl (2aR,3S,4S,4aR,5S,7aS,8S,10R,10aS,10bR)-10-acetoxy-3,5-dihydroxy-4-[(1aR,2S,3aS,6aS,7S,7aS)-6a-hydroxy-7a-methyl-3a,6a,7,7a-tetrahydro-2,7-methanofuro[2,3-b]oxireno[c]oxepin-1a(2H)-yl]-4-methyl-8-{[(2E)-2-methylbut-2-enoyl]oxy}octahydro-1H-naphtho[1,8a-c:4,5-b'c']difuran-5,10a(8H)-dicarboxylate.	Expressed as azadirachtin A: ≥ 111 g/kg Sum of the aflatoxins B1, B2, G1, G2 must not exceeding 300 µg/kg of the azadirachtin A content.	1 June 2011	► M449 31 January 2027 ◀	PART A ► M339 For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azadirachtin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 and of the addendum to the review report on azadirachtin, and in particular Appendices I and II thereto, as finalised by the Standing Committee on Plants, Animals, Food and Feed on 17 July 2020 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; (2) the protection of non-target arthropods and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. ◀ PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azadirachtin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

▼B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of non target arthropods and aquatic organisms. Risk mitigation measures shall be applied where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: — the relationship between azadirachtin A and the rest of the active components in the neem seeds extract with respect to amount, biological activity and persistence, in order to confirm the lead active compound approach with regard to azadirachtin A and to confirm specification of the technical material, residue definition and groundwater risk assessment. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 December 2013.
344	Diclofop CAS No 40843-25-2 (parent) CAS No 257-141-8 (diclofop-methyl) CIPAC No 358 (parent) CIPAC No 358.201 (diclofop-methyl)	Diclofop (RS)-2-[4-(2,4-dichlorophenoxy)propionic acid Diclofop-methyl methyl (RS)-2-[4-(2,4-dichlorophenoxy)phenoxy]propionate	≥ 980 g/kg (expressed as diclofop-methyl)	1 June 2011	►M415 31 August 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diclofop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall: — pay particular attention to the operators and workers safety and include as a condition for authorisation the application of adequate personal protective equipment;

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— pay particular attention to the risk to aquatic organisms and non target plants and require risk mitigation measures to be applied. The Member States concerned shall request the submission of confirmatory information as regards: (a) a metabolism study on cereals; (b) an update of the risk assessment concerning the possible environmental impact of the preferential degradation/conversion of the isomers. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in point (a) by 31 May 2013 and the information set out in point (b) at latest two years after the adoption of a specific guidance document on evaluation of isomers mixtures.
345	Lime sulphur CAS No 1344 - 81 - 6 CIPAC No 17	Calcium polysulfide	≥ 290 g/Kg.	1 June 2011	►M449 31 January 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lime sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — operator safety and shall ensure that the conditions of authorisation include appropriate protective measures; — to the protection of aquatic organisms and non target arthropods and shall ensure that the conditions of use include risk mitigation measures as appropriate.

▼ B

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
346	Aluminium sulfate CAS No 10043-01-3 CIPAC not available	Aluminium sulfate	970 g/kg	1 June 2011	► <u>M449</u> 15 July 2026 ◀	PART A Only indoor uses as post-harvest bactericide for ornamental plants may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aluminium sulfate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. The Member States concerned shall request the submission of confirmatory information as regards the specification of the technical material, as commercially manufactured, in the form of appropriate analytical data. The Member States concerned shall ensure that the applicant submits such information to the Commission by 30 November 2011.

▼ M394▼ B

348	Paclobutrazol CAS No 76738-62-0 CIPAC No 445	(2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol	≥ 930 g/kg	1 June 2011	► <u>M415</u> 31 August 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on paclobutrazol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic plants and ensure that conditions of use include the risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards:
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▼ B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						(1) the specification of the technical material, as commercially manufactured; (2) the analytical methods in soil and surface water for the metabolite NOA457654; (3) the residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin; (4) the potential endocrine disrupting properties of paclobutrazol; (5) the potential adverse effects of breakdown products of the different optical structures of paclobutrazol and its metabolite CGA 149907 on the environmental compartments soil, water and air. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 30 November 2011, the information set out in points (3) by 31 May 2013, the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption and the information set out in point (5) within two years after the adoption of specific guidance.
▼ <u>M394</u>						
▼ <u>B</u>	350	Tebufenozide CAS No 112410-23-8 CIPAC No 724	N-tert-butyl-N'-(4-ethylbenzoyl)-3,5-dimethylbenzohydrazide	≥ 970 g/kg Relevant impurity t-butyl hydrazine < 0,001 g/kg	1 June 2011	► <u>M449</u> 31 January 2027 ◀ PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tebufenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

▼B

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall: — pay particular attention to the safety of operators and workers after re-entry and ensure that conditions of authorisation prescribe appropriate protective equipment; — pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — pay particular attention to the protection of aquatic organism and ensure that conditions of use prescribe adequate mitigation measures; — pay particular attention to the risk to Lepidoptera non-target insects. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information, as regards: (1) the relevance of metabolites RH-6595, RH-2651, M2; (2) the degradation of tebufenozide in anaerobic soils and soils of alkaline pH. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 31 May 2013.
351	Dithianon CAS No 3347-22-6 CIPAC No 153	5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4-dithiine-2,3-dicarbonitrile	≥ 930 g/kg	1 June 2011	►M449 31 January 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dithianon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall: — pay particular attention to the protection of aquatic organisms; conditions of use shall include risk mitigation measures, where appropriate, — pay particular attention to the operator safety; conditions of use shall include the application of adequate personal protective equipment, where appropriate, — pay particular attention to the long-term risks to birds; conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: — the storage stability and the nature of residues in processed products, — the aquatic and groundwater exposure assessment for phthalic acid, — the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol. The Member States concerned shall ensure that the applicant submits such information to the Commission by 31 May 2013.
352	Hexythiazox CAS No 78587-05-0 CIPAC No 439	(4RS,5RS)-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxo-1,3-thiazolidine-3-carboxamide	≥ 976 g/kg (1:1 mixture of (4R, 5R) and (4S, 5S))	1 June 2011	► M449 31 January 2027 ◀	PART A Only uses as acaricide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on hexythiazox, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account.

▼ **B**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate; — the operators and workers safety. Conditions of use shall include protective measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (a) the toxicological relevance of the metabolite PT-1-3 ⁽¹⁴⁾; (b) the potential occurrence of the metabolite PT-1-3 in processed commodities; (c) the potential adverse effects of hexythiazox on bee brood; (d) the possible impact of the preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environment. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (a), (b) and (c) by 31 May 2013 and the information set out in point (d) two years after the adoption of specific guidance.
▼ M394						

▼B

▼C1

Number	Common name, identification numbers	IUPAC name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
354	Flurochloridone CAS No 61213-25-0 CIPAC No 430	<i>(3RS,4RS;3RS,4SR)-3-chloro-4-chloro-methyl-1-(α,α,α-trifluoro-m-tolyl)-2-pyrrolidone</i>	≥ 940 g/kg. Relevant impurities: Toluene: max 8 g/kg	1 June 2011	►M415 15 March 2026 ◀	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flurochloridone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 February 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: 1. the risk for non-target plants and aquatic organisms; 2. the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall ensure that the applicant submits to the Commission further confirmatory information as regards: 1. the relevance of impurities other than toluene; 2. the compliance of ecotoxicological test material with the technical specifications; 3. the relevance of the groundwater metabolite R42819 ⁽¹⁵⁾ ; 4. the potential endocrine disrupting properties of flurochloridone.

▼ **C1**

Number	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) by 1 December 2011, the information set out in point (3) by 31 May 2013 and the information set out in point (4) within two years after the adoption of the OECD test guidelines on endocrine disruption.

▼ **B**

⁽¹⁾ Further details on identity and specification of active substances are provided in their review reports.

⁽²⁾ Suspended by order of the General Court of 19 July 2007 in case T-31/07 R, Du Pont de Nemours (France) SAS and others v Commission, [2007] ECR II-2767.

⁽³⁾ OJ L 353, 31.12.2008, p. 1.

⁽⁴⁾ 2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide.

⁽⁵⁾ 2-ethyl-7-nitro-1H-benzimidazole-5-sulfonamide.

⁽⁶⁾ De-ethyl-bupirimate.

⁽⁷⁾ 2- {[anilino(oxo)acetyl]sulfanyl}ethyl acetate.

⁽⁸⁾ (2*RS*)-2-hydroxy-2-methyl-*N*-phenyl-1,4-oxathiane-3-carboxamide 4-oxide.

⁽⁹⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4-oxide.

⁽¹⁰⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4,4-dioxide.

⁽¹¹⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4-oxide.

⁽¹²⁾ 2-methyl-5,6-dihydro-1,4-oxathiine-3-carboxamide 4,4-dioxide.

⁽¹³⁾ (2*RS*)-2-hydroxy-2-methyl-*N*-phenyl-1,4-oxathiane-3-carboxamide 4-oxide.

⁽¹⁴⁾ (4*S*,5*S*)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one and (4*R*,5*R*)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one.

► **C1** ⁽¹⁵⁾ R42819: (4*RS*)-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one. ◀

► **M23** ⁽¹⁶⁾ 1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol. ◀

► **M31** ⁽¹⁷⁾ OJ L 300, 14.11.2009, p. 1.

⁽¹⁸⁾ OJ L 54, 26.2.2011, p. 1. ◀

► **M202** ⁽¹⁹⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁽²⁰⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1). ◀

PART B

Active substances approved under Regulation (EC) No 1107/2009

General provisions applying to all substances listed in this Part:

- for the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009 in relation to each substance, the conclusions of the review report on it, and in particular the Appendices I and II thereof, shall be taken into account;
- Member States shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make it available to them on specific request.

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
1	Bispyribac CAS No 125401-75-4 CIPAC No 748	2,6-bis(4,6-dimethoxypyrimidin-2-yl)benzoic acid	≥ 930 g/kg (referred to as bispyribac-sodium)	1 August 2011	► <u>M395</u> 31 July 2022 ◀	PART A Only uses as herbicide in rice may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bispyribac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment, Member States shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures where appropriate. The Member States concerned shall request the submission of further information as regards the possible groundwater contamination by metabolites M03 ⁽²⁾, M04 ⁽³⁾ and M10 ⁽⁴⁾. They shall ensure that the applicant provides such information to the Commission by 31 July 2013.

▼ **M1**▼ **M394**▼ **M4**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
4	Azoxystrobin CAS No 131860-33-8 CIPAC No 571	methyl (E)-2-[2[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]phenyl]-3-methoxyacrylate	≥ 930 g/kg Toluene maximum content 2 g/kg Z-isomer maximum content 25 g/kg	1 January 2012	► M463 31 May 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on azoxystrobin and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the fact that the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material; (2) the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) the protection of aquatic organisms. The Member States must ensure that the conditions of authorisation include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards the risk assessment on groundwater and aquatic organisms. The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.

▼ **M1**▼ **M6**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
5	Imazalil CAS No 35554-44-0 73790-28-0 (replaced) CIPAC No 335	(RS)-1-(β-allyloxy-2,4-dichlorophenethyl)imidazole or allyl (RS)-1-(2,4-dichlorophenyl)-2-imidazol-1-ylethyl ether	≥ 950 g/kg	1 January 2012	► M463 31 May 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on imazalil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall: (1) pay particular attention to the fact that the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material; (2) pay particular attention to the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels; (3) pay particular attention to the operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure; (4) ensure that appropriate waste management practices to handle the waste solution remaining after application, such as the cleaning water of the drenching system and the discharge of the processing waste are put in place. Prevention of any accidental spillage of treatment solution. Member States permitting the release of waste water into the sewage system shall ensure that a local risk assessment is carried out;

▼ **M6**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(5) pay particular attention to risk to aquatic organisms and soil micro-organisms and long-term risk to granivorous birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) route of degradation of imazalil in soil and surface water systems; (b) environmental data to support the managing measures that Member States have to put in place to ensure that groundwater exposure is negligible; (c) a hydrolysis study to investigate the nature of residues in processed commodities. The notifier shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.

▼ **M3**

6	Prohexadione CAS No 127277-53-6 <i>(prohexadione-calcium)</i> CIPAC No 567 <i>(prohexadione)</i> No 567.020 <i>(prohexadione-calcium)</i>	3,5-dioxo-4-propionylcyclohexanecarboxylic acid	≥ 890 g/kg (expressed as prohexadione-calcium)	1 January 2012	► M440 31 May 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prohexadione and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.
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▼ **M13**

7	Spiroxamine CAS No 1181134-30-8 CIPAC No 572	8- <i>tert</i> -butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine (ISO)	≥ 940 g/kg (diastereomers A and B combined)	1 January 2012	► M440 31 May 2026 ◀	PART A Only uses as fungicide may be authorised.
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▼ **M13**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiroxamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (1) the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment; (2) the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (3) the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the possible impact on the worker, the consumer and the environmental risk assessment of the potential stereo-selective degradation of each isomer in plant, animals and the environment; (b) the toxicity of the plant metabolites formed in fruit crops and the potential hydrolysis of fruit crop residues in processed commodities; (c) the groundwater exposure assessment for metabolite M03 ⁽⁷⁾; (d) the risk to aquatic organisms. The notifier shall submit to the Member States, the Commission and the Authority the information set out in point (a) by two years after the adoption of specific guidance and the information set out in points (b), (c) and (d) by 31 December 2013.

▼ **M1**▼ **M18**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
8	Kresoxim-methyl CAS No 143 390-89-0 CIPAC No 568	methyl (E)-methoxyimino[a-(o-tolyloxy)-o-tolyl] acetate	≥ 910 g/kg Methanol: max. 5 g/kg Methyl chloride: max. 1 g/kg Toluene: max. 1 g/kg	1 January 2012	► M463 31 May 2027 ◀	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on kresoxim-methyl and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account. Member States shall pay particular attention to the protection of groundwater under vulnerable conditions; the conditions of authorisation shall include, where appropriate, risk mitigation measures. The applicant shall submit confirmatory information as regards: Groundwater exposure risk assessment, and in particular: — on the lysimeter study to support the statement that the two unidentified peaks observed do not correspond to metabolites individually exceeding the trigger value of 0,1 µg/L, — on the recovery of metabolite BF 490-5 in order to confirm its absence in the lysimeter leachate at levels exceeding 0,1 µg/L, — on a groundwater exposure risk assessment for the late application in apples, pears and grapes. The applicant shall submit to the Member States, the Commission and the Authority such information by 31 December 2013.

▼ **M1**▼ **M8**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
9	Fluroxypyr CAS No 69377-81-7 CIPAC No 431	4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid	► M225 ≥ 950 g/kg (fluroxypyr-meptyl) The following manufacturing impurity is of toxicological concern and must not exceed the following amount in the technical material: N-methyl-2-pyrrolidone (NMP): < 3 g/kg ◀	1 January 2012	► M463 15 February 2027 ◀	► M225 PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluroxypyr, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 23 March 2017 shall be taken into account. In this overall assessment, Member States must pay particular attention to: — the potential contamination of groundwater by metabolite fluroxypyr pyridinol, when the active substance is applied in regions with alkaline or vulnerable soil or with vulnerable climatic conditions; — the risk to aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. ◀
10	Tefluthrin CAS No: 79538-32-2 CIPAC No: 451	2,3,5,6-tetrafluoro-4-methylbenzyl (1 <i>R</i> , 3 <i>R</i>)-3-[(<i>Z</i>)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethyl-cyclopropanecarboxylate Tefluthrin is a 1:1 mixture of <i>Z</i> -(1 <i>R</i> , 3 <i>R</i>) and <i>Z</i> -(1 <i>S</i> , 3 <i>S</i>) enantiomers.	≥ 920 g/kg Hexachlorobenzene: not more than 1 mg/kg	1 January 2012	► M463 31 May 2027 ◀	PART A Only uses as insecticide may be authorised. The seed coating shall only be performed in professional seed treatment facilities. These facilities shall apply the best available techniques in order to exclude the release of dust clouds during storage, transport and application. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tefluthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account.

▼ **M15**

▼ **M15**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the operators and workers safety and include among the authorised conditions of use the application of adequate personal protective equipment as well as respiratory protective equipment, — the risk to birds and mammals. Risk mitigation measures should be applied to grant a high degree of incorporation in soil and avoidance of spillage, — ensure that the label of treated seed includes the indication that the seeds were treated with tefluthrin and sets out the risk mitigation measures provided for in the authorisation. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured; (2) a validated analytical method for water; (3) the possible environmental impact of the preferential degradation/ conversion of the isomers and an estimation of the relative toxicity and risk assessment for the workers. The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (1) by 30 June 2012, the information set out in point (2) by 31 December 2012, and the information set out in point (3) 2 years after the adoption of a specific guidance document on evaluation of isomers mixture.

▼ **M14**

11	Oxyfluorfen CAS No 42874-03-3 CIPAC No 538	2-chloro-α,α,α-trifluoro-<i>p</i>-tolyl 3-ethoxy-4-nitrophenyl ether	≥ 970 g/kg Impurities: N,N-dimethylnitrosamine: not more than 50 µg/kg	1 January 2012	► M463 31 May 2027 ◀	► M203 PART A Only uses as herbicide for banded applications close to ground from autumn to early spring may be authorised, at a rate not exceeding 150 g active substance per hectare, per year.
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▼ **M14**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxyfluorfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed, shall be taken into account. In this overall assessment, Member States must pay particular attention to: — operator safety and ensure that conditions of use impose the application of adequate personal protective equipment where appropriate, — the risks to aquatic organisms, earthworm-eating mammals, soil-living macro-organisms, non-target arthropods and non-target plants. Conditions of authorisation shall include risk mitigation measures such as no-spray buffer zones and drift reducing nozzles and shall provide for respective labelling of plant protection products. Those conditions shall include further risk mitigation measures, where appropriate. ◀

▼ **M10**

12	1-naphthylacetamide CAS No 86-86-2 CIPAC No 282	2-(1-naphthyl)acetamide	≥ 980 g/kg	1 January 2012	► M440 31 May 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-naphthylacetamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account. In this overall assessment Member States:
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▼ **M10**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(a) shall pay particular attention to the risk to operators and workers and ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (c) shall pay particular attention to the risk to aquatic organisms; (d) shall pay particular attention to the risk to non-target plants; (e) shall pay particular attention to the risk to birds. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the risk to non-target plants; (2) the long-term risk to birds. The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.

▼ **M11**

13	1-naphthylacetic acid CAS No 86-87-3 CIPAC No 313	1-naphthylacetic acid	≥ 980 g/kg	1 January 2012	► M440 31 May 2026 ◀	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1-naphthylacetic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 shall be taken into account. In this overall assessment Member States:
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▼ **M11**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(a) shall pay particular attention to the risk to operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) shall pay particular attention to the dietary exposure situation of consumers in view of future revisions of maximum residue levels; (c) shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; (d) shall pay particular attention to the risk to aquatic organisms; (e) shall pay particular attention to the risk to birds. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the route and rate of degradation in soil including an assessment of the potential for photolysis; (2) the long-term risk to birds. The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.
▼ M394						

▼ **M12**

15	Fluazifop P CAS No 83066-88-0 (fluazifop-P) CIPAC No 467 (fluazifop-P)	(R)-2-{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy}propionic acid (fluazifop-P)	≥ 900 g/kg in fluazifop P-butyl The following impurity 2-chloro-5-(trifluoromethyl)pyridine must not exceed 1,5 g/kg in the material as manufactured.	1 January 2012	► M440 31 May 2026 ◀	► M53 PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluazifop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013, shall be taken into account.
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▼ **M12**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall: — pay particular attention to consumer safety as regards the occurrence in groundwater of the metabolite compound X ⁽⁵⁾; — pay particular attention to operator safety and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; — pay particular attention to the protection of surface water and groundwater in vulnerable zones; — pay particular attention to the risk for non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the specification of the technical material, as commercially manufactured, including information on the relevance of the impurity R154719; (2) the equivalence between the specifications of the technical material, as commercially manufactured, and the specifications of the test material used in the toxicity studies; (3) the potential long-term risk to herbivorous mammals; (4) the fate and behaviour in the environment of the metabolite compounds X ⁽⁵⁾ and IV ⁽⁶⁾; (5) the potential risk to fish and aquatic invertebrates for the metabolite compound IV ⁽⁶⁾. The applicant shall submit to the Commission, the Member States and the Authority the information set out in points (1) and (2) by 30 June 2012 and the information set out in points (3), (4) and (5) by 31 December 2013. ◀

▼ **M1**▼ **M362**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
16	Terbuthylazine CAS No 5915-41-3 CIPAC No 234	N2-tert-butyl-6-chloro-N4-ethyl-1,3,5-triazine-2,4-diamine	≥ 950 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: — Propazine: maximum of 9 g/kg — Atrazine: maximum of 1 g/kg — Simazine: maximum of 9 g/kg	1 January 2012	► M463 31 May 2027 ◀	PART A Only uses as herbicide may be authorised. Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on terbuthylazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 and updated by the Standing Committee on Plants, Animals, Food and Feed on 24 March 2021 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the consumer risk assessment from exposure to metabolites of terbuthylazine, — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions, — the risk to mammals and earthworms. Conditions of use shall include risk mitigation measures and the obligation to carry out monitoring programmes to verify potential groundwater contamination in vulnerable zones, where appropriate.
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▼ **M394**

▼ **M1**▼ **M21**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
18	8-hydroxyquinoline CAS No 148-24-3 (8-hydroxyquinoline) CIPAC No 677 (8-hydroxyquinoline)	8-quinolinol	≥ 990 g/kg	1 January 2012	► M463 31 December 2025 ◀	PART A Only uses as fungicide and bactericide in greenhouses may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 8-hydroxyquinoline, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the operator safety and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate. The applicant shall submit confirmatory information on 8-hydroxyquinoline and its salts as regards: (1) the method of analysis for air; (2) a new storage stability covering the storage time periods of samples from both the metabolism study and from the supervised residue trials. The applicant shall submit to the Commission, the Member States and the Authority such information by 31 December 2013.
▼ M394						
▼ M72						

▼ **M1**▼ **M30**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
22	Metam CAS No 144-54-7 CIPAC No 20	Methyldithiocarbamic acid	≥ 965 g/kg Expressed as metam-sodium on a dry weight basis ≥ 990 g/kg Expressed as metam-potassium on a dry weight basis Relevant impurities: methylisothiocyanate (MITC) — max. 12 g/kg on dry weight basis (metam-sodium), — max. 0,42 g/kg on dry weight basis (metam-potassium). <i>N,N'</i>-dimethylthiourea (DMTU) — max. 23 g/kg on a dry weight basis (metam-sodium), — max. 6 g/kg on a dry weight basis (metam-potassium).	1 July 2012	► M415 30 November 2025 ◀	PART A Only uses as nematocide, fungicide, herbicide and insecticide may be authorised for application as soil fumigant prior to planting, limited to one application every third year on the same field. The application may be authorised in open field by soil injection or drip irrigation, and in greenhouse by drip irrigation only. The use of gas-tight plastic film for drip irrigation shall be prescribed. The maximum application rate shall be 153 kg/ha (corresponding to 86,3 kg/ha of MITC) in case of open field applications. Authorisations shall be limited to professional users. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 March 2012, shall be taken into account. In this overall assessment Member States: (a) shall pay particular attention to the protection of operators and shall ensure that the conditions of use include risk mitigation measures such as application of adequate personal protective equipment and a limitation in the daily work rate; (b) shall pay particular attention to the protection of workers and shall ensure that the conditions of use include risk mitigation measures, such as use of adequate personal protective equipment, re-entry period and limitation in the daily work rate;

▼ **M30**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(c) shall pay particular attention to the protection of bystanders and residents and shall ensure that the conditions of use include risk mitigation measures, such as an appropriate buffer zone during and until 24 hours after the application from the perimeter of the application area to any occupied residences and areas used by the general public with obligation to use warning signs and ground markers; (d) shall pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions and shall ensure that the conditions of use include risk mitigation measures, such as appropriate buffer zone; (e) shall pay particular attention to the risk to non-target organisms and shall ensure that conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information on methyl isothiocyanate as regards: (1) the assessment of the long-range atmospheric transport potential and related environmental risks; (2) the potential groundwater contamination. The applicant shall submit to the Commission, the Member States and the Authority such information by 31 May 2014.

▼ **M394**

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▼ **M34**

24	Fluxapyroxad CAS No 907204-31-3 CIPAC No 828	3-(difluoromethyl)-1-methyl- <i>N</i> -(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide	≥ 950 g/kg The impurity toluene must not exceed 1 g/kg in the technical material	1 January 2013	► M475 31 October 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluxapyroxad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account.
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▼ **M34**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to the risk to groundwater, if the active substance is applied under vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The purity given in this entry is based on a pilot plant production. The examining Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

▼ **M35**

25	Fenpyrazamine CAS No 473798-59-3 CIPAC No 832	S-allyl 5-amino-2,3-dihydro-2-isopropyl-3-oxo-4-(o-tolyl)pyrazole-1-carbothioate	► M354 ≥ 960 g/kg The following manufacturing impurity is of toxicological concern and must not exceed the following amount in the technical material: Hydrazine: maximum content: < 0,0001 % (1 mg/kg) ◀	1 January 2013	► M466 15 January 2025 ◀	► M354 PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpyrazamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 and the Standing Committee on Plants, Animals, Food and Feed on 18 May 2020 shall be taken into account. The purity given in this entry is based on a commercial plant production. ◀
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▼ **M40**

26	<i>Adoxophyes orana granulovirus</i> Culture collection No DSM BV-0001 CIPAC No 782	Not applicable	No relevant impurities	1 February 2013	► M343 31 January 2024 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Adoxophyes orana granulovirus</i>, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 July 2012 shall be taken into account.
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▼ M1▼ M392▼ M42▼ M45

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
28	Phosphane CAS No 7803-51-2 CIPAC No 127	Phosphane	≥ 994 g/kg The relevant impurity arsane must not exceed 0,023 g/kg in the technical material	1 April 2013	► <u>M444</u> 15 March 2026 ◀	Authorisations shall be limited to professional users. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on phosphane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 September 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators in and around the treated premises during the treatment as well as during and after the aeration; — the protection of workers in and around the treated premises during the treatment as well as during and after the aeration; — the protection of bystanders around the treated premises during the treatment as well as during and after the aeration. Conditions of use shall include risk mitigation measures, like permanent monitoring of the phosphane concentration by automatic devices, the use of personal protection equipment and setting-up an area around the treated premise where bystanders are denied, where appropriate.
29	<i>Trichoderma asperellum</i> (strain T34) CECT number: 20417	Not applicable	1×10^{10} cfu/g	1 June 2013	► <u>M415</u> 31 October 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma asperellum</i> (strain T34), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account.

▼ **M45**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Trichoderma asperellum</i> (strain T34) is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures where appropriate.

▼ **M44**

30	<i>Zucchini Yellow Mosaic Virus</i> — weak strain ATCC accession number: PV-593	Not applicable	≥ 0,05 mg/l	1 June 2013	31 May 2023	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Zucchini Yellow Mosaic Virus</i> — weak strain, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to non-target plants, if the crop plants are co-infected with another virus which can be transmitted by aphids. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M47**

31	Cyflumetofen CAS No 400882-07-7 CIPAC No 721	2-methoxyethyl (<i>RS</i>)-2-(4- <i>tert</i> -butylphenyl)-2-cyano-3-oxo-3-(α,α,α -trifluoro- <i>o</i> -tolyl) propionate	≥ 975 g/kg (racemic)	1 June 2013	► M415 31 October 2025 ◀	► M304 Plant protection products containing cyflumetofen shall only be authorised for uses where the level of metabolite B3 in groundwater is expected to be below 0,1 µg/L.
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▼ **M47**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyflumetofen, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — the protection of operators and workers; — the protection of groundwater, in particular for metabolite B3, when the substance is applied in regions with vulnerable soils and/or climatic conditions; — the protection of drinking water; — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. ◀

▼ **M46**

32	<i>Trichoderma atroviride</i> strain I-1237 CNCM number: I-1237	Not applicable	1×10^9 cfu/g (1×10^{10} spores/g)	1 June 2013	▶ M415 31 October 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> strain I-1237, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Trichoderma atroviride</i> strain I-1237 is to be considered a potential sensitizer. Conditions of use shall include risk mitigation measures where appropriate.
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▼ **M1**▼ **M52**▼ **M50**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
33	Ametoctradin CAS No 865318-97-4 CIPAC No 818	5-ethyl-6-octyl [1,2,4]triazolo[1,5-a] pyrimidin-7-amine	≥ 980 g/kg ► C2 The impurities amitrole and o-xylene are of toxicological relevance and shall not exceed 50 mg/kg and 2 g/kg respectively in the technical material. ◀	1 August 2013	► M415 31 December 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ametoctradin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the leakage of metabolite M650F04 ⁽¹⁴⁾ to groundwater under vulnerable conditions. Conditions of use shall include risk mitigation measures, where appropriate.
34	Mandipropamid CAS No 374726-62-2 CIPAC No 783	(RS)-2-(4-chloro-phenyl)-N-[3-methoxy-4-(prop-2-ynyloxy)phenethyl]-2-(prop-2-ynyloxy)acetamide	≥ 930 g/kg The impurity N-{2-[4-(2-chloro-allyloxy)-3-methoxy-phenyl]-ethyl}-2-(4-chloro-phenyl)-2-prop-2-ynyloxy-acetamide is of toxicological relevance and shall not exceed 0,1 g/kg in the technical material.	1 August 2013	► M415 31 December 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mandipropamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the potential for preferential enantiomeric transformation or racemisation of mandipropamid at the soil surface as a result of soil photolysis. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 July 2015.

▼ **M1**▼ **M56**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
35	Halosulfuron-methyl CAS No 100785-20-1 CIPAC No 785.201	methyl 3-chloro-5-(4,6-dimethoxypyrimidin-2-ylcarbamoylsulfamoyl)-1-methylpyrazole-4-carboxylate	≥ 980 g/kg	1 October 2013	► M468 15 November 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on halosulfuron-methyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk of leakage to groundwater of the metabolite ‘halosulfuron’ rearrangement (HSR) ⁽¹⁵⁾ under vulnerable conditions. This metabolite is considered toxicologically relevant based on the available information for halosulfuron, — the risk to non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) information as regards the equivalence between the specifications of the technical material, as commercially manufactured, and the test material used in the toxicological and ecotoxicological studies; (b) information on the toxicological relevance of the impurities present in the technical specification as commercially manufactured; (c) data to clarify the potential genotoxic properties of chlorosulfonamide acid ⁽¹⁶⁾. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.
36	<i>Bacillus firmus</i> I-1582 Collection number: CNCMI-1582	Not applicable	Minimum concentration: $7,1 \times 10^{10}$ CFU/g	1 October 2013	30 September 2023	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus firmus</i> I-1582, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Bacillus firmus</i> I-1582 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M58**

▼ **M1**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
37	<i>Candida oleophila</i> strain O Collection number: MUCL40654	Not applicable	Nominal content: 3×10^{10} CFU/g dried product Range: $6 \times 10^9 - 1 \times 10^{11}$ CFU/g dried product	1 October 2013	► M463 31 May 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Candida oleophila</i> strain O, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.
38	<i>Helicoverpa armigera nucleopolyhedrovirus</i> DSMZ number: BV-0003	Not applicable	Minimum concentration: $1,44 \times 10^{13}$ OB/l (occlusion bodies/l)	1 June 2013	► M415 31 October 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Helicoverpa armigera nucleopolyhedrovirus</i> , and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.
39	<i>Paecilomyces fumosoroseus</i> strain FE 9901 Collection number: USDA-ARS collection of Entomopathogenic Fungal Cultures U.S. Plant Soil and Nutrition laboratory. New York. Accession No ARSEF 4490	Not applicable	Minimum $1,0 \times 10^9$ CFU/g Maximum $3,0 \times 10^9$ CFU/g	1 October 2013	► M463 31 May 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Paecilomyces fumosoroseus</i> strain FE 9901, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.

▼ **M64**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Paecilomyces fumosoroseus</i> strain FE 9901 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M61**

40	Potassium phosphonates (no ISO name) CAS No 13977-65-6 for potassium hydrogen phosphonate 13492-26-7 for dipotassium phosphonate Mixture: none CIPAC No 756 (for potassium phosphonates)	Potassium hydrogen phosphonate, Dipotassium phosphonate	31,6 to 32,6 % phosphonate ions (sum of hydrogen phosphonate and phosphonate ions) 17,8 to 20,0 % potassium ≥ 990 g/kg on dry weight basis	1 October 2013	► M343 31 January 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to birds and mammals, — the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.
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▼ **M63**

41	Spiromesifen CAS No 283594-90-1 CIPAC No 747	3-mesityl-2-oxo-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutyrate	≥ 965 g/kg (racemic) The impurity N,N-dimethylacetamide is of toxicological relevance and must not exceed 4 g/kg in the technical material.	1 October 2013	30 September 2023	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spiromesifen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account.
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▼ **M63**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the long-term risk to aquatic invertebrates, — the risk to pollinating hymenoptera and non-target arthropods if exposure is not negligible, — the protection of workers and operators. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the recalculation of the predicted concentration in groundwater (PECGW) with a FOCUS GW scenario adapted to the supported uses using a Q10 value of 2,58. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.

▼ **M59**

42	<i>Spodoptera littoralis nucleopolyhedrovirus</i> DSMZ number: BV-0005	Not applicable	Maximum concentration: 1×10^{12} OB/l (occlusion bodies/l)	1 June 2013	► M415 31 October 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Spodoptera littoralis nucleopolyhedrovirus</i> , and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account.
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▼ **M54**

43	Bixafen CAS No 581809-46-3 CIPAC No 819	<i>N</i> -(3',4'-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide	≥ 950 g/kg	1 October 2013	► M475 31 October 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bixafen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the residues of bixafen and of its metabolites in rotational crops;
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▼ **M54**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (c) the risk to aquatic organisms; (d) the risk to soil and sediment-dwelling organisms. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M55**

44	Maltodextrin CAS No 9050-36-6 CIPAC No 801	None allocated	≥ 910 g/kg	1 October 2013	► M429 28 February 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on maltodextrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the potential increased growth of fungi and possible presence of mycotoxins on the surface of treated fruits; (b) the potential risk to honeybees and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M68**

45	Eugenol CAS No 97-53-0 CIPAC No 967	4-allyl-2-methoxyphenol	≥ 990 g/kg Relevant impurity: methyl eugenol maximum 0,1 % of the technical material	1 December 2013	► M434 30 April 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on eugenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013 shall be taken into account.
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▼ **M68**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — the risk to aquatic organisms, — the risk to insectivorous birds. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the storage stability (2 years) at ambient temperature on the formulated product; (b) data comparing natural background exposure situations of eugenol and methyl eugenol in relation to exposure from the use of eugenol as a plant protection product. This data shall cover human exposure as well as exposure of birds and aquatic organisms; (c) the groundwater exposure assessment for potential metabolites of eugenol, in particular for methyl eugenol. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015.

▼ **M70**

46	Geraniol CAS No 106-24-1 CIPAC No 968	(E) 3,7-dimethyl-2,6-octadien-1-ol	≥ 980 g/kg	1 December 2013	► M434 30 April 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on geraniol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013 shall be taken into account.
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▼ **M70**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms; — the risk to birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards (a) data comparing natural background exposure situations of geraniol in relation to exposure from the use of geraniol as a plant protection product. This data shall cover human exposure as well as exposure of birds, mammals and aquatic organisms; (b) the groundwater exposure. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015.

▼ **M69**

47	Thymol CAS No 89-83-8 CIPAC No 969	5-methyl-2-propan-2-yl-phenol	≥ 990 g/kg	1 December 2013	► M434 30 April 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thymol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to — the protection of operators, workers, bystanders and residents, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate;
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▼ **M69**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						— the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms; — the risk to birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards (a) data comparing natural background exposure situations of thymol in relation to exposure from the use of thymol as a plant protection product. This data shall cover human exposure as well as exposure of birds, mammals and aquatic organisms; (b) the long-term and reproductive toxicity, in a form of a full report (in English) of the Combined Test of Repeated Oral-Administration Toxicity and Reproductive Toxicity of Thymol; (c) the groundwater exposure. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 November 2015.

▼ **M77**

48	Sedaxane CAS No 874967-67-6 (trans isomer: 599197-38-3/cis isomer: 599194-51-1) CIPAC No 833	mixture of 2 cis-isomers 2'- [(1RS,2RS)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 trans-isomers 2'- [(1RS,2SR)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide	≥ 960 g/kg Sedaxane (range 820-890 g/kg for the 2 trans-isomers 50:50 mixture of enantiomers and range 100-150 g/kg for the 2 cis-isomers 50:50 mixture of enantiomers)	1 February 2014	► M475 31 October 2027 ◀	PART A Only uses for seed treatment may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sedaxane, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;
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▼ **M77**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(b) the long-term risk to birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite CSCD465008 in vulnerable zones, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards the relevance of the metabolite CSCD465008, and the corresponding groundwater risk assessment, if sedaxane is classified under Regulation (EC) No 1272/2008 as ‘suspected of causing cancer’. The notifier shall submit to the Commission, the Member States and the Authority the relevant information within six months from the application date of the Regulation classifying sedaxane.

▼ **M79**

49	Emamectin CAS No emamectin: 119791-41-2 (formerly 137335-79-6) and 123997-28-4 emamectin benzoate: 155569-91-8 (formerly 137512-74-4 and 179607-18-2)	Emamectin B1a: (10<i>E</i>,14<i>E</i>,16<i>E</i>)- (1<i>R</i>,4<i>S</i>,5'<i>S</i>,6<i>S</i>,6' <i>R</i>,8<i>R</i>,12<i>S</i>,13 <i>S</i>,20<i>R</i>,21<i>R</i>,24<i>S</i>)-6'- [(<i>S</i>)-<i>sec</i>-butyl]-21,24- dihydroxy- 5',11,13,22-tetra- methyl-2-oxo-(3,7,19- trioxatetracyclo- [15.6.1.1^{4,8}.0^{20,24}] pentacosa- 10,14,16,22-tetraene)- 6-spiro-2'-(5',6'- dihydro-2'<i>H</i>-pyran)- 12-yl 2,6-dideoxy-3- <i>O</i>-methyl-4-<i>O</i>-(2,4,6- trideoxy-3-<i>O</i>-methyl- 4-methylamino-α-L- <i>lyxo</i>-hexapyranosyl)- α-L-<i>arabino</i>-hexapyr- anoside	≥ 950 g/kg as emamectin benzoate anhydrous (a mixture of min. 920 g/kg emamectin B1a benzoate and max. 50 g/kg emamectin B1b benzoate)	1 May 2014	► M460 15 November 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on emamectin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to non-target invertebrates; — the protection of workers and operators. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the risk of enantio-selective metabolism or degradation. The applicant shall submit to the Commission, Member States and the Authority the relevant information two years after adoption of the pertinent guidance document on evaluation of isomer mixtures.
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▼ **M79**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
	emamectin B1a benzoate: 138511-97-4 emamectin B1b benzoate: 138511-98-5 CIPAC No emamectin: 791 emamectin benzoate: 791.412	Emamectin B1b: (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i>)- (1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21- <i>R</i> ,24 <i>S</i>)-21,24-dihydroxy-6'-isopropyl- 5',11,13,22-tetramethyl-2-oxo-(3,7,19- trioxatetracyclo-[15.6.1.1 ^{4,8} .0 ^{20,24}] pentacosa- 10,14,16,22-tetraene)- 6-spiro-2'-(5',6'- dihydro-2' <i>H</i> -pyran)- 12-yl 2,6-dideoxy-3- <i>O</i> -methyl-4- <i>O</i> -(2,4,6- trideoxy-3- <i>O</i> -methyl- 4-methylamino- α -L- lyxo-hexapyranosyl)- α -L- <i>arabino</i> -hexapyranoside Emamectin B1a benzoate: (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i>)- (1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21- <i>R</i> ,24 <i>S</i>)-6'-[(<i>S</i>)- <i>sec</i> - butyl]-				

▼ M79

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
		21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.1^{4,8}.0^{20,24}] pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'<i>H</i>-pyran)-12-yl 2,6-dideoxy-3-<i>O</i>-methyl-4-<i>O</i>-(2,4,6-trideoxy-3-<i>O</i>-methyl-4-methylamino-α-L-<i>lyxo</i>-hexapyranosyl)-α-L-<i>arabino</i>-hexapyranoside benzoate Emamectin B1b benzoate: (10<i>E</i>,14<i>E</i>,16<i>E</i>)-(1<i>R</i>,4<i>S</i>,5'<i>S</i>,6<i>S</i>,6'<i>R</i>,8<i>R</i>,12<i>S</i>,13<i>S</i>,20<i>R</i>,21<i>R</i>,24-<i>S</i>)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.1^{4,8}.0^{20,24}] pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'<i>H</i>-pyran)-12-yl 2,6-dideoxy-3-<i>O</i>-methyl-4-<i>O</i>-(2,4,6-trideoxy-3-<i>O</i>-methyl-4-methylamino-α-L-<i>lyxo</i>-hexapyranosyl)-α-L-<i>arabino</i>-hexapyranoside benzoate				

▼ **M1**▼ **M80**▼ **M76**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
50	<i>Pseudomonas</i> sp. strain DSMZ 13134 Collection number: DSMZ 13134	Not applicable	Minimum concentration: 3×10^{14} cfu/kg	1 February 2014	► M468 30 June 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pseudomonas</i> sp. strain DSMZ 13134, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Pseudomonas</i> sp. strain DSMZ 13134 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit information to confirm the absence of an acute intratracheal and intraperitoneal toxicity/infectivity/pathogenicity potential. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016.
51	Fluopyram CAS No 658066-35-4 CIPAC No 807	N-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}- α,α,α -trifluoro-o-toluamide	≥ 960 g/kg	1 February 2014	► M444 30 June 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluopyram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to birds and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the long-term risk to insectivorous birds;

▼ **M76**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(2) the potential for causing endocrine disrupting effects in non-target vertebrates other than mammals. The applicant shall submit to the Commission, Member States and the Authority the information set out in point 1 by 1 February 2016 and the information set out in point 2 within two years after adoption of the corresponding OECD test guidelines on endocrine disruption.

▼ **M78**

52	<i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941) Collection number: German Collection of Microorganisms and cell Cultures (DSMZ) with the accession numbers DSM 14940 and DSM 14941	Not applicable	Minimum $5,0 \times 10^9$ CFU/g for each strain; Maximum $5,0 \times 10^{10}$ CFU/g for each strain	1 February 2014	► M468 30 June 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Aureobasidium pullulans</i> (strains DSM 14940 and DSM 14941) is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M82**

53	Pyriofenone: CAS No 688046-61-9 CIPAC No 827	(5-chloro-2-methoxy-4-methyl-3-pyridyl) (4,5,6-trimethoxy-o-tolyl)methanone	≥ 965 g/kg	1 February 2014	► M468 30 June 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyriofenone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards
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▼ **M82**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(a) the identity of two impurities to fully support the provisional specification; (b) the toxicological relevance of the impurities present in the proposed technical specification except for the one impurity for which an acute oral study and an Ames test were provided. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016.

▼ **M81**

54	Disodium phosphonate CAS No 13708-85-5 CIPAC No 808	disodium phosphonate	281-337 g/kg (TK) ≥ 917 g/kg (TC)	1 February 2014	► M343 31 January 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on disodium phosphonate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 16 July 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to eutrophication of surface water. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards (a) the chronic risk to fish; (b) the long term risk to earthworms and soil macro-organisms. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 January 2016.
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▼ M1▼ M83

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
55	Penflufen CAS No 494793-67-8 CIPAC No 826	2'-[(RS)-1,3-dimethylbutyl]-5-fluoro-1,3-dimethylpyrazole-4-carbox-anilide	≥ 950 g/kg 1:1 (R:S) ratio of enantiomers	1 February 2014	► <u>M430</u> 31 January 2024 ◀	► <u>M398</u> PART A Only uses to treat cereal seeds before or during sowing may be authorised, limited to one application every third year on the same field. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penflufen, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment, Member States shall pay particular attention to: (a) the protection of operators; (b) the protection of birds; (c) the protection of groundwater, when the substance is applied to regions with vulnerable soil and/or climatic conditions; (d) to the residues in surface water abductured for drinking water purposes, in or from areas where products containing penflufen are used. Conditions of use shall include risk mitigation measures, where appropriate. ◀

▼ **M1**▼ **M88**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
56	Orange oil CAS No 8028-48-6 (Orange extract) 5989-27-5 (D-limonene) CIPAC No 902	(R)-4-isopropenyl-1-methylcyclohexene or <i>p</i> -mentha-1,8-diene	≥ 945 g/kg (of D-limonene) The active substance shall comply with the specifications of Ph. Eur. (Pharmacopoeia Europea) 5.0 (<i>Aurantii dulcis aetheroleum</i>) and ISO 3140:2011(E)	1 May 2014	► M449 31 December 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on orange oil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers; (b) the risk to birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the metabolite fate of orange oil and the route and rate of degradation in soil and on the validation of endpoints used in the ecotoxicological risk assessment. The applicant shall submit that information to the Commission, Member States and the Authority by 30 April 2016.
57	Penthiopyrad CAS No 183675-82-3 CIPAC No 824	(RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide	≥ 980 g/kg (50:50 racemic mixture)	1 May 2014	► M475 31 October 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on penthiopyrad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers;

▼ **M94**

▼ **M94**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(b) the risk to aquatic and soil organisms; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (d) the level of residues in rotational crops following consecutive application of the active substance over several years. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the non-relevance of metabolite M11 (3-methyl-1-{3-[(1-methyl-3-trifluoromethyl-1H-pyrazole-4-carbonyl)amino]thiophen-2-yl}pentanoic acid) for groundwater with the exception of evidence related to the risk of carcinogenicity, which is dependent on the classification of the parent and specified separately at (3) below; (2) the toxicological profile and the reference values of the metabolite PAM; (3) the relevance of the metabolites M11 (3-methyl-1-{3-[(1-methyl-3-trifluoromethyl-1H-pyrazole-4-carbonyl)amino]thiophen-2-yl}pentanoic acid), DM-PCA (3-trifluoromethyl-1H-pyrazole-4-carboxylic acid), PAM (1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide) and PCA (1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxylic acid) and their risk to contaminate groundwater, if penthiopyrad is classified under Regulation (EC) No 1272/2008 as carcinogenic cat. 2. The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in points (1) and (2) by 30 April 2016 and the information set out in point (3) within six months from the notification of the classification decision concerning penthiopyrad.

▼ **M1**▼ **M90**▼ **M95**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
58	Benalaxyl-M CAS No 98243-83-5 CIPAC No 766	Methyl <i>N</i> -(phenylacetyl)- <i>N</i> -(2,6-xylyl)-D-alaninate	≥ 950 g/kg	1 May 2014	► M468 30 September 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on benalaxyl-M, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of workers at re-entry, — the risk to groundwater from the metabolites BM-M2 (N-(malonyl)-N-(2,6-xylyl)-DL-alanine) and BM-M3 (N-(malonyl)-N-(2,6-xylyl)-D-alanine), when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate.
59	Tembotrione CAS No 335104-84-2 CIPAC No 790	2-{2-chloro-4-mesyl-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione	≥ 945 g/kg The following relevant impurities must not exceed a certain threshold in the technical material: Toluene: ≤ 10 g/kg HCN: ≤ 1 g/kg	1 May 2014	► M449 31 December 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on tembotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M1**▼ **M92**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
60	Spirotetramat CAS No 203313-25-1 CIPAC No 795	<i>cis</i> -4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro [4.5]dec-3-en-2-one	≥ 970 g/kg	1 May 2014	► M386 30 April 2024 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spirotetramat, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to insectivorous birds. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the potential for endocrine disruptor effects in birds and fish to the Commission, the Member States and the Authority within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.
61	Pyroxsulam CAS No 422556-08-9 CIPAC No 793	<i>N</i> -(5,7-dimethoxy [1,2,4]triazolo[1,5- <i>a</i>] pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide	≥ 965 g/kg	1 May 2014	► M468 30 September 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyroxsulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to groundwater, when the active substance is applied in regions with vulnerable soil or climatic conditions; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M91**

▼ **M91**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit confirmatory information as regards: (1) the toxicological relevance of impurity number 3 (as referred to in the review report); (2) the acute toxicity of the metabolite PSA; (3) the toxicological relevance of metabolite 6-Cl-7-OH-XDE-742. The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016.

▼ **M97**

62	Chlorantraniliprole CAS No 500008-45-7 CIPAC No 794	3-bromo-4'-chloro-1-(3-chloro-2-pyridyl)-2'-methyl-6'-(methyl-carbamoyl) pyrazole-5-carboxanilide	≥ 950 g/kg The following relevant impurities must not exceed a certain threshold in the technical material: Acetonitrile: ≤ 3 g/kg 3-picoline: ≤ 3 g/kg Methanesulfonic acid: ≤ 2 g/kg	1 May 2014	► M463 31 May 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chlorantraniliprole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and to soil macroorganisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the risk to groundwater from the active substance and its metabolites IN-EQW78 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one), IN-ECD73 (2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one), IN-F6L99 (3-bromo-N-methyl-1H-pyrazole-5-carboxamide), IN-GAZ70 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1H)-one) and IN-F9N04 (3-bromo-N-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide);
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▼ **M97**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(2) the risk to aquatic organisms from the photolysis metabolites IN-LBA22 (2-{{[(4Z)-2-bromo-4H-pyrazolo[1,5-d]pyrido[3,2-b][1,4]oxazin-4-ylidene] amino}-5-chloro-N,3-dimethylbenzamide), IN-LBA23 (2-[3-bromo-1-(3-hydroxypyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one) and IN-LBA24 (2-(3-bromo-1H-pyrazol-5-yl)-6-chloro-3,8-dimethylquinazolin-4(3H)-one). The applicant shall submit to the Commission, Member States and the Authority that information by 30 April 2016.

▼ **M96**

63	Sodium silver thiosulfate CAS No not allocated CIPAC No 762	Not applicable	≥ 10,0 g Ag/kg Expressed as silver (Ag)	1 May 2014	► M449 31 December 2026 ◀	PART A Only indoor uses in non-edible crops shall be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium silver thiosulfate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 October 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to (a) the protection of operators and workers; (b) limiting the possible release of silver ions through disposal of used solutions; (c) the risk to terrestrial vertebrates and soil invertebrates from the use of sewage sludge in agriculture. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M101**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
64	Pyridalyl CAS No 179101-81-6 CIPAC No 792	2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether	≥ 910 g/kg	1 July 2014	► M416 30 June 2024 ◀	PART A Only uses in greenhouses with permanent structure may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyridalyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to re-entry workers; (b) the risk to groundwater when the substance is applied in regions with vulnerable soils and/or climatic conditions; (c) the risk to birds, mammals and aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the toxicological and ecotoxicological information to address the relevance of impurities 4, 13, 16, 22 and 23; (2) the relevance of the metabolite HTFP and, concerning that metabolite, the groundwater risk assessment for all uses on crops in greenhouse; (3) the risk to aquatic invertebrates.

▼ **M101**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, the Member States and the Authority the relevant information as regards point (1) by 31 December 2014 and information as regards point (2) and (3) by 30 June 2016. The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential groundwater contamination from the metabolite HTFP in vulnerable zones by 30 June 2016. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 30 June 2018.

▼ **M105**

65	S-abscisic acid CAS No 21293-29-8 CIPAC No Not allocated	(2Z,4E)-5-[(1S)-1-hydroxy-2,6,6-trimethyl-4-oxocyclohex-2-en-1-yl]-3-methylpenta-2,4-dienoic acid or (7E,9Z)-(6S)-6-hydroxy-3-oxo-11-apo-ε-caroten-11-oic acid	960 g/kg	1 July 2014	► M457 15 September 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on S-abscisic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M104**

66	L-ascorbic acid CAS No 50-81-7 CIPAC No 774	(5R)-5-[(1S)-1,2-dihydroxyethyl]-3,4-dihydroxyfuran-2(5H)-one	≥ 990 g/kg The following relevant impurities shall not exceed: Methanol: ≤ 3 g/kg Heavy Metals: ≤ 10 mg/kg (expressed as Pb)	1 July 2014	► M386 30 June 2024 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on L-ascorbic acid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic and soil organisms; (b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.
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▼ **M104**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the natural background of L-ascorbic acid in the environment confirming a low chronic risk for fish and a low risk for aquatic invertebrates, algae, earthworms and soil microorganisms; (2) the risk to contaminate groundwater. The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.

▼ **M99**

67	Spinetoram CAS No 935545-74-7 CIPAC No 802	<i>XDE-175-J (Major factor)</i> (2<i>R</i>,3<i>aR</i>,5<i>aR</i>,5<i>bS</i>,9<i>S</i>,13<i>S</i>,14<i>R</i>,16<i>aS</i>, 16<i>bR</i>)-2-(6-deoxy-3-<i>O</i>-ethyl-2,4-di-<i>O</i>-methyl-α-L-mannopyranosyloxy)-13-[(2<i>R</i>,5<i>S</i>,6<i>R</i>)-5-(dimethylamino)tetrahydro-6-methylpyran-2-yloxy]-9-ethyl-2,3,3<i>a</i>,4,5,5<i>a</i>,5<i>b</i>,6,9,10,11,12,13,14,16<i>a</i>,16<i>b</i>-hexadecahydro-14-methyl-1<i>H</i>-as-indaceno[3,2-<i>d</i>]oxacyclododecine-7,15-dione <i>XDE 175-L (Minor factor)</i>	≥ 830 g/kg 50-90 % XDE-175-J; and 50-10 % XDE-175-L Tolerance limits (g/kg): XDE-175-J = 581-810 XDE-175-L = 83-270	1 July 2014	► M386 30 June 2024 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on spinetoram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic and soil organisms; (b) the risk to non-target arthropods in-field; (c) the risk to bees during the application (overspray) and subsequently. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M99**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
		(2S,3aR,5aS,5bS,9S,-13S,14R,16aS,16bS)-2-(6-deoxy-3-O-ethyl-2,4-di-O-methyl- α -L-mannopyranosyloxy)-13-[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methylpyran-2-yloxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione				The applicant shall submit confirmatory information as regards the equivalence between the stereochemistry of metabolites identified in the metabolism/degradation studies and in the testing material used for the toxicity and ecotoxicity studies. The applicant shall submit to the Commission, the Member States and the Authority the relevant information ► C3 within 6 months after the adoption of pertinent guidance on the assessment of isomers ◀.

▼ **M108**

68	1,4-dimethylnaphthalene CAS No 571-58-4 CIPAC No 822	1,4-dimethylnaphthalene	≥ 980 g/kg	1 July 2014	► M475 30 November 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 1,4-dimethylnaphthalene, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and of workers at re-entry and during inspection of the warehouse; (b) the risk to aquatic organisms and fish-eating mammals the active substance is discharged from warehouses into air and surface water without further treatment. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M108**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit confirmatory information as regards the residue definition for the active substance. The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.

▼ **M109**

69	Amisulbrom CAS No 348635-87-0 CIPAC No 789	3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-<i>N,N</i>-dimethyl-1<i>H</i>-1,2,4-triazole-1-sulfonamide	≥ 985 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole: ≤ 2 g/kg	1 July 2014	► M457 15 September 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on amisulbrom, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic and soil organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the non-significance of photodegradation in the soil metabolism of amisulbrom concerning the metabolites 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole and 1-(dimethylsulfamoyl)-1<i>H</i>-1,2,4-triazole-3-sulfonic acid to contaminate groundwater; (2) the low potential of amisulbrom (FOCUS drainage scenarios only) and metabolites 1-(dimethylsulfamoyl)-1<i>H</i>-1,2,4-triazole-3-sulfonic acid, 1<i>H</i>-1,2,4-triazole-3-sulfonic acid, 1<i>H</i>-1,2,4-triazole, <i>N,N</i>-dimethyl-1<i>H</i>-1,2,4-triazole-3-sulfonamide, 2-acetamido-4-fluorobenzoic acid, 2-acetamido-4-fluoro-hydroxybenzoic acid and 2,2'-oxybis(6-fluoro-2-methyl-1,2-dihydro-3<i>H</i>-indol-3-one) to contaminate surface water or to expose aquatic organisms by runoff;
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▼ **M109**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(3) depending on the outcome of the assessment under (1) and (2), where there is considerable photodegradation in soil or where there is high potential for contamination or exposure, additional analytical methods to determine all compounds of the residue definition for monitoring in surface water; (4) the risk from secondary poisoning for birds and mammals by 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole; (5) the potential for causing endocrine disrupting effects in birds and fish by amisulbrom and its metabolite 3-bromo-6-fluoro-2-methyl-1-(1<i>H</i>-1,2,4-triazol-3-ylsulfonyl)-1<i>H</i>-indole. The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in points (1) to (4) by 30 June 2016 and under point (5) within two years after the adoption of pertinent OECD test guidelines on endocrine disruption.

▼ **M102**

70	Valifenalate CAS No 283159-90-0 CIPAC No 857	Methyl <i>N</i> -(isopropoxycarbonyl)-L-valyl-(3 <i>RS</i>)-3-(4-chlorophenyl)-β-alaninate	≥ 980 g/kg	1 July 2014	► M457 1 March 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on valifenalate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the potential of metabolite S5 to contaminate groundwater. The notifier shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.
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▼ **M1**▼ **M103**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
71	Thiencarbazone CAS No 317815-83-1 CIPAC No 797	Methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1 <i>H</i> -1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate	≥ 950 g/kg	1 July 2014	► M457 1 March 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiencarbazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account. In this overall assessment Member States shall pay particular attention to (a) the risk to groundwater if the substance is applied under vulnerable geographical or climatic conditions; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the potential of thiencarbazone for long-range atmospheric transport and the related environmental impacts. That confirmatory information shall consist of the results of a monitoring programme to assess the potential of thiencarbazone for long-range atmospheric transport and the related environmental impacts. The applicant shall submit to the Commission, the Member States and the Authority this monitoring programme by 30 June 2016 and the results in form of a monitoring report by 30 June 2018.
72	Acequinocyl CAS No 57960-19-7 CIPAC No 760	3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate	≥ 960 g/kg	1 September 2014	► M460 15 November 2026 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on acequinocyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to:

▼ **M114**

▼ **M114**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						— the protection of workers and operators; — the risk to birds, mammals and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) an analytical method for residues in body fluids and tissues; (b) the acceptability of the long-term risk to small granivorous birds and small herbivorous and frugivorous mammals, concerning the use on apple and pear orchards; (c) the acceptability of the long-term risk to small omnivorous and small herbivorous mammals, concerning the use on outdoor ornamentals. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 August 2016.

▼ **M417**

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▼ **M119**

74	Flubendiamide CAS No 272451-65-7 CIPAC No 788	3-iodo-<i>N</i>-(2-mesyl-1,1-dimethylethyl)-<i>N</i>-{4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-<i>o</i>-tolyl}phthalamide	≥ 960 g/kg	1 September 2014	► M386 31 August 2024 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flubendiamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic invertebrates; (b) the potential presence of residues in rotational crops. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M111**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
75	<i>Bacillus pumilus</i> QST 2808 USDA Agricultural Research Service (NRRL) Patent culture collection in Peoria Illinois, USA under the reference number B-30087	Not applicable	$\geq 1 \times 10^{12}$ CFU/kg	1 September 2014	► M430 31 August 2024 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus pumilus</i> QST 2808, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Bacillus pumilus</i> QST 2808 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the identification of the aminosugar produced by <i>Bacillus pumilus</i> QST 2808; (b) analytical data for the content of that aminosugar in the production batches. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 August 2016.
76	Metobromuron CAS No 3060-89-7 CIPAC No 168	3-(4-bromophenyl)-1-methoxy-1-methylurea	≥ 978 g/kg	1 January 2015	► M463 31 May 2027 ◀	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metobromuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of workers and operators;

▼ **M123**

▼ **M123**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(b) the risk to birds, mammals, aquatic organisms and terrestrial non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the toxicological assessment of the metabolites CGA 18236, CGA 18237, CGA 18238 and 4-bromoaniline; (b) the acceptability of the long-term risk to birds and mammals. The applicant shall submit that information to the Commission, the Member States and the Authority by 31 December 2016.

▼ **M124**

77	Aminopyralid CAS No 150114-71-9 CIPAC No 771	4-amino-3,6-dichloro-pyridine-2-carboxylic acid	≥ 920 g/kg The following relevant impurity shall not exceed a certain threshold: Picloram ≤ 40 g/kg	1 January 2015	► M463 31 May 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aminopyralid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions; (b) the risk to aquatic macrophytes and terrestrial non-target plants; (c) chronic risk to fish. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M129**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
78	Metaflumizone CAS No 139968-49-3 CIPAC No 779	(EZ)-2'-[2-(4-cyanophenyl)-1-(α,α,α -trifluoro-m-tolyl)ethylidene]-4-(trifluoromethoxy)carbanilohydrazide	≥ 945 g/kg (90-100 % E-isomer 10-0 % Z-isomer) The following relevant impurities shall not exceed a certain threshold: Hydrazine $\leq$ 1 mg/kg 4-(trifluoromethoxy)phenyl isocyanate $\leq$ 100 mg/kg Toluene $\leq$ 2 g/kg	1 January 2015	31 December 2024	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metaflumizone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to fish and sediment dwelling organisms; (b) the risk to snail- or earthworm-eating birds. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the equivalence of the material used in the toxicological and ecotoxicological studies with the proposed technical specification; (2) information addressing the potential of metaflumizone for bioaccumulation in aquatic organisms and biomagnification in aquatic food chains. The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under (1) by 30 June 2015 and under (2) by 31 December 2016.

▼ **M1**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ M126						
79	<i>Streptomyces lydicus</i> strain WYEC 108 Collection number: American Type Culture Collection (USDA) ATCC 55445	Not applicable	Minimum concentration: $5,0 \times 10^8$ CFU/g	1 January 2015	► M343 31 December 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Streptomyces lydicus</i> strain WYEC 108, and in particular Appendices I and II thereto, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to aquatic organisms; (b) the risk to soil dwelling organisms. Conditions of use shall include risk mitigation measures, where appropriate.
▼ M131						
80	Meptyldinocap CAS No 6119-92-2 CIPAC No 811	Mixture of 75-100 % (RS)-2-(1-methylheptyl)-4,6-dinitrophenyl crotonate and 25— 0 % (RS)-2-(1-methylheptyl)-4,6-dinitrophenyl isocrotonate	≥ 900 g/kg (mixture of <i>trans</i> - and <i>cis</i> -isomers with a defined ratio range of 25:1 to 20:1) Relevant impurity: 2,6-dinitro-4-[(4RS)-octan-4-yl]phenyl (2E/Z)-but-2-enoate max content 0,4 g/kg	1 April 2015	► C5 31 March 2025 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on meptyldinocap, and in particular Appendices I and II thereof, as finalised in the ► C5 Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 ◀ shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators; (b) the risk to aquatic invertebrates. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (a) the groundwater exposure assessment for metabolites (3RS)-3-(2-hydroxy-3,5-dinitro-phenyl)-butanoic acid (X103317) and (2RS)-2-(2-hydroxy-3,5-dinitro-phenyl)-propionic acid (X12335709);

▼ **M131**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(b) the possible impact of any preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environment. The applicant shall submit to the Commission, the Member States and the Authority the information set out in point (a) by 31 March 2017 and the information set out in point (b) two years after the adoption of specific guidance by the Commission.

▼ **M133**

81	Chromafenozide CAS No 143807-66-3 CIPAC No 775	<i>N'</i>-tert-butyl-5-methyl-N'-(3,5-xyloyl)chromane-6-carbohydrazide	≥ 935 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: Butyl acetate (n-buthyl acetate, CAS No 123-86-4): ≤ 8 g/kg	1 April 2015	31 March 2025	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on chromafenozide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to groundwater, if the substance is applied under vulnerable soil or climatic conditions; (b) the risk to non-target Lepidoptera in off-crop areas; (c) the risk to sediment-dwelling organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the non-significance of the difference between the material used for ecotoxicological testing and the agreed specification of the technical material for the risk assessment; (2) the assessment of the risk to sediment dwelling organisms from metabolite M-010;
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▼ **M133**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(3) the leaching potential of metabolites M-006 and M-023 to groundwater. The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under (1) by 30 September 2015 and under (2) and (3) by 31 March 2017.

▼ **M132**

82	Gamma-cyhalothrin CAS No 76703-62-3 CIPAC No 768	(<i>S</i>)-α-cyano-3-phenoxymethyl (1<i>R</i>,3<i>R</i>)-3-[(<i>Z</i>)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or (<i>S</i>)-α-cyano-3-phenoxymethyl (1<i>R</i>)-<i>cis</i>-3-[(<i>Z</i>)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate	≥ 980 g/kg	1 April 2015	31 March 2025	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on gamma-cyhalothrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the safety of operators and workers; (b) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) analytical methods for the monitoring of residues in body fluids, tissues and environmental matrices; (2) the toxicity profile of the metabolites CPCA, PBA and PBA(OH); (3) the long-term risk to wild mammals; (4) the potential for biomagnification in terrestrial and aquatic food chains. The applicant shall submit to the Commission, the Member States and the Authority the relevant information by 31 March 2017.
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▼ **M1**▼ **M130**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
83	<i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747 Accession number in the Agricultural Research Culture Collection (NRRL), Peoria, Illinois, USA: B-50405 Deposit number in the International Patent Organism Depositary, Tokyo, Japan: FERM BP-8234.	Not applicable	Minimum concentration: $2,0 \times 10^{11}$ CFU/g	1 April 2015	► M468 31 August 2027 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
84	Terpenoid blend QRD 460 CIPAC No: 982	Terpenoid blend QRD 460 is a blend of three components: — α-terpinene: 1-isopropyl-4-methylcyclohexa-1,3-diene; — <i>p</i>-cymene: 1-isopropyl-4-methylbenzene; — <i>d</i>-limonene: (<i>R</i>)-4-isopropenyl-1-methylcyclohexene.	The nominal concentration of each component in the active substance as manufactured should be as follows: — α-terpinene: 59,7 %; — <i>p</i>-cymene: 22,4 %; — <i>d</i>-limonene: 17,9 %.	10 August 2015	10 August 2025	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on terpenoid blend QRD-460, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the stability of formulations on storage; (b) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (c) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (d) the protection of surface water and aquatic organisms; (e) the protection of bees and non-target arthropods.

▼ **M154**

▼ **M154**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			Each component should have a minimum purity as follows: — α-terpinene: 89 %; — <i>p</i>-cymene: 97 %; — <i>d</i>-limonene: 93 %.			Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (5 batch analysis for the blend should be provided), supported by acceptable and validated methods of analysis. It should be confirmed that there are no relevant impurities present in the technical material; (2) the equivalence of the material used in the toxicological and ecotoxicological studies with the confirmed technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 10 February 2016.

▼ **M155**

85	Fenhexamid CAS No: 126833-17-8 CIPAC No: 603	N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexane-1-carboxamide	≥ 975 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: — toluene: max. 1 g/kg, — 4-amino-2,3-dichlorophenol: max. 3 g/kg.	1 January 2016	31 December 2030	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenhexamid, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators during field crop handheld operations, — the protection of workers re-entering indoor-treated crops, — the risk to aquatic organisms, — the long-term risk to mammals for field uses. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M151**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
86	Halauxifen-methyl CAS No: 943831-98-9 CIPAC No: 970.201 (halauxifen-methyl) 970 (halauxifen)	methyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)pyridine-2-carboxylate	≥ 930 g/kg	5 August 2015	► M475 5 January 2028 ◀	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on halauxifen-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — The risk to aquatic and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: — The technical specification of the active substance as manufactured (based on commercial scale production). The relevance of impurities present in the technical material should be confirmed, — The compliance of the toxicity batches with the technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 5 February 2016.
87	Pyridate CAS No: 55512-33-9 CIPAC No: 447	O-6-chloro-3-phenylpyridazin-4-yl S-octyl thiocarbonate	≥ 900 g/kg	1 January 2016	31 December 2030	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyridate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, non-target terrestrial plants, and herbivorous mammals. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M148**

▼ **M1**▼ **M156**▼ **M150**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
88	Sulfoxaflor CAS No: 946578-00-3 CIPAC No: 820	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ ⁶ -sulfanylidene] cyanamide	≥ 950 g/kg	18 August 2015	► M475 18 January 2028 ◀	► M389 Only uses in permanent greenhouses may be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfoxaflor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 May 2015 and updated on 28 January 2022, shall be taken into account. In this overall assessment, Member States shall pay particular attention to the risk to bees and bumble bees released for pollination, when products containing the substance are applied in greenhouses. Conditions of use shall include risk mitigation measures, where appropriate. ◀
89	Sulfosulfuron CAS No: 141776-32-1 CIPAC No: 601	1-(4,6-dimethoxy-pyrimidin-2-yl)-3-(2-ethylsulfonylimidazo [1,2-a]pyridine-3-ylsulfonyl)urea	≥ 980 g/kg The following relevant impurity must not exceed a certain threshold in the technical material: Phenol: < 2 g/kg	1 January 2016	31 December 2030	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfosulfuron, and in particular Appendices I and II thereof shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to soil non-target macro-organisms other than earthworms, non-target terrestrial plants and aquatic organisms.

▼ **M1**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
▼ M159						
90	Florasulam CAS No 145701-23-1 CIPAC No 616	2',6',8-trifluoro-5-methoxy[1,2,4]triazolo[1,5- <i>c</i>]pyrimidine-2-sulfon-anilide	≥ 970 g/kg Impurity: 2,6-DFA, not more than 2 g/kg	1 January 2016	31 December 2030	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on florasulam, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.
▼ M164						
91	Flupyradifurone CAS No: 951659-40-8 CIPAC No: 987	4-[(6-chloro-3-pyridylmethyl)(2,2-difluoroethyl) amino]furan-2(5H)-one	≥ 960 g/kg	9 December 2015	9 December 2025	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flupyradifurone, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of workers and operators, — the risk to non-target arthropods, aquatic invertebrates and small herbivorous mammals, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — residues in animal matrices and rotational crops. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities, (2) the compliance of the toxicity batches with the confirmed technical specification, (3) the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water.

▼ **M164**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, the Member States and the Authority the information requested under point (1) and (2) by 9 June 2016, the information requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M167**

92	Rescalure CAS No: 67601-06-3 CIPAC No: Not available	(3 <i>S</i> ,6 <i>R</i>)-(3 <i>S</i> ,6 <i>S</i>)-6-isopropenyl-3-methyldec-9-en-1-yl acetate	≥ 750 g/kg The ratio of (3 <i>S</i> ,6 <i>R</i>)/(3 <i>S</i> ,6 <i>S</i>) shall be in a range of 55/45 to 45/55. The purity range for each isomer shall be 337,5 g/kg to 412,5 g/kg.	18 December 2015	18 December 2025	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on rescalure, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M165**

93	Mandestrobin CAS No: 173662-97-0 CIPAC No: Not available	(<i>RS</i>)-2-methoxy- <i>N</i> -methyl-2-[α-(2,5-xylyloxy)- <i>o</i> -tolyl] acetamide	≥ 940 g/kg (on a dry weight basis) Xylenes (ortho, meta, para), ethyl benzene max. 5 g/kg (TK)	9 December 2015	9 December 2025	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mandestrobin, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of some individual impurities; (2) the compliance of the toxicity batches with the confirmed technical specification. The applicant shall submit that information to the Commission, the Member States and the Authority by 9 June 2016.
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▼ **M1**▼ **M161**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
94	2,4-D CAS No: 94-75-7 CIPAC No: 1	(2,4-dichlorophenoxy) acetic acid	≥ 960 g/kg Impurities: Free phenols (expressed as 2,4-DCP): not more than 3 g/kg. Sum of dioxins and furans (WHO-TCDD TEQ) ⁽¹³⁾: not more than 0,01 mg/kg.	1 January 2016	31 December 2030	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,4-D, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha. Conditions of use shall include risk mitigation measures, where appropriate. The notifier shall submit to the Commission, the Member States and the Authority: (1) confirmatory information in the form of the submission of the complete study results from the existing extended one-generation study; (2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential endocrine properties of the substance. The information set out in point (1) shall be submitted by 4 June 2016 and the information set out in point (2) by 4 December 2017.
95	Pyraflufen-ethyl CAS No 129630-19-9 CIPAC No 605.202	ethyl [2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxy]acetate	≥ 956 g/kg	1 April 2016	31 March 2031	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pyraflufen-ethyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M173**

▼ **M1**▼ **M171**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
96	Iprovalicarb CAS No 140923-17-7 CIPAC No 620	isopropyl [(1S)-2-methyl-1-{{[(1RS)-1-p-tolylolethyl] carbamoyl}propyl] carbamate	≥ 950 g/kg Impurities: Toluene: not more than 3 g/kg	1 April 2016	31 March 2031	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on iprovalicarb, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater from the relevant soil metabolite PMPA ⁽¹⁷⁾ when the active substance is applied in regions with low clay containing soil types, — the safety of operators and workers, — the protection of aquatic organisms in the case of formulated products containing other active substances. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority, confirmatory information as regards the genotoxic potential of soil metabolite PMPA. This information shall be submitted by 30 September 2016.
97	Pinoxaden CAS No 243973-20-8 CIPAC No 776	8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropionate	≥ 970 g/kg Toluene max. content 1 g/kg	1 July 2016	30 June 2026	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pinoxaden, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 29 January 2016 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. The Member States concerned shall carry out monitoring programmes to verify potential groundwater contamination from the metabolite M2 in vulnerable zones, where appropriate.

▼ **M174**

▼ **M174**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit confirmatory information as regards: (a) a validated method of analysis of metabolites M11, M52, M54, M55 and M56 in ground water; (b) the relevance of the metabolites M3, M11, M52, M54, M55 and M56, and the corresponding groundwater risk assessment, if pinoxaden is classified under Regulation (EC) No 1272/2008 as H361d (suspected of damaging the unborn child). The applicant shall submit to the Commission, the Member States and the Authority the relevant information set out in point (a) by 30 June 2018 and the information set out in point (b) within six months from the notification of the classification decision under Regulation (EC) No 1272/2008 concerning pinoxaden.

▼ **M453**

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▼ **M189**

99	Cyantraniliprole CAS No: 736994-63-1 CIPAC No: Not allocated.	3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methyl-carbamoyl)pyrazole-5-carboxanilide	≥ 940 g/kg IN-Q6S09 max. 1 mg/kg IN-RYA13 max. 20 mg/kg methanesulfonic acid max. 2 g/kg acetonitrile max. 2 g/kg heptane max. 7 g/kg 3-picoline max. 3 g/kg.	14 September 2016	14 September 2026	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyantraniliprole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators; (b) the risk to aquatic organisms, bees and other non-target arthropods; (c) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses; (d) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M189**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M192**

100	Isofetamid CAS No: 875915-78-9 CIPAC No: 972	<i>N</i> -[1,1-dimethyl-2-(4-isopropoxy- <i>o</i> -tolyl)-2-oxoethyl]-3-methylthiophene-2-carboxamide	≥ 950 g/kg	15 September 2016	15 September 2026	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on isofetamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to operators, workers and aquatic organisms, in particular fish. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification; (3) the effect of water treatment process chlorination on the nature of residues, including the potential for the formation of chlorinated residues that may be formed from residues present in surface water, when surface water is abstracted for drinking water. The applicant shall submit the information requested under points (1) and (2) by 15 March 2017 and the information requested under point (3) within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.
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▼ **M1**▼ **M194**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
101	<i>Bacillus amyloliquefaciens</i> strain MBI 600. Accession number in the National Collection of Industrial, Marine and Food Bacteria Ltd (NCIMB), Scotland: NCIMB 12376 Deposit number in the American Type Culture Collection (ATCC): SD-1414	Not applicable	Minimum concentration: $5,0 \times 10^{14}$ CFU/kg	16 September 2016	16 September 2026	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> strain MBI 600, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites; (b) the protection of operators and workers, taking into account that <i>Bacillus amyloliquefaciens</i> strain MBI 600 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
102	Ethofumesate CAS No 26225-79-6 CIPAC No 233	(RS)-2-ethoxy-2,3-dihydro-3,3-dimethyl-benzofuran-5-yl methanesulfonate	≥ 970 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material:	1 November 2016	31 October 2031	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on ethofumesate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M193**

▼ **M193**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			— EMS; ethyl methane sulfonate: maximum of 0,1 mg/kg — iBMS; iso-butyl methane sulfonate: maximum of 0,1 mg/kg			

▼ **M190**

103	Picolinafen CAS No 137641-05-5 CIPAC No 639	4'-fluoro-6-(α,α,α -trifluoro-m-tolyloxy) pyridine-2-carbox-anilide	≥ 980 g/kg	1 November 2016	30 June 2031	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on picolinafen, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the impurities in the technical active substance; — the protection of mammals, especially of large herbivorous mammals; — the protection of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of aquatic organisms, especially to algae. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M191**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
104	Thifensulfuron-methyl CAS No 79277-27-3 CIPAC No 452	methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl) thiophene-2-carboxylate	≥ 960 g/kg	1 November 2016	31 October 2031	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thifensulfuron-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater; — the protection of non-target plants and aquatic organisms. Conditions of use shall include risk mitigation measures and the obligation to monitor the groundwater, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the absence of genotoxicity of metabolites IN-A4098 and its derivative IN-B5528, IN-A5546 and IN-W8268; (2) mechanistic data to rule out an endocrine mediated mode of action for mammary gland tumours; (3) the risk to aquatic organisms from thifensulfuron-methyl and metabolite IN-D8858 and the risk to soil organisms from metabolites IN-JZ789 and 2 acid 3 triuret; (4) the relevance of the metabolites IN-A4098, IN-L9223 and IN-JZ789 if thifensulfuron-methyl is classified as reprotoxic category 2 under Regulation (EC) No 1272/2008 and the risk that those metabolites contaminate groundwater.

▼ **M191**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit the information requested under point (1) by 31 March 2017, under points (2) and (3) by 30 June 2017 and under point (4) within six months after the notification of the classification decision concerning thifensulfuron-methyl.

▼ **M198**

105	Thiabendazole CAS No 148-79-8 CIPAC No 323	2-(thiazol-4-yl) benzimidazole	≥ 985 g/kg	1 April 2017	31 March 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiabendazole, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and consumers, — the protection of groundwater, — the control of waste water from post-harvest uses. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit by 31 March 2019 to the Commission, the Member States and the Authority confirmatory information regarding Level 2 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of thiabendazole.
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▼ **M200**

106	Oxathiapiprolin CAS No: 1003318-67-9 CIPAC No: 985	1-(4-{4-[(5RS)-5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}-1-piperidyl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]ethanone	≥ 950 g/kg	3 March 2017	3 March 2027	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxathiapiprolin, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M200**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification. The applicant shall submit the information requested under points (1) and (2) by 3 September 2017.

▼ **M207**

107	Iodosulfuron CAS No 185119-76-0 (parent) CAS No 144550-36-7 (iodosulfuron-methyl-sodium) CIPAC No 634 (parent) CIPAC No 634.501 (iodosulfuron-methyl-sodium)	4-iodo-2-[(4-methoxy-6-methyl-1,3,5-triazin-2-yl) carbamoylsulfamoyl] benzoic acid (iodosulfuron) sodium ([5-iodo-2-(methoxycarbonyl) phenyl]sulfonyl} carbamoyl)(4-methoxy-6-methyl-1,3,5-triazin-2-yl) azanide (iodosulfuron-methyl-sodium)	≥ 910 g/kg (expressed as iodosulfuron-methyl-sodium)	1 April 2017	31 March 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on iodosulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers, — the risk to non-target terrestrial plants, — the risk to aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the genotoxic potential of the metabolite triazine-amine (IN-A4098), in order to confirm that this metabolite is not genotoxic and not relevant for the risk assessment; (2) the effect of water treatment processes on the nature of residues present in drinking water.
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▼ **M207**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit the information requested under point (1) 1 October 2017 and the information requested under point (2) by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M218**

108	Flazasulfuron CAS No 104040-78-0 CIPAC No 595	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulphonyl)urea	≥ 960 g/kg	1 August 2017	31 July 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on flazasulfuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic plants, — the protection of non-target terrestrial plants, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.
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▼ **M223**

109	<i>Beauveria bassiana</i> strain NPP111B005 Accession number in the CNCM (Collection Nationale de Culture de Microorganismes) — Institut Pasteur, Paris, France: I-2961.	Not applicable	Max. level of beauvericin 24 µg/L	7 June 2017	7 June 2027	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain NPP111B005, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M223**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that <i>Beauveria bassiana</i> strain NPP111B005 is to be considered, as any micro-organism, as a potential sensitizer, and paying special attention to exposure through inhalation, — the maximum level of the metabolite beauvericin in the formulated product. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M220**

110	<i>Beauveria bassiana</i> strain 147 Accession number in the CNCM (Collection nationale de cultures de micro-organismes) — Institut Pasteur, Paris, France: I-2960.	Not applicable	Max. level of beauvericin: 24 µg/L	6 June 2017	6 June 2027	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain 147, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that <i>Beauveria bassiana</i> strain 147 is to be considered, as any micro-organism, as a potential sensitizer, and paying special attention to exposure through inhalation, — the maximum level of the metabolite beauvericin in the formulated product. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M216**▼ **M214**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
111	Mesosulfuron (parent) Mesosulfuron-methyl (variant) CAS No 208465-21-8 (mesosulfuron-methyl) CIPAC No 663 (mesosulfuron) CIPAC No 663.201 (mesosulfuron-methyl)	Mesosulfuron-methyl: methyl-2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-(methanesulfonamido)-<i>p</i>-toluate Mesosulfuron: 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-methanesulfonamido-<i>p</i>-toluic acid	≥ 930 g/kg (expressed as mesosulfuron-methyl)	1 July 2017	30 June 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on mesosulfuron and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms and non-target terrestrial plants; — the protection of groundwater. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.
112	Mesotrione CAS No 104206-82-8 CIPAC No 625	Mesotrione 2-(4-mesyl-2-nitrobenzoyl) cyclohexane-1,3-dione	≥ 920 g/kg R287431 max 2 mg/kg R287432 max 2 g/kg 1,2-dichloroethane max 1 g/kg	1 June 2017	31 May 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on mesotrione, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, — the protection of groundwater in vulnerable regions, — the protection of mammals, aquatic and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the genotoxic profile of the metabolite AMBA;

▼ **M214**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						2. the potential endocrine disrupting mode of action of the active substance in particular level 2 and 3 tests, currently indicated in the OECD Conceptual framework (OECD 2012) and analysed in the EFSA Scientific opinion on the hazard assessment of endocrine disruptors; 3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under point 1 by 1 July 2017 and the relevant information requested under point 2 by 31 December 2017. The applicant shall submit to the Commission, the Member States and the Authority the confirmatory information requested under point 3 within a period of two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.

▼ **M215**

113	Cyhalofop-butyl CAS No 122008-85-9 CIPAC No 596	butyl (R)-2-[4-(4-cyano-2-fluorophenoxy) phenoxy] propionate	950 g/kg	1 July 2017	30 June 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyhalofop-butyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, — the technical specification, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M228**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
114	Propoxycarbazone (parent) Propoxycarbazone-sodium (variant) CAS No 145026-81-9 (propoxycarbazone) CAS No 181274-15-7 (propoxycarbazone-sodium) CIPAC No 655 (propoxycarbazone) CIPAC No 655.011 (propoxycarbazone-sodium)	Propoxycarbazone: methyl 2-[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazole-1-carboxamido)sulfonyl]benzoate Propoxycarbazone-sodium: sodium {[2-(methoxycarbonyl)phenyl]sulfonyl}[(4,5-dihydro-4-methyl-5-oxo-3-propoxy-1H-1,2,4-triazol-1-yl)carbonyl]azanide	≥ 950g/kg <i>(expressed as Propoxycarbazone-sodium)</i>	1 September 2017	31 August 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on propoxycarbazone, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic organisms, in particular aquatic plants and of and non-target terrestrial plants, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water within a period of 2 years of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.

▼ **M226**

115	Benzoic acid CAS No 65-85-0 CIPAC No 622	Benzoic acid	≥ 990 g/kg	1 September 2017	31 August 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on benzoic acid and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators, ensuring that conditions of use impose the use of adequate personal protective equipment. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M232**

116	2,4-DB CAS No 94-82-6 CIPAC No 83	4-(2,4-dichlorophenoxy) butyric acid	≥ 940 g/kg Impurities:	1 November 2017	31 October 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,4-DB, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M232**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
			Free phenols (expressed as 2,4-dichlorophenol (2,4-DCP)): max. 15 g/kg. Dibenzo- <i>p</i> -dioxins and polychlorinated dibenzofurans (TCDD toxic equivalents (TEQ)): max. 0,01 mg/kg.			In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, — the protection of consumers from products of animal origin, — the protection of wild mammals, — the protection of soil non-target organisms, — the protection of aquatic organisms, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M234**

117	Maleic hydrazide CAS No 123-33-1 CIPAC No 310	6-hydroxy-2H-pyridazin-3-one	≥ 979 g/kg Until 1 November 2018, the impurity hydrazine shall not exceed 1 mg/kg in the technical material. From 1 November 2018, the impurity hydrazine shall not exceed 0,028 mg/kg in the technical material.	1 November 2017	31 October 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on maleic hydrazide, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers, — the operator and worker safety; the conditions of the use should include the application of adequate personal protective equipment. Member States shall ensure, where appropriate, that the label of the treated crops includes the indication that the crops were treated with maleic hydrazide, and the accompanying instructions to avoid exposure of the live-stock. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M442**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
118	Glyphosate CAS No: 1071-83-6 CIPAC No: 284	N-(phosphonomethyl) glycine	≥ 950 g/kg The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: — <i>N</i>-nitroso-glyphosate (NNG): &amp;lt; 1 mg/kg — formaldehyde: < 1 g/kg — triethylamine: ≤ 2g/kg — formic acid: ≤ 4 g/kg — <i>N,N</i>-bis(phosphonomethyl) glycine (glyphosine): ≤ 3 g/kg	16 December 2023	15 December 2033	Only uses as herbicide may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on glyphosate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the co-formulants present in glyphosate-containing plant protection products, taking into account in particular the criteria for identification of unacceptable co-formulants as set out in Commission Implementing Regulation (EU) 2023/574 ⁽²⁹⁾; — the consumer exposure assessment with regards to residues that may be present in succeeding crops grown in rotation; — the protection of groundwater in vulnerable areas and of surface waters, in particular those used for the abstraction of drinking water, considering specifically uses on sealed surfaces; — the protection of small herbivorous mammals. Member States shall, where considered necessary impose mitigation measures such as limiting the timing of use, the number of applications or the maximum dose rate. The following maximum application rates shall not be exceeded unless the outcome of the risk assessment undertaken for the specific uses for which authorisation is applied for demonstrates that a higher rate does not lead to any unacceptable effects on small herbivorous mammals: — For use in agriculture: 1,44 kg glyphosate per hectare, per year;

▼ M442

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— For use to control invasive species in agricultural and non-agricultural areas: 1,8 kg glyphosate per hectare, per year; — For use in non-agricultural areas: 3,6 kg glyphosate per hectare, per year; — the protection of non-target terrestrial and aquatic plants from exposure by spray drift; — indirect effects on biodiversity via trophic interactions once relevant methods and guidance to identify such effects are agreed at Union level. In the absence of such methods and guidance, Member States may apply methods which they consider appropriate to determine the potential indirect effects of plant protection products containing glyphosate and which take into account their local agro-environmental conditions. When doing so, if they identify any such possible indirect effects on biodiversity, Member States shall set specific conditions or restrictions of use for plant protection products containing glyphosate, considering in particular if practical alternative control or prevention methods with lower impacts on biodiversity are available; — uses by non-professional users; — compliance of pre-harvest uses with the provisions of Directive 2009/128/EC in conjunction with Article 55 of Regulation (EC) No 1107/2009. Uses for desiccation to control the time point of harvest or to optimise threshing shall not be authorised. Conditions of use shall include risk mitigation measures, including combinations thereof, as required. In particular, drift shall be reduced for spray applications made by professional users in agricultural fields. By default, to protect non-target terrestrial plants, an in-field non-sprayed buffer strip of at least 5 to 10 m from the field border depending on the

▼ **M442**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						particular use and drift reduction nozzles reducing spray drift by at least 75 %, or other risk mitigation measures with equivalent reduction of drift, shall be required, unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift. In addition, Member States may set monitoring requirements when granting authorisations, in order to complement the monitoring under Directive 2000/60/EC of the European Parliament and of the Council ⁽³⁰⁾ and Directive 2009/128/EC. Member States shall ensure that use of plant protection products containing glyphosate is minimised or prohibited in the specific areas listed in Article 12(a) of Directive 2009/128/EC. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the possible indirect effects on biodiversity via trophic interactions, within three years from the date of applicability of a relevant guidance document endorsed by the Standing Committee on Plants, Animals, Food and Feed.

▼ **M247**

119	Acetamiprid CAS No 135410-20-7 CIPAC No 649	(E)-N1-[(6-Chloro-3-pyridyl)methyl]-N2-cyano-N1-methyl-acetamidine	≥ 990 g/kg	1 March 2018	28 February 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on acetamiprid, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to:
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▼ **M247**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						— the risk to aquatic organisms, bees and other non-target arthropods, — the risk to birds and mammals, — the risk to consumers, — the risk to operators. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M253**

120	Bentazone CAS No 25057-89-0 CIPAC No 366	3-isopropyl-1 <i>H</i> -2,1,3-benzothiadiazin-4(3 <i>H</i>)-one 2,2- dioxide	≥ 960 g/kg 1,2-dichloroethane < 3 mg/kg	1 June 2018	► M475 31 October 2027 ◀	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bentazone, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the technical specification, — the protection of operators and workers, — the risk to birds and mammals, — the protection of groundwater, particularly but not only in drinking water protected areas, and shall carefully consider the timing of application, soil and/or climatic conditions. Conditions of use shall include risk mitigation measures where appropriate. The applicant shall submit by 1 February 2019 to the Commission, the Member States and the Authority confirmatory information as regards Level 2/3 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of bentazone.
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▼ **M1**▼ **M259**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
121	Silthiofam CAS No 175217-20-6 CIPAC No 635	N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide	≥ 980 g/kg	1 July 2018	30 June 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on silthiofam and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of operators, — the protection of groundwater in vulnerable regions, — the protection of birds, mammals and earthworms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water; 2. the relevance of the metabolites M2 and M6 taking into account any relevant classification for silthiofam in accordance with Regulation (EC) No 1272/2008, in particular as reprotoxic category 2. The applicant shall submit the information mentioned in point (1) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater is made public by the Commission and the information requested under point (2) within one year after the publication in the European Chemicals Agency (ECHA) webpage of the opinion adopted by the Committee for risk assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to silthiofam.

▼ **M1**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ M255						
122	Forchlorfenuron CAS No 68157-60-8 CIPAC No 633	1-(2-chloro-4-pyridyl)-3-phenylurea	≥ 978 g/kg	1.6.2018	31.5.2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on forchlorfenuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers as regards the potential risk from metabolites in fruit crops with edible peels. Conditions of use shall include risk mitigation measures, where appropriate.
▼ M258						
123	Zoxamide CAS No 156052-68-5 CIPAC No 640	(RS)-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-p-toluamide	≥ 953 g/kg	1 July 2018	30 June 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on zoxamide, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater from metabolite RH-141455, — the protection of bees, aquatic organisms and earthworms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment

▼ **M258**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						processes on the nature of residues present in drinking water within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater is made public by the Commission.

▼ **M267**

124	Trifloxystrobin CAS No 141517-21-7 CIPAC No 617	methyl (E)-methoxyimino- {(E)- α -[1-(α , α , α -trifluoro-m-tolyl) ethylideneaminoxy]-o-tolyl} acetate	≥ 975 g/kg AE 1344136 (max. 4 g/kg)	1 August 2018	31 July 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on trifloxystrobin, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the protection of aquatic organisms, bees, and of fish-eating birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for trifloxystrobin in accordance with Regulation (EC) No 1272/2008, in particular as toxic for reproduction category 2; (2) the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water.
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▼ **M267**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit the information requested under point (1) within one year after the publication, on the website of the European Chemicals Agency (ECHA), of the opinion adopted by the Committee for Risk Assessment of the ECHA in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to trifloxystrobin. The applicant shall submit the information requested under point (2) within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.

▼ **M268**

125	Carfentrazone-ethyl CAS No 128639-02-1 CIPAC No 587.202	Ethyl (RS)-2-chloro-3-[2-chloro-4-fluoro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]propionate	≥ 910 g/kg	1 August 2018	31 July 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on carfentrazone-ethyl, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the protection of soil non-target organisms; — the protection of aquatic organisms; — the protection of non-target terrestrial higher plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:
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▼ **M268**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						(1) the relevance of metabolites that may occur in groundwater, taking into account any relevant classification for carfentrazone-ethyl in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁹⁾, in particular as carcinogen category 2; (2) the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit the information mentioned in point (1) within one year after the publication on the website of the European Chemicals Agency of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) of Regulation (EC) No 1272/2008 with respect to carfentrazone-ethyl. The applicant shall submit the information requested under point (2) within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission.

▼ **M273**

126	Fenpicoxamid CAS No: 517875-34-2 CIPAC No: 991	(3 <i>S</i> ,6 <i>S</i> ,7 <i>R</i> ,8 <i>R</i>)-8-benzyl-3-{3-[(isobutyryloxy)methoxy]-4-methoxypyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate	≥ 750 g/kg	11 October 2018	11 October 2028	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpicoxamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the impact of processing on the consumer risk assessment, — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification;
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▼ **M273**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of fenpicoxamid as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify according to Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ⁽²⁰⁾, whether the effects observed in the studies submitted for approval are or are not related to a thyroid endocrine disrupting mode of action. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 1 by 11 October 2019, in point 2 within 2 years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission and in point 3 by 10 November 2020.

▼ **M272**

127	Pethoxamid CAS No 106700-29-2 CIPAC No 665	2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl) acetamide	≥ 940 g/kg Impurities: Toluene: max 3 g/kg.	1 December 2018	30 November 2033	PART A Use shall be limited to one application every two years in the same field at a maximum dose of 1 200 g active substance per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on pethoxamid, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the risk of groundwater metabolites when pethoxamid is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms and earthworms; — the risk to consumers from residues in the succeeding crops or in case of crop failure.
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▼ M272

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the relevance of the metabolites that may occur in groundwater, taking into account any relevant classification for pethoxamid in accordance with Regulation (EC) No 1272/2008 of the Parliament and of the Council ⁽¹⁹⁾, in particular as carcinogen category 2; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of pethoxamid as regards the thyroid modality/pathway as a minimum providing mechanistic data to clarify whether there is a thyroid endocrine disrupting mode of action. The applicant shall submit the information requested under point 1 within one year after the publication of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council with respect to pethoxamid and the information requested. The applicant shall submit the information requested under point 2 within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission. The applicant shall submit the information requested under point 3 by 10 November 2020 in accordance with Commission Regulation (EU) 2018/605 ⁽²⁰⁾ amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties and the joint guidance document to identify endocrine disrupting substances as adopted by EFSA and ECHA.

▼ **M1**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
▼ M283						
128	Tribenuron (parent) CAS No 106040-48-6 CIPAC No 546	2-[[[4-methoxy-6-methyl-1,3,5-triazin-2-yl)-methylcarbamoyl]sulfonyl] benzoic acid	≥ 960 g/kg (expressed as tribenuron-methyl)	1 February 2019	30 January 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on tribenuron, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers, in particular to residues on animal products, — the protection of groundwater, — the protection of aquatic organisms and of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.
▼ M285						
129	<i>Metschnikowia fructicola</i> strain NRRL Y-27328 Accession number in the Agriculture Research Service Culture Collection at the National center for agricultural utilisation research in Peoria, Illinois USA	Not applicable	Minimum concentration: 1×10^{10} CFU/g	27 December 2018	27 December 2028	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Metschnikowia fructicola</i> strain NRRL Y-27328, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that <i>Metschnikowia fructicola</i> strain NRRL Y-27328 is to be considered as a potential sensitizer. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be ensured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M1**▼ **M289**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
130	<i>Beauveria bassiana</i> strain IMI389521 Accession number in the CABI Genetic Resource Collection: IMI389521	Not applicable	Max. level of beauvericin: 0,09 mg/kg	19 February 2019	19 February 2029	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain IMI389521, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the storage stability of the formulation(s) containing <i>B. bassiana</i> strain IMI389521 including the level of the metabolite beauvericin content after storage; — the content of the metabolite beauvericin produced under the application conditions; — the risk posed by beauvericin in infected insects present in the stored grain. Measures are required to ensure that such products do not enter the food and feed chain, taking into account the natural background level of beauvericin on cereal grains; — the protection of operators and workers, taking into account that <i>B. bassiana</i> strain IMI389521 is to be considered, as any micro-organism, as a potential sensitiser. The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²¹⁾. Conditions of use shall include risk mitigation measures where appropriate.

▼ **M290**

131	<i>Beauveria bassiana</i> strain PPRI 5339 Accession number in the Agricultural Research Culture Collection (NRRL) International Depositary Authority: NRRL 50757	Not applicable	Max. level of beauvericin: 0,5 mg/kg	20 February 2019	20 February 2029	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain PPRI 5339, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the level of the metabolite beauvericin content in a shelf-life study after storage of the formulation(s) containing <i>B. bassiana</i> strain PPRI 5339;
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▼ **M290**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						— the effects on pollinators introduced in glasshouses following exposure to formulation(s) different from the representative one supporting this approval; — the protection of operators and workers, taking into account that <i>B. bassiana</i> strain PPRI 5339 is to be considered, as any micro-organism, as a potential sensitizer. The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (21). Conditions of use shall include risk mitigation measures where appropriate.

▼ **M297**

132	Mefentrifluconazole CAS No: 1417782-03-6 CIPAC No: Not assigned	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	≥ 970 g/kg The impurity N, N-dimethyl-formamide shall not exceed 0,5 g/kg in the technical material. The impurity toluene shall not exceed 1 g/kg in the technical material The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material	20 March 2019	20 March 2029	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mefentrifluconazole, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, such as buffer zones and/or vegetative strips, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: - the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; - the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water.
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▼ **M297**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit the information referred to in point 1 by 20 March 2020 and the information referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M299**

133	Flutianil CAS No [958647-10-4] CIPAC No 835	(Z)-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene](α , α , α , 4-tetrafluoro- <i>m</i> -tolylthio)acetonitrile	≥ 985 g/kg	14 April 2019	14 April 2029	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flutianil, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, — the risk to aquatic organisms, — the risk to groundwater from metabolites, if the substance is applied under vulnerable soil or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water; 3. an updated assessment of the information submitted and, where relevant further information, confirming that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, applying also the ECHA and EFSA guidance for identification of endocrine disruptors ⁽²²⁾.
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▼ **M299**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit the information: — referred to in point 1 by 14 April 2020; — referred to in point 2 within two years from the date of publication, from the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater; and — referred to in point 3 by 14 April 2021.

▼ **M305**

134	Isoxaflutole CAS No 141112-29-0 CIPAC No 575	(5-cyclopropyl-1,2-oxazol-4-yl)(α,α,α-trifluoro-2-mesyl-p-tolyl)methanone	≥ 972 g/kg	1 August 2019	31 July 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on isoxaflutole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment, Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of aquatic organisms, wild mammals and non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit this information within 2 years from the date of publication, by the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. The applicant shall also provide an updated assessment to confirm that isoxaflutole is not an endocrine disruptor within the meaning of points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 and in accordance with the guidance for identification of endocrine disruptors⁽²³⁾ by 10 May 2021.
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▼ **M1**▼ **M327**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
135	carvone 2244-16-8 (d-carvone = S-carvone = (+)-carvone) Carvone: 602 d-carvone: not allocated	(S)-5-isopropenyl-2-methylcyclohex-2-en-1-one Or (S)-p-mentha-6,8-dien-2-one	923 g/kg d-carvone	1 August 2019	31 July 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on carvone, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. Conditions of use shall include risk mitigation measures, where appropriate. In particular, consideration should be given to the necessary time period before entry into storage rooms after the application of plant protection products containing carvone. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: — the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water is abstracted for drinking water. The applicant shall submit that information within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.
136	1-methylcyclopropene CAS No 3100-04-7 CIPAC No 767	1-methylcyclopropene	≥ 980 g/kg (technical concentrate) The following impurities are of toxicological concern and must not exceed the following levels in the technical material (technical concentrate):	1 August 2019	31 July 2034	Only uses as plant growth regulator for post-harvest storage in sealable warehouse may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on 1-methylcyclopropene, and in particular Appendices I and II thereto, shall be taken into account.

▼ **M307**

▼ **M307**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			— 1-chloro-2-methylpropene: maximum of 0,2 g/kg, — 3-chloro-2-methylpropene: maximum of 0,2 g/kg. For 1-methylcyclopropene generated <i>in situ</i>, Heptane and methylcyclohexane are toxicologically relevant impurities. These impurities should remain below 10 %.			

▼ **M311**

137	Dimethenamid-P CAS No 163515-14-8 CIPAC No 638	(S)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)acetamide	≥ 930 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: 1,1,1,2-Tetrachloroethane (TCE): ≤ 1,0 g/kg	1 September 2019	31 August 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on dimethenamid-P, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of groundwater, in particular regarding the metabolites of dimethenamid-P; — the protection of aquatic organisms and small herbivorous mammals.
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▼ **M311**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water. The applicant shall submit the requested information within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M310**

138	Tolclofos-methyl CAS No 57018-04-9 CIPAC No 479	O-2,6-dichloro-p-tolyl O, O-dimethyl phosphorothioate O-2,6-dichloro-4-methylphenyl O, O-dimethyl phosphorothioate	≥ 960 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: Methanol max. 1 g/kg	1 September 2019	31 August 2034	Only for use on ornamentals and on potatoes. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on tolclofos-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to aquatic organisms and mammals, — the risk to consumers, in particular the potential risk from metabolite DM-TM-CH₂OH in potatoes, — the risk to operators, workers and bystanders; Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**▼ **M312**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
139	Florpyrauxifen-benzyl CAS No: 1390661-72-9 CIPAC No: 990.227	benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate	≥ 920 g/kg The impurity toluene shall not exceed 3 g/kg in the technical material.	24 July 2019	24 July 2029	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 22 March 2019, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic and terrestrial non-target plants. Conditions of use shall include risk mitigation measures such as buffer zones and/or drift reduction nozzles, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine activity in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 by 24 July 2021.
140	Metalaxyl-M CAS No 70630-17-0 (R) CIPAC No 580	methyl N-(methoxyacetyl)-N-(2,6-xylyl)-D-alaninate	≥ 920 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: 2,6-dimethyl-phenylamine: max. content: 0,5 g/kg	1 June 2020	31 May 2035	When used for seed treatment, only the treatment of seeds intended to be sown in greenhouses may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metalaxyl-M, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured, — the protection of operators and workers, ensuring that the conditions of use prescribe the use of adequate personal protective equipment, where appropriate, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions,

▼ **M454**

▼ **M454**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
			4-methoxy-5-methyl-5H-[1,2]oxathiole 2,2-dioxide: max. content: 1 g/kg 2-[(2,6-dimethylphenyl)-(2-methoxyacetyl)-amino]propionic acid 1-methoxycarbonyl-ethyl ester: max. content < 10 g/kg			— the protection of non-target arthropods, birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine disrupting properties in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, by 26 May 2022. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water, by 10 July 2026.

▼ **M323**

141	Foramsulfuron CAS No 173159-57-4 CIPAC No 659	1-(4,6-dimethoxypyrimidin-2-yl)-3-[2-(dimethylcarbamoyl)-5-formamidophenylsulfonyl]urea	≥ 973 g/kg	1 June 2020	31 May 2035	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on foramsulfuron, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to consumers and operators, — the risk to aquatic organisms and non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water, within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.
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▼ **M1**▼ **M330**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
142	Pyriproxyfen. 2-((1-(4-Phenoxyphenoxy)propan-2-yl)oxy)pyridine. CIPAC No: 715. CAS No: 95737-68-1. EC No (Einecs or ELINCS): 429-800-1	4-phenoxyphenyl (<i>RS</i>)-2(2-pyridyloxy) propyl ether	≥ 970 g/kg Max. impurity: Toluene 5 g/Kg	1 August 2020	31 July 2035	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on pyriproxyfen and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the dietary exposure of consumers to residues of pyriproxyfen, — the protection of sediment-dwelling organisms and aquatic organisms, — the protection of bees. As regards the protection of sediment-dwelling organisms and aquatic organisms, for outdoor use of the plant protection products containing pyriproxyfen Member States shall include in the specific conditions appropriate risk mitigation measures, e.g. no-spray buffer zones and/or spray drift reduction, to achieve a low risk for sediment-dwelling organisms and aquatic organisms. As regards the protection of bees, for outdoor use of plant protection products containing pyriproxyfen Member States shall include in the specific conditions a restriction of application to periods outside of the flowering of bee attractive crops, and appropriate risk mitigation measures, e.g. no-spray buffer zones and/or spray drift reduction, to achieve a low risk for bees and bee larvae. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water is abstracted for drinking water.

▼ **M330**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit the requested confirmatory information within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M345**

143	Kieselgur (Diatomaceous earth) CAS No 61790-53-2 CIPAC No 647	No IUPAC name exists for kieselgur Other synonyms: Diatomaceous earth, Diatomite	1 000 g/kg Minimum content of amorphous silica of 800 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: Crystalline silica with particle size below 10 µm – maximum of 1 g/kg	1 February 2021	31 January 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on kieselgur (diatomaceous earth), and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment, in particular respiratory protective equipment, and other risk mitigation measures, where appropriate. Only indoor use is permitted. Member States shall assess any extension of the use pattern beyond use in closed storage environments, in order to establish whether the proposed extensions of use fulfil the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
▼ M350						
144	Garlic extract Marker components: diallylsulfide (DAS1), diallyldisulfide (DAS 2), diallyltrisulfide (DAS3), diallyltetrasulfide (DAS 4) CAS No 8000-78-0 8008-99-9 CIPAC No 916	Garlic extract	1 000 g/kg	1 March 2021	29 February 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on garlic extract, and in particular Appendices I and II thereto, shall be taken into account. On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate: — The risk to aquatic organisms.
▼ M364						
145	<i>Streptomyces</i> strain K61	Not applicable	No relevant impurities	1 July 2021	30 June 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Streptomyces</i> strain K61 and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are considered as potential sensitisers, and shall ensure that adequate personal protective equipment is included as a condition of use. Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination ⁽²¹⁾ .
▼ M363						
146	Cyazofamid CAS No: 120116-88-3 CIPAC No: 653	4-chloro-2-cyano-N,N-dimethyl-5-p-tolylimidazole-1-sulfonamide	≥ 935 g/kg	01/08/2021	31/07/2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on cyazofamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to:

▼ **M363**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(a) the specification of the technical material as commercially manufactured; (b) the impact of processing on the consumer risk assessment; (c) the protection of non-target arthropods and earthworms. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water; 2. points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. The applicant shall submit the requested information referred to in point 1 within two years from the date of publication by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. As regards point 2 the applicant shall provide an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity by 16 June 2023

▼ **M366**

147	Clopyralid CAS No 1702-17-6 CIPAC No 455	3,6-dichloropyridine-2-carboxylic acid or 3,6dichloropicolinic acid	≥ 950 g/kg	1 October 2021	30 September 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on clopyralid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured;
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▼ **M366**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment; — possible presence of clopyralid residues in rotational crops; — the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops; — the protection of groundwater under vulnerable conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M378**

148	<i>Purpureocillium lilacinum</i> strain 251	Not applicable	No relevant impurities	1 March 2022	28 February 2037	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Purpureocillium lilacinum</i> strain 251, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²¹⁾;
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▼ **M378**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						(b) the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M379**

149	Flumioxazin CAS No 103361-09-7 CIPAC No 578	<i>N</i>-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2<i>H</i>-1,4-benzoxazin-6-yl) cyclohex-1-ene-1,2-dicarboximide	≥ 960 g/kg	1 March 2022	28 February 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on flumioxazin, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material that is authorised for use in plant protection products; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of non-target plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine disrupting properties in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ⁽²⁴⁾ by 1 March 2024.
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▼ **M384**

150	Carbon dioxide CAS No: 124-38-9 CIPAC No: 844	Carbon dioxide	999 g/kg	1 May 2022	30 April 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on carbon dioxide, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M384**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			The following impurities are of toxicological concern and shall not exceed the following levels in the technical material: phosphane max. 0,3 ppm v/v benzene max. 0,02 ppm v/v carbon monoxide max. 10 ppm v/v methanol max. 10 ppm v/v hydrogen cyanide max. 0,5 ppm v/vv			In this overall assessment Member States shall pay particular attention to: — adequate ventilation (e.g. with a ‘certificate of gas clearance’) before humans can re-enter treated and/or surrounding areas (i.e. chambers, buildings and silos). — the need of buffer zones for residents (subjected to revision considering the wind-speeds in the different Member States). Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M388**

151	<i>Beauveria bassiana</i> strain 203 Accession number at Centraal Bureau voor Schimmelcultures (Fungal Biodiversity Centre, Institute of the Royal Netherlands Academy of Arts and Sciences, Utrecht, Netherlands): CBS 121097	Not applicable	Max. level of beauvericin: 80 µg/kg in the formulated product.	19 April 2022	18 April 2032	Only uses on ornamental palm trees shall be authorised. For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Beauveria bassiana</i> strain 203, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the maximum level of the metabolite beauvericin in the plant protection product;
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▼ **M388**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						b) the protection of operators and workers, taking into account that the species <i>Beauveria bassiana</i>, irrespective of the strain, is a potential human allergen by both skin and inhalatory exposure, and therefore ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²¹⁾. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M390**

152	Bifenazate 149877-41-8 736	isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinoformate	980 g/kg Toluene is of toxicological concern and must not exceed 0,7 g/kg in the technical material.	1 July 2022	30 June 2037	Only uses on non-edible crops in permanent greenhouses shall be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on bifenazate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; — the risk to bees and bumble bees released for pollination in permanent greenhouses. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M390**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit by 24 May 2024 to the Commission, the Member States and the Authority confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, in particular an updated assessment of the information submitted previously and, where relevant, further information to confirm the absence of endocrine activity.

▼ **M397**

153	Straight Chain Lepidopteran Pheromones (aldehydes)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	1 September 2022	30 August 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.
154	Straight Chain Lepidopteran Pheromones (alcohols)	Review Report SANTE/10828/2021	Review Report SANTE/10828/2021	1 September 2022	30 August 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M1**▼ **M402**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
155	<i>Pythium oligandrum</i> strain M1 Culture collection No ATCC 38472	Not applicable	No relevant impurities	1 March 2023	28 February 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Pythium oligandrum</i> strain M1, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured, — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers and that physical effects on the respiratory system due to the remnants of culture medium and co-formulants in the Microbial Pest Control Product (MPCP) cannot be excluded. Conditions of use shall include risk mitigation measures, such as: — adequate personal protective and respiratory protective equipment for operators using products containing <i>Pythium oligandrum</i> strain M1.
156	<i>Pseudomonas chlororaphis</i> strain MA 342 Culture collection: NCIMB, UK: NCIMB 40616	Not applicable	The amount of the secondary metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the in the Microbial Pest Control Agent (MPCA) must not exceed the LOQ (2.0 µg/ml).	1 March 2023	28 February 2038	Only uses as fungicide for seed dressing in closed seed dressing machinery may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Pseudomonas chlororaphis</i> strain MA 342, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to:

▼ **M411**

▼ M411

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the level of the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the Microbial Pest Control Agent (MPCA), which must not exceed 2 µg/ml; — the protection of operators and workers, taking into account that <i>Pseudomonas chlororaphis</i> strain MA 342 is to be considered, as any micro-organism, as a potential sensitiser, and paying special attention to exposure through inhalation. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process, shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the phylogenetic taxonomic identification of the micro-organism in accordance with point 1.3 (identity, taxonomy and phylogeny) of Annex II, Part B of Commission Regulation (EU) 2022/1439 ⁽²⁵⁾; 2. the secondary metabolite DDR in accordance with SANCO/2020/12258 ⁽²⁶⁾, in particular on its degradation rate; 3. the potential for gene transfer of antibiotic resistance from <i>Pseudomonas chlororaphis</i> strain MA 342 to other micro-organisms in accordance with SANTE/2020/12260 ⁽²⁷⁾. The applicant shall submit the requested information referred to in points 1, 2 and 3 by 23 February 2025.

▼ **M1**▼ **M412**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
157	Abamectin CAS No 71751-41-2 Avermectin B1a CAS No 65195-55-3 Avermectin B1b CAS No 65195-56-4 Abamectin CIPAC No 495	Avermectin B1a (10E,14E,16E)- (1R,4S,5'S,6S,6' R,8R,12S,13S,20R,2- 1R,24S)-6'-[(S)-sec- butyl]-21,24-dihy- droxy-5',11,13,22- tetramethyl-2-oxo- (3,7,19-trioxatet- racyclo [15.6.1.14,8.020,24] pentacosa- 10,14,16,22-tetraene)- 6-spiro-2'-(5',6'- dihydro-2'H-pyran)- 12-yl 2,6-dideoxy-4- O-(2,6-dideoxy-3-O- methyl- α -L-arabino- hexopyranosyl)-3-O- methyl- α -L-arabino- hexopyranoside Avermectin B1b (10E,14E,16E)- (1R,4S,5'S,6S,6' R,8R,12S,13S,20R,2- 1R,24S)-21,24-dihy- droxy-6'-isopropyl- 5',11,13,22-tetra- methyl-2-oxo-(3,7,19- trioxatetracyclo [15.6.1.14,8.020,24] pentacosa- 10,14,16,22-tetraene)- 6-spiro-2'-(5',6'- dihydro-2'H-pyran)- 12-yl 2,6-dideoxy-4-	≥ 850 g/kg abamectin (sum of avermectin B1a and avermectin B1b), min. 800 g/ kg avermectin B1a and max. 200 g/kg avermectin B1b	1 April 2023	31 March 2038	Only uses which allow controlled exchange of material and energy with the surroundings and prevent release of plant protection products into the environment may be authorised, in particular uses in permanent greenhouses. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Abamectin, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, such as the the use of gloves; — The effect of photolysis on the levels of pesticide residues in crops. Particular attention is required to ensure that available residue trials on crops reflect the most critical residue situation. Where appropriate, depending on the zone, seasonal restrictions for the timing of application shall be applied (cf. representative uses excluded application from November till February).

▼ **M412**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
		O-(2,6-dideoxy-3-O-methyl- α -L-arabino-hexopyranosyl)-3-O-methyl- α -L-arabino-hexopyranoside				

▼ **M422**

158	<i>Bacillus amyloliquefaciens</i> strain QST 713	n.a.	The nominal content of <i>Bacillus amyloliquefaciens</i> strain QST 713 in the technical product and formulation is Minimum: 1×10^{12} CFU/kg Maximum: 3×10^{13} CFU/kg No relevant impurities	1 July 2023	30 June 2038	When authorising plant protection products containing <i>Bacillus amyloliquefaciens</i> strain QST 713 for spray applications outdoors, in order to ensure the protection of non-target organisms, including bees, Member States shall: — only authorise field applications in flowering crops or in presence of flowering weed in the field outside the daily foraging period of bees; — implement risk mitigation measures which aim to reduce drift to off-field areas (e.g. considering the application of buffer zones and drift reduction nozzles). For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Bacillus amyloliquefaciens</i> strain QST 713, and in particular Appendices I and II thereof, shall be taken into account. In addition, Member States shall pay particular attention to: — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾ — the specification of the technical material as commercially manufactured used in plant protection products; — the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.
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▼ **M1**▼ **M423**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
159	<i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 and in particular Appendices I and II thereto, are taken into account. In this overall assessment the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾; — the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate. Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 below 10⁵ CFU/g at harvest. The applicant shall submit to the Commission, the Member States and the Authority additional information as regards:

▼ **M423**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— data in at least one representative edible crop (i.e. peppers and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABTS-1857 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.

▼ **M421**

160	<i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 and in particular Appendices I and II thereto, are taken into account. In this overall assessment the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾; — the protection of wild pollinators (in particular honey bee larvae and bumble bees). Conditions of use shall include specific risk mitigation measures, where appropriate. Conditions of use shall include the following risk mitigation measures:
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▼ **M421**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 below 10⁵ CFU/g at harvest. The applicant shall submit to the Commission, the Member States and the Authority additional information as regards: — data in at least one representative edible crop (i.e. pome fruits, grapes and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> GC-91 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. The applicant shall submit the requested information by 13 December 2025.

▼ **M420**

161	<i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52 Culture collection No ATCC 1276	Not applicable	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the renewal report on <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52, and in particular Appendices I and II thereof, are taken into account. In this overall assessment, the Member States shall pay particular attention to:
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▼ **M420**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitizers; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾. — the protection of wild pollinators and of aquatic organisms (e.g. aquatic invertebrates from Diptera taxon in particular) in case of uses in open field. Conditions of use shall include specific risk mitigation measures, where appropriate. Conditions of use shall include risk mitigation measures, such as: — adequate personal protective equipment for operators using products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> strain AM65-52; — In case of authorisation of uses on edible crops, a minimum time period of 3 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 below 10⁵ CFU/g at harvest.

▼ **M419**

162	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and in particular Appendices I and II thereto, are taken into account. In this overall assessment, the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;
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▼ **M419**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾. Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 below 10⁵ CFU/g as recommended by EFSA. The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: — Data in at least one representative edible crop (i.e. on cabbage and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> ABTS-351 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.
163	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 and in particular Appendices I and II thereto, are taken into account.

▼ **M424**

▼ M424

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment, the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾. Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 below 10⁵ CFU/g as recommended by EFSA. The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: — data in at least one representative edible crop (i.e. on pome fruits and solanaceous vegetables during the fruiting period) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> EG2348 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.

▼ M1▼ M427

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
164	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> PB 54	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> PB 54 and in particular Appendices I and II thereto, are taken into account. In this overall assessment, the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾. Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> PB 54 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> PB 54 below 10⁵ CFU/g as recommended by EFSA. The applicant shall submit to the Commission, the Member States and the Authority additional information as regards:

▼ **M427**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— data in at least one representative edible crop (i.e. on stone fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> PB 54 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10 ⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 14 December 2025.

▼ **M425**

165	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, provided for in Article 29(6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 and in particular Appendices I and II thereto, are taken into account. In this overall assessment, the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use; — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾.
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▼ **M425**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						Conditions of use shall include the following risk mitigation measures: — a minimum time period of 2 days shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 below 10⁵ CFU/g as recommended by EFSA. The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: — data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-11 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State. by 13 December 2025.

▼ **M426**

166	<i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12	n.a.	No relevant impurities	1 July 2023	30 June 2038	The implementation of the uniform principles, as provided for in Article 29 (6) of Regulation (EC) No 1107/2009, requires that the conclusions of the review report on <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and in particular Appendices I and II thereto, are taken into account. In this overall assessment, the Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are <i>per se</i> considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use;
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▼ **M426**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁸⁾. Conditions of use shall include the following risk mitigation measures: — A minimum time period of 1 day shall be kept between the application of plant protection products containing <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 and the harvest of edible crops used for fresh consumption, unless available measured or estimated residues data show levels of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 below 10⁵ CFU/g as recommended by EFSA. The applicant shall submit, to the Commission, the Member States and the Authority, additional information as regards: — data in at least one representative edible crop (i.e. on pome fruits and tomatoes) regarding the density decline of viable spores of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> SA-12 on edible plant parts from the time of application of a plant protection product containing this active substance until the time of harvest or until levels found are below 10⁵ CFU/g, including storage stability data of the micro-organisms between the sampling and the spore counting analysis. The relevant methods and protocols to be employed shall be agreed between the applicant and the Rapporteur Member State by 13 December 2025.

▼ **M438**

167	Aluminium ammonium sulfate (dodecahydrate) CAS No: 7784-26-1 CIPAC No: 840	Aluminium ammonium sulfate	— 975 g/kg — Anhydrous - Not less than 510 g/kg — No relevant impurities	1.2.2024	31.1.2039	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Aluminium ammonium sulfate, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to:
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▼ **M438**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						— the protection of operators and workers where relevant, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms when the substance is applied in regions with acidic or basic soil conditions; — the protection of bees from spray applications during the flowering period of adjacent fields or when flowering weeds are present in the treated field; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions (i.e. situations when soil pH is lower than 5,5, e.g. grassland in upland areas, areas of coniferous forestry and areas of ericaceous ornamental plant growing); — the authorisation, for use on row and combinable crops, as a barrier treatment only on field edges. Conditions of use shall include risk mitigation measures where relevant.

▼ **M439**

168	Ethephon CAS No: 16672-87-0 CIPAC No: 373	2-chloroethylphosphonic acid	≥ 692 g/kg (TK) ≥ 910 g/kg (TC, theoretical) The following impurities are of toxicological concern and shall not exceed the following levels in the technical material:	1 February 2024	31 January 2039	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ethephon, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of bystanders and residents, ensuring that conditions of use include the use of drift reduction equipment during application. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M439**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			TK: 1,2-dichloroethane < 0,3 g/kg 2-chloroethanol < 0,3 g/kg TC (theoretical): 1,2-dichloroethane < 0,5 g/kg 2-chloroethanol < 0,3 g/kg			

▼ **M447**

169	Trinexapac-ethyl CAS No 95266-40-3 CIPAC No 732.202	ethyl (1 <i>RS</i> ,4 <i>EZ</i>)-4-cyclopropyl(hydroxy)methylene-3,5-dioxocyclohexanecarboxylate	≥ 950 g/kg The following impurities shall not exceed the following levels in the technical material: — toluene: 3 g/kg — ethyl (1 <i>RS</i>)-3-hydroxy-5-oxocyclohex-3-ene-1-carboxylate (CGA158377): 6 g/kg	1 May 2024	30 April 2039	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on trinexapac-ethyl, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the specification of technical material used in plant protection products, in particular when carrying out assessments of equivalence in accordance with Article 38 of Regulation (EC) No 1107/2009; — the assessment of consumer intake from the diet taking into account the residues of the metabolites of trinexapac-ethyl and the impact of processing; — the levels of residues of the metabolites of trinexapac-ethyl, when straw is used as animal feeding stuff. Conditions of use shall include restrictions for feeding of straw to animals and risk mitigation measures, where appropriate.
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▼ **M447**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues of trinexapac-ethyl and its metabolites present in surface water, when surface water is abstracted for drinking water, by 1 April 2026.

▼ **M458**

170	Captan CAS No 133-06-2 CIPAC No 40	N-[(trichloromethyl)thio]cyclohex-4-ene-1,2-dicarboximide	≥ 930 g/kg perchloromethyl-mercaptan: ≤ 5 g/kg folpet: ≤ 10 g/kg carbon tetrachloride: ≤ 0,1 g/kg	1 November 2024	31 October 2039	For outdoor uses the following conditions shall apply: — only uses outside flowering of the crop and when no flowering weeds are present in the rows of the treated crops may be authorised, — Member States shall require that applications in orchards (e.g. apples, cherries) are only done with application equipment that increases the precision and accuracy of the application (e.g. emission shields, shielded sprayers, hooded sprayers, tunnel sprayers, sensor-controlled sprayers), and, while maintaining the application rate on the target surfaces, achieves an average reduction of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional application equipment and practice. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on captan, and in particular Appendices I and II thereto, shall be taken into account. In addition, risk mitigations such as no-spray buffer zones from field margins, shall be required, when appropriate, by the Member States on the basis of their risk assessment to protect bees and aquatic organisms. In this overall assessment Member States shall pay particular attention to: — the compliance with the technical specification of the active substance contained in the plant protection product for which applications for authorisation are submitted,
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▼ M458

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the protection of operators and workers ensuring that conditions of use include the application of adequate personal protective equipment taking into account the high skin sensitising potential of the active substance, — the protection of bystanders and residents ensuring that conditions of use include adequate risk mitigation measures taking into account the high skin sensitising potential of the active substance. In addition, Member States may set monitoring requirements when granting authorisations, in order to supplement the monitoring under Directives 2000/60/EC ⁽³¹⁾ and 2009/128/EC ⁽³²⁾ of the European Parliament and of the Council. Within two years from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: (1) the effect of water treatment processes on the nature of residues of captan's metabolites THPI and THPAM present in ground water, when it is abstracted for drinking water; (2) the relevance of metabolites THPI and THPAM that may occur in groundwater, taking into account the proposal of classification of captan as toxic to reproduction Category 2 and as STOT-RE Category 1 in the Opinion of the Risk Assessment Committee of the European Chemicals Agency of 14 September 2023; (3) the storage stability of captan in high acid content matrices, in compliance with the relevant OECD Test Guideline; and Furthermore, within 18 months from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority: (4) information and exposure data demonstrating that the pesticide application equipment used on orchards increases the precision and accuracy of the application and achieves a reduction of exposure of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional equipment and practices.

▼ **M1**▼ **M461**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
171	Metrafenone CAS No: 220899-03-6 CIPAC No: 752	3'-bromo-2,3,4,6'-tetramethoxy-2',6-dimethylbenzophenone	≥ 980 g/kg The impurity dimethyl sulphate shall not exceed 0,01 g/kg in the technical material.	1 November 2024	31 October 2039	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on metrafenone, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers; — the consumer exposure assessment with regards to residues that may be present in food. Conditions of use shall include risk mitigation measures, where appropriate. 1) An updated assessment for point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 to confirm the absence of endocrine activity concerning the T-modality of non-target organisms other than mammals, including where relevant, further information. 2) An updated assessment of the genotoxicity of the metabolites CL 1500834 and CL 3000402. The applicant shall submit the information related to point 1 by 29 March 2026 and the information related to point 2 by 29 December 2024.
172	Folpet CAS No: 133-07-3 CIPAC No: 75	N-[(trichloromethyl)thio]phthalimide	≥ 940 g/kg The following impurities shall not exceed the following levels in the technical material:	1 November 2024	31 October 2039	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on folpet, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to:

▼ **M459**

▼ **M459**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			— (trichloro (chloro-sulfanyl) methane) (PCMM): 2 g/kg — carbon tetrachloride: 2 g/kg — captan: 3 g/kg — carbon disulphide: 2,5 g/kg			— the protection of aquatic organisms, ensuring a minimum of 95 % spray drift reduction next to water bodies such as that provided by a 20 m no spray buffer zone unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift; — the protection of operators (use of PPE for operators during mixing, loading and application) and workers (use of workwear and protective gloves for re-entry activities); and — the protection of bystanders and residents, ensuring that conditions of use include the adequate risk mitigation measures, such as drift reduction equipment, with the aim of minimising exposure. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information to determine the levels of phthalic acid deriving from the use of folpet taking into account the background levels of phthalic acid in wheat and barley during residue field trials for the uses listed in Appendix II of the renewal report only. The applicant shall submit to the Commission, the Member States and the Authority this information by 25 March 2025.

▼ **M474**

173	Mepiquat chloride CAS No: 24307-26-4 CIPAC No: 440.302	1,1-dimethylpiperidinium chloride	≥ 990 g/kg (theoretical dry technical material, TC) 615-665 g/L (technical concentrate, TK)	1 March 2025	29 February 2040	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on mepiquat chloride, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured;
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▼ **M474**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
			The impurity N-methylpiperidine shall not exceed 3 g/kg (on theoretical dry weight basis) or 2 g/L (in the technical concentrate, TK).			— the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M469**

174	<i>Pythium oligandrum</i> B301	Not applicable	No relevant impurities	11 February 2025	10 February 2035	For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pythium oligandrum</i> B301, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitisers, ensuring that adequate personal protective equipment is included as a condition of use, — the guarantee by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure adherence to the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 ⁽⁵³⁾ . Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M1**

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

► **M9** ⁽²⁾ 2-hydroxy-4,6-dimethoxypyrimidine.

⁽³⁾ 2,4-dihydroxy-6-methoxypyrimidine.

⁽⁴⁾ sodium 2-hydroxy-6-(4-hydroxy-6-methoxypyrimidin-2-yl)oxybenzoate. ◀

► **M53** ⁽⁵⁾ 5-(trifluoromethyl)-2(1H)-pyridinone.

⁽⁶⁾ 4-{{[5-(trifluoromethyl)-2-pyridinyl]oxy}phenol}. ◀

▼ M1

- **M13** ⁽⁷⁾ M03: [(8-tert-butyl-1,4-dioxaspiro[4.5]dec-2-yl)methyl]ethyl(propyl)amine oxide. ◀
- **M14** ⁽⁸⁾ 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-[(methoxymethyl)amino]phenol.
- ⁽⁹⁾ 3-chloro-4-[3-(ethenyloxy)-4-hydroxyphenoxy]benzoic acid.
- ⁽¹⁰⁾ 2-chloro-1-(3-methoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene.
- ⁽¹¹⁾ 4-(3-ethoxy-4-hydroxyphenoxy)benzoic acid. ◀
- **M20** ⁽¹²⁾ 3-phenoxybenzaldehyde. ◀
- **M25** ⁽¹³⁾ Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent (TEQ) using the WHO-toxic equivalency factors (WHO-TEFs)). ◀
- **M52** ⁽¹⁴⁾ 7-amino-5-ethyl[1,2,4]triazolo[1,5-a]pyrimidine-6-carboxylic acid. ◀
- **M56** ⁽¹⁵⁾ 3-chloro-5-[(4,6-dimethoxy-2-pyrimidinyl)amino]-1-methyl-1 *H*-pyrazole-4-carboxylic acid.
- ⁽¹⁶⁾ 3-chloro-1-methyl-5-sulfamoyl-1 *H*-pyrazole-4-carboxylic acid. ◀
- **M171** ⁽¹⁷⁾ *p*-methyl-phenethylamine. ◀
- **M249** ⁽¹⁸⁾ OJ L 353, 31.12.2008, p. 1. ◀
- **M268** ⁽¹⁹⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1). ◀
- **M273** ⁽²⁰⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33). ◀
- **M289** ⁽²¹⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-an_a_microbial-contaminant-limits.pdf ◀
- **M299** ⁽²²⁾ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311; ECHA-18-G-01-EN. ◀
- **M305** ⁽²³⁾ Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 <https://efsa.onlinelibrary.wiley.com/doi/epdt710.2903/i.efsa.2018.5311> ◀
- **M379** ⁽²⁴⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0605&from=EN> ◀
- **M411** ⁽²⁵⁾ Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms (OJ L 227, 1.9.2022, p. 8).
- ⁽²⁶⁾ Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf.
- ⁽²⁷⁾ Guidance on the approval and low-risk criteria linked to ‘antimicrobial resistance’ applicable to microorganisms used for plant protection (SANTE/2020/12260): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180652_microorganism-amr_202011.pdf. ◀
- **M419** ⁽²⁸⁾ [pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf) (europa.eu). ◀
- **M442** ⁽²⁹⁾ Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable coformulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 75, 14.3.2023, p. 7).
- ⁽³⁰⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1). ◀
- ⁽³¹⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: <http://data.europa.eu/eli/dir/2000/60/oj>).
- ⁽³²⁾ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71, ELI: <http://data.europa.eu/eli/dir/2009/128/oj>).
- ⁽³³⁾ Organisation for Economic Cooperation and Development (2014), OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products, Series on Pesticides and Biocides, No 65, OECD Publishing, Paris, <https://doi.org/10.1787/9789264221642-en>.

▼ **M110**

PART C

Basic Substances

General provisions applying to all substances listed in this Part: the Commission shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make them available to them on specific request.

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
1	<i>Equisetum arvense</i> L. CAS No: not allocated CIPAC No: not allocated	Not applicable	European Pharmacopeia	1 July 2014	<i>Equisetum arvense</i> L. may be used in accordance with the specific conditions included in the conclusions of the review report on <i>Equisetum arvense</i> L. (SANCO/12386/2013) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014.
2	Chitosan hydrochloride CAS No: 70694-72-3	Not applicable	European Pharmacopeia Max. content of heavy metals: 40 ppm	1 July 2014	Chitosan hydrochloride shall comply with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011. Chitosan hydrochloride may be used in accordance with specific conditions included in the conclusions of the review report on chitosan hydrochloride (SANCO/12388/2013) and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014.
3	Sucrose CAS no: 57-50-1	α -D-glucopyranosyl-(1→2)- β -D-fructofuranoside or β -D-fructofuranosyl-(2→1)- α -D-glucopyranoside	Food grade	1 January 2015	Only uses as basic substance being an elicitor of the crop's natural defence mechanisms are approved. Sucrose shall be used in accordance with the specific conditions included in the conclusions of the review report on sucrose (SANCO/11406/2014) and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

▼ **M110**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Specific provisions
▼ M144					
4	Calcium Hydroxide CAS No 1305-62-0	Calcium Hydroxide	920 g/kg Food grade The following impurities are of toxicological concern and must not exceed the levels below (expressed in mg/kg on dry matter): Barium 300 mg/kg Fluoride 50 mg/kg Arsenic 3 mg/kg Lead 2 mg/kg.	1 July 2015	Calcium hydroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on Calcium Hydroxide (SANCO/10148/2015) and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 20 March 2015.
▼ M147					
5	Vinegar CAS No: 90132-02-8	Not available	Food grade containing a maximum of 10 % acetic acid.	1 July 2015	► M291 Vinegar shall be used in accordance with the specific conditions included in the conclusions of the review report on vinegar (SANCO/12896/2014) and in particular Appendices I and II thereof. ◀
▼ M149					
6	Lecithins CAS No: 8002-43-5 CIPAC No: not allocated Einecs 232-307-2	Not allocated	As described in the Annex to Regulation (EU) No 231/2012.	1 July 2015	Only uses as basic substance being a fungicide are approved. Lecithins shall be used in accordance with the specific conditions included in the conclusions of the review report on lecithins (SANCO/12798/2014) and in particular Appendices I and II thereof.
▼ M146					
7	<i>Salix</i> spp. cortex CAS No: not allocated CIPAC No: not allocated	Not applicable	European Pharmacopeia	1 July 2015	<i>Salix</i> cortex shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Salix</i> spp. cortex (SANCO/12173/2014) and in particular Appendices I and II thereof.

▼ **M110**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
▼ M157					
8	Fructose CAS No: 57-48-7	β-D-fructofuranose	Food grade	1 October 2015	Only uses as basic substance being an elicitor of the crop's natural defence mechanisms are approved. Fructose shall be used in accordance with the specific conditions included in the conclusions of the review report on fructose (SANCO/12680/2014) and in particular Appendices I and II thereof.
▼ M163					
9	Sodium hydrogen carbonate CAS no: 144-55-8	Sodium hydrogen carbonate	Food grade	8 December 2015	Sodium hydrogen carbonate shall be used in accordance with the specific conditions included in the conclusions of the review report on sodium hydrogen carbonate (SANTE/10667/2015) and in particular Appendices I and II thereof.
▼ M178					
10	Whey CAS No: 92129-90-3	Not available	CODEX STAN 289-1995 ⁽²⁾	2 May 2016	Whey shall be used in accordance with the specific conditions included in the conclusions of the review report on whey (SANTE/12354/2015) and in particular Appendices I and II thereof.
▼ M176					
11	Diammonium phosphate CAS No: 7783-28-0	Diammonium hydrogen phosphate	Oenological grade	29 April 2016	Diammonium phosphate shall be used in accordance with the specific conditions included in the conclusions of the review report on diammonium phosphate (SANTE/12351/2015) and in particular Appendices I and II thereto.
▼ M195					
12	Sunflower oil CAS No: 8001-21-6	Sunflower oil	Food grade	2 December 2016	Sunflower oil shall be used in accordance with the specific conditions included in the conclusions of the review report on sunflower oil (SANTE/10875/2016) and in particular Appendices I and II thereof.
▼ M211					
13	Clayed charcoal CAS No 7440-44-0 231-153-3 (Einecs) (activated charcoal) CAS No 1333-86-4 215-609-9 (Einecs) (carbon black) CAS No 1302-78-9 215-108-5 (Einecs) (bentonite)	Not available.	Charcoal: Purity required by Regulation (EU) No 231/2012 ⁽³⁾ Bentonite: Purity required by Implementing Regulation (EU) No 1060/2013 ⁽⁴⁾	31 March 2017	Clayed charcoal shall be used in accordance with the specific conditions included in the conclusions of the review report on clayed charcoal (SANTE/11267/2016) and in particular Appendices I and II thereof.

▼ **M110**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Specific provisions
▼ M210					
14	<i>Urtica</i> spp. CAS No 84012-40-8 (<i>Urtica dioica</i> extract) CAS No 90131-83-2 (<i>Urtica urens</i> extract)	<i>Urtica</i> spp.	European Pharmacopeia	30 March 2017	<i>Urtica</i> spp. shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Urtica</i> spp. (SANTE/11809/2016) and in particular Appendices I and II thereof.
▼ M209					
15	Hydrogen peroxide CAS No 7722-84-1	Hydrogen peroxide	Solution in water ($< 5\%$) The hydrogen peroxide used to manufacture the solution shall have a purity according to the FAO JECFA specifications.	29 March 2017	Hydrogen peroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on hydrogen peroxide (SANTE/11900/2016) and in particular Appendices I and II thereof.
▼ M237					
16	Sodium chloride CAS No 7647-14-5	Sodium chloride	970 g/kg Food grade	28 September 2017	Only uses as basic substance being a fungicide and insecticide are approved. ► M355 Sodium chloride shall be used in accordance with the specific conditions included in the conclusions of the review report on sodium chloride (SANTE/10383/2017) and in particular Appendices I and II thereof. ◀
▼ M242					
17	Beer CAS No 8029-31-0	Not applicable	Food grade	5 December 2017	Beer shall be used in accordance with the specific conditions included in the conclusions of the review report on beer (SANTE/11038/2017) and in particular Appendices I and II thereto.
▼ M240					
18	Mustard seeds powder	Not applicable	Food grade	4 December 2017	Mustard seeds powder shall be used in accordance with the specific conditions included in the conclusions of the review report on mustard seeds powder (SANTE/11309/2017) and in particular Appendices I and II thereof.

▼ **M110**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
▼ M257					
19	Talc E553B CAS No: 14807-96-6	Magnesium hydrogen metasilicate silicate mineral	Food grade in conformity with Commission Regulation (EU) No 231/2012 ⁽³⁾ . < 0,1 % of respirable Crystalline Silica	28 May 2018	Talc E553B shall be used in accordance with the specific conditions included in the conclusions of the review report on Talc E553B (SANTE/11639/2017) and in particular Appendices I and II thereof.
▼ M276					
20	Onion oil CAS No: 8002-72-0	Not applicable	Food grade	17 October 2018	Onion oil shall be used in accordance with the specific conditions included in the conclusions of the review report on Onion oil (SANTE/10615/2018) and in particular Appendices I and II thereto.
▼ M325					
21	L-cysteine (E 920) CAS No: 52-89-1 EINECS: 200-157-7 (L-cysteine hydrochloride) CAS No: 7048-04-6 EINECS: 615-117-8 (L-cysteine hydrochloride monohydrate)	L-cysteine hydro- chloride (1:1)	Min. 98,0 % L-cysteine hydrochloride (on anhydrous basis) Food grade in conformity with Commission Regu- lation (EU) No 231/2012. max. 1,5 mg/kg As max. 5 mg/kg Pb	2.6.2020	L-cysteine (E 920) shall be used as a mixture with matrix (flour, food grade) at a concentration of maximum 8% (of L-cysteine hydrochloride, on anhydrous basis) in accordance with the specific conditions included in the conclusions of the review report on L-cysteine (SANTE/11056/2019) and in particular Appendices I and II thereto.
▼ M332					
22	Cow Milk CAS No: 8049-98-7	Not available.	Not applicable	30.7.2020	Cow milk shall comply with Regulation (EC) No 1069/2009 and Commission Regulation (EU) No 142/2011. Cow milk shall be used in accordance with the specific conditions included in the conclusions of the review report on cow milk (SANTE/12816/2019), and in particular Appendices I and II thereto.

▼ **M110**▼ **M349**▼ **M385**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Specific provisions
23	<i>Allium cepa</i> L. bulb extract CAS No: not allocated CIPAC No: not allocated	Not applicable	The onion bulbs used to prepare the extracts shall be of food grade quality meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on <i>Bulbus Allii Cepae</i>	17.2.2021	<i>Allium cepa</i> L. bulb extract shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Allium cepa</i> L. bulb extract (SANTE/10842/2020 Rev2) and in particular Appendices I and II thereof.
24	Chitosan CAS No: 9012-76-4 EC No: 618-480-0	Chemical name (not IUPAC): poly[4-O-(2-acetamido-2-deoxy-β-D-glucopyranosyl)-2-amino-2-deoxy-β-D-glucopyranose]	≥ 85 % chitosan heavy metals: max. 20 mg/kg Food grade, meeting the specifications for 'chitosan extract from fungi' as set out in Commission Implementing Regulation (EU) 2017/2470 (⁵)	11 April 2022	Chitosan shall be used in accordance with the specific conditions included in the conclusions of the review report on chitosan (SANTE/10594/2021) and in particular Appendices I and II thereto.

▼ **M110**

Number	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Specific provisions
▼ M448					
25	magnesium hydroxide E528 CAS No: 1309-42-8 CIPAC No: Not available	magnesium dihydroxide	95 % Relevant impurities: Lead < 2 mg/kg Arsenic < mg/kg	2 April 2024	Magnesium hydroxide shall be used in accordance with the specific conditions included in the conclusions of the review report on magnesium hydroxide (PLAN/2023/2331 RR Rev2) and in particular Appendices I and II thereof.
▼ M456					
26	<i>Onobrychis viciifolia</i> (sainfoin) dried pellets CAS No: Not available CIPAC No: Not available	Not available	1 000 g/kg Relevant impurities: Arsenic (1 g/kg), Cadmium (0,1 g/kg), Chromium-VI (0,1 g/kg), Mercury (1 g/kg), Nickel (0,1 g/kg), Lead (0,3 g/ kg)	17 July 2024	<i>Onobrychis viciifolia</i> (sainfoin) dried pellets shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Onobrychis viciifolia</i> (sainfoin) dried pellets (PLAN/2024/790 RR rev1) and in particular Appendices I and II thereof.
▼ M465					
27	<i>Allium fistulosum</i> , processed CAS No: Not available CIPAC No: Not available	Not available	Food grade compliant with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council (⁶), Regu- lation (EC) No 396/2005 of the European Parliament and of the Council (⁷), Commission Regulation (EU) 2023/ 915 on maximum levels	1 December 2024	<i>Allium fistulosum</i> , processed, shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Allium fistulosum</i> , processed, (PLAN/2024/798) and in particular Appendices I and II thereof.

▼ **M465**

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
			for certain contaminants in food and repealing Regulation (EC) No 1881/2006 ⁽⁸⁾		
▼ M467 28	<i>Vitis vinifera</i> L. seed extract (grape seed extract) CAS No: Not available CIPAC No: Not available	Not available	Minimum content of 75 % of Oligomeric proanthocyanidins on the anhydrous basis	11 February 2025	<i>Vitis vinifera</i> L. seed extract (grape seed extract) shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Vitis vinifera</i> L. seed extract (grape seed extract) (PLAN/2024/800 RR rev3) and in particular Appendices I and II thereof.

▼ **M110**

⁽¹⁾ Further details on identity, specification and manner of use of basic substance are provided in the review report.

► **M178** ⁽²⁾ Available online: <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/> ◀

► **M211** ⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species (OJ L 289, 31.10.2013, p. 33). ◀

► **M385** ⁽⁵⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72). ◀

► **M465** ⁽⁶⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

⁽⁷⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/2024-05-11>).

⁽⁸⁾ Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: <http://data.europa.eu/eli/reg/2023/915/oj>). ◀

▼ **M136**

PART D

Low-risk active substances'

General provisions applying to all substances listed in this Part: the Commission shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make them available to them on specific request.

	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
1	<i>Isaria fumosorosea</i> strain Apopka 97 Deposited in the American Type Culture Collection (ATCC) under the name <i>Paecilomyces fumosoroseus</i> Apopka ATCC 20874	Not applicable	Minimum concentration: $1,0 \times 10^8$ CFU/ml Maximum concentration: $2,5 \times 10^9$ CFU/ml	1 January 2016	31 December 2030	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Isaria fumosorosea</i> strain Apopka 97, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Isaria fumosorosea</i> strain Apopka 97 is to be considered as a potential sensitiser. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
▼ M142 2	COS-OGA CAS No: not allocated CIPAC No: 979	Linear copolymer of α -1,4-D-galactopyranosyluronic acids and methylesterified galactopyranosyluronic acids (9 to 20 residues) with linear copolymer β -1,4-linked 2-amino-2-deoxy-D-glucopyranose and 2-acet-amido-2-deoxy-D-glucopyranose (5 to 10 residues).	≥ 915 g/kg — OGA/COS ratio comprised between 1 and 1,6 — Degree of polymerisation of COS comprised between 5 and 10 — Degree of polymerisation of OGA comprised between 9 and 20 — Degree of methylation of OGA < 10 % — Degree of acetylation of COS < 50 %	22 April 2015	22 April 2030	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on COS-OGA, and in particular Appendices I and II thereof, shall be taken into account.

▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
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▼ **M143**

3	Cerevisane (no ISO name adopted) CAS No: not allocated CIPAC No: 980	Not relevant	≥ 924 g/kg	23 April 2015	23 April 2030	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cerevisane, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M153**

4	<i>Pepino mosaic</i> virus strain CH2 isolate 1906 GenBank, accession number JN835466 CIPAC No: not allocated	Not applicable	minimum concentration 5×10^5 viral genome copies per μ L	7 August 2015	7 August 2030	Only the use in greenhouses may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pepino mosaic</i> virus strain CH2 isolate 1906, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Pepino mosaic</i> virus strain CH2 isolate 1906 is to be considered as a potential sensitiser. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
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▼ **M152**

5	Ferric phosphate CAS No: 10045-86-0 CIPAC No: 629	Ferric phosphate	Ferric phosphate 703 g/kg equivalent to 260 g/kg iron and 144 g/kg phosphorus	1 January 2016	31 December 2030	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ferric phosphate, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ M186						
6	<i>Saccharomyces cerevisiae</i> strain LAS02 Accession number in the collection of the 'Collection Nationale de Cultures de Micro-organismes' (CNCM) of the Pasteur Institute: CNCM I-3936	Not applicable	Minimum concentration: 1×10^{13} CFU/kg	6 July 2016	6 July 2031	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Saccharomyces cerevisiae</i> strain LAS02, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Saccharomyces cerevisiae</i> strain LAS02 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
▼ M185						
7	<i>Trichoderma atroviride</i> strain SC1 Accession number CBS 122089 in the collection of the Centraalbureau voor Schimmelcultures (CBS) in Utrecht, The Netherlands CIPAC No: 988	Not applicable	minimum concentration 1×10^{10} CFU/g	6 July 2016	6 July 2031	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> strain SC1, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
▼ M208						
8	Mild Pepino Mosaic Virus isolate VC1 Reference number DSM 26973 in the German Collection of Micro-organisms and Cell Cultures (DSMZ)	Not applicable	Nicotine < 0,1 mg/L	29 March 2017	29 March 2032	Only the use in greenhouses may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Mild Pepino Mosaic Virus isolate VC1, and in particular Appendices I and II thereof, shall be taken into account.

▼ **M208**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that Mild Pepino Mosaic Virus isolate VC1 is to be considered, as any microorganism, a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.

▼ **M206**

9	Mild Pepino Mosaic Virus isolate VX1 Reference number DSM 26974 in the German Collection of Micro-organisms and Cell Cultures (DSMZ)	Not applicable	Nicotine < 0,1 mg/L	29 March 2017	29 March 2032	Only the use in greenhouses may be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Mild Pepino Mosaic Virus isolate VX1, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that Mild Pepino Mosaic Virus isolate VX1 is to be considered, as any microorganism, a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
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▼ **M219**

10	<i>Bacillus amyloliquefaciens</i> strain FZB24. Accession number in the culture collection of the 'Deutsche Sammlung von Mikroorganismen' (DSMZ), Germany: 10271	Not applicable	Minimum concentration: 2×10^{14} CFU/kg	1 June 2017	1 June 2032	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> strain FZB24, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to:
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▼ **M219**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
	Accession number at the Agricultural Research Service Culture Collection (NRRL), USA: B-50304					— specification of the technical material as commercially manufactured, including full characterisation of impurities and metabolites; — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M222**

11	<i>Coniothyrium minitans</i> strain CON/M/91-08 Accession number in the culture collection of the 'Deutsche Sammlung von Mikroorganismen' (DSMZ), Germany: DSM 9660 CIPAC No 614	Not applicable	► C4 Minimum content of viable spores: $1,17 \times 10^{12}$ CFU/kg ◀	1 August 2017	31 July 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Coniothyrium minitans</i> strain CON/M/91-08, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M246**

12	Laminarin CAS No 9008-22-4 CIPAC No 671	(1→3)-β-D-glucan (according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)	≥ 860 g/kg on dry matter (TC)	1 March 2018	28 February 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on laminarin, and in particular Appendices I and II thereto, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ M275						
13	<i>Pasteuria nishizawae</i> Pn1 Culture collection: ATCC Safe Deposit (SD-5833) CIPAC No Not allocated	Not applicable	minimum concentration 1×10^{11} spores/g	14 October 2018	14 October 2033	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pasteuria nishizawae</i> Pn1, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Pasteuria nishizawae</i> Pn 1 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.
▼ M269						
14	<i>Ampelomyces quisqualis</i> strain AQ10	Not applicable	Minimum content of viable spores: $3,0 \times 10^{12}$ CFU/kg	1 August 2018	1 August 2033	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Ampelomyces quisqualis</i> strain AQ10, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers and ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
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▼ **M292**

15	<i>Clonostachys rosea</i> strain J1446 Accession number in the culture collection of the German Collection of Micro-organisms and Cell Cultures (DSMZ): DSM 9212	Not applicable	Not applicable Gliotoxin content: max. 50 µg/kg in the technical grade of the MCPA.	1 April 2019	31 March 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Clonostachys rosea</i> strain J1446, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of technical material as commercially manufactured in plant protection products, including full characterisation of potential metabolites of concern; — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use; — the studies or information from the scientific literature recently made available in relation to antifungal susceptibility of <i>Clonostachys rosea</i> J1446. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbial contamination as referred to in the Working Document SANCO/12116/2012 (²). Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M300**

16	ABE-IT 56 (components of lysate of <i>Saccharomyces cerevisiae</i> strain DDSF623)	Not Applicable	1 000 g/kg (active substance)	20 May 2019	20 May 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ABE-IT 56 (components of lysate of <i>Saccharomyces cerevisiae</i> strain DDSF623) and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ M314						
17	<i>Bacillus subtilis</i> strain IAB/BS03 Accession number in the Spanish Type Culture Collection (CECT), Spain: CECT 7254 Accession number in the German Type Culture Collection (DSMZ), Germany: DSM 24682	Not applicable	Minimum concentration: 1×10^{13} CFU/kg Maximum concentration: 5×10^{13} CFU/kg	20 October 2019	20 October 2034	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus subtilis</i> strain IAB/BS03, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitisers, and ensuring that adequate personal protective equipment is included as a condition of use. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Working Document SANCO/12116/2012 (²). Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ M316						
18	<i>Verticillium albo-atrum</i> strain WCS850 (culture collection No CBS 276.92)	Not applicable	Minimum concentration: $0,7 \times 10^7$ CFU/ml distilled water Maximum concentration: $1,5 \times 10^7$ CFU/ml distilled water No relevant impurity	1 November 2019	31 October 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Verticillium albo-atrum</i> strain WCS850, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Verticillium albo-atrum</i> strain WCS850 is to be considered as a potential sensitiser. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in OECD Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products, contained in the Commission Working Document SANCO/12116/2012 (²).
▼ M326						
19	Lavandulyl senecioate CAS No: 23960-07-8 CIPAC No: n.a.	(RS)-5-methyl-2-(prop-1-en-2-yl)hex-4-en-1-yl 3-methylbut-2-enoate	≥ 894 g/kg	3 June 2020	3 June 2035	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on Lavandulyl senecioate, and in particular Appendices I and II thereto, shall be taken into account. Member State shall assess any extension of the use pattern beyond passive dispensers, in order to establish whether the proposed extensions of use fulfil the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Commission Regulation (EU) No 546/2011 (³).
▼ M333						
20	Ferric pyrophosphate CAS No: 10058-44-3 CIPAC No: —	iron(3+) diphosphate	≥ 802 g/kg The following impurities are of toxicological and environmental concern and must not exceed the following levels in the technical material:	3.8.2020	3.8.2035	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ferric pyrophosphate, and in particular Appendices I and II thereto, shall be taken into account.

▼ **M333**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
			— Lead: 3 mg/kg — Mercury: 0,1 mg/kg — Cadmium: 1 mg/kg			

▼ **M331**

21	<i>Phlebiopsis gigantea</i> strain VRA 1835	Not applicable	No relevant impurities	1 September 2020	31 August 2035	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Phlebiopsis gigantea</i> strain VRA 1835, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers. Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination.
22	<i>Phlebiopsis gigantea</i> strain VRA 1984	Not applicable	No relevant impurities	1 September 2020	31 August 2035	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Phlebiopsis gigantea</i> strain VRA 1984, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers. Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination.

▼ **M331**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
23	<i>Phlebiopsis gigantea</i> strain FOC PG 410.3	Not applicable	No relevant impurities	1 September 2020	31 August 2035	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Phlebiopsis gigantea</i> strain FOC PG 410.3, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers. Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination.

▼ **M336**

24	Sodium hydrogen carbonate CAS No: 144-55-8	Sodium hydrogen carbonate	≥ 990 g/kg Arsenic ≤ 3 mg/kg Lead ≤ 2 mg/kg Mercury ≤ 1 mg/kg	1 October 2020	1 October 2035	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sodium hydrogen carbonate, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M351**

25	<i>Akanthomyces muscarius</i> strain Ve6 (formerly <i>Lecanicillium muscarium</i> strain Ve6) (⁴)	Not applicable	No relevant impurities	1 March 2021	29 February 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Akanthomyces muscarius</i> strain Ve6 (formerly <i>Lecanicillium muscarium</i> strain Ve6) and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitisers, and shall ensure that adequate personal protective equipment is included as a condition of use.
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▼ **M351**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						Producers shall ensure strict maintenance of environmental conditions and quality control analysis during the manufacturing process as laid down in Working Document SANCO/12116/2012 as regards the limits on microbiological contamination ⁽²⁾ .

▼ **M352**

26	Blood meal 90989-74-5 909	Not applicable	100 % blood meal haemoglobin content: min 80 %.	1 April 2021	31 March 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on blood meal, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention: — to the protection of fish and aquatic invertebrates when less targeted spraying techniques are used, and — on the need of blood meal-containing plant protection products to be swirled before use to wet the product.
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▼ **M353**

27	24-epibrassinolide CAS No: 78821-43-9 CIPAC No: Not applicable	(3aS,5R,6S,7aR,7bS,9aS,10R,12aS,12bS)-10((2S,3R,4R,5R)-3,4-dihydroxy-5,6-dimethylheptan-2-yl)5,6-dihydroxy-7a,9a-dimethylhexadecahydro-3Hbenzo[c]indeno[5,4-e]oxepin-3-one	≥ 900 g/kg	31 March 2021	31 March 2036	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 4 December 2020, and in particular Appendices I and II thereto, shall be taken into account.
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▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ M357						
28	Aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> CAS No: Not available for the extract BLAD protein: 1219521-95-5 CIPAC No: Not allocated	Not applicable	► M473 The minimum purity is not relevant for the extract. BLAD protein content: 195–210 g/kg. The following relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured were identified: Total quinolizidine alkaloids (QA): (<i>lupanine</i>, <i>13α-OH-lupanine</i>, <i>13α-angeloyloxylupanine</i>, <i>lupinine</i>, <i>albine</i>, <i>angustifoline</i>, <i>13α-tigloyloxylupanine</i>, <i>α-isolupanine</i>, <i>tetrahydrorhombifoline</i>, <i>multiflorine</i>, <i>sparteine</i>) Maximum content: set at 0,05 g/kg. Level of <i>lupanine</i>, as a marker compound: set at 0,035 g/kg. ◀	27 April 2021	27 April 2036	► M473 For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i>, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment, Member States shall pay particular attention to the necessary labelling instructions concerning the measures to address foaming and stability of dilutions of the formulation. ◀

▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ M365						
29	<i>Pepino Mosaic Virus</i> , EU strain, mild isolate Abp1	Not applicable	The impurity nicotine shall not exceed the following values in the technical material: max. 0,005 mg/L in Abp1 TK max. 3,87 x 10⁻⁵ mg/kg in MPCP (Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the production method).	28 June 2021	28 June 2036	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pepino Mosaic Virus</i>, EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i>, CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (²). b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate
30	<i>Pepino Mosaic Virus</i> , CH2 strain, mild isolate Abp2	Not applicable	The impurity nicotine shall not exceed the following values in the technical material: max. 0,007 mg/L in Abp2 TK	28 June 2021	28 June 2036	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Pepino Mosaic Virus</i>, EU strain, mild isolate Abp1 and <i>Pepino Mosaic Virus</i>, CH2 strain, mild isolate Abp2, and in particular Appendices I and II thereto, shall be taken into account.

▼ **M365**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
			max. $3,87 \times 10^{-5}$ mg/kg in MPCP (Nicotine has been reported to be present in tomato plants, therefore, as the microbial pest control agent (MPCA) is produced in tomato plants, nicotine is present as a consequence of the production method).			In this overall assessment Member States shall pay particular attention to: a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (²). b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate

▼ **M418**

31	Calcium carbonate CAS No 471-34-1 CIPAC No 843 Limestone CAS No 1317-65-3 CIPAC No 852	IUPAC name: Calcium carbonate	950 g/kg	1 November 2021	31 October 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on calcium carbonate and the review report on limestone, and in particular Appendices I and II thereto, shall be taken into account.
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▼ **M372**

32	Potassium hydrogen carbonate CAS No 298-14-6 CIPAC No 853	IUPAC name: Potassium hydrogen carbonate	990 g/kg	1 November 2021	31 October 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report of potassium hydrogen carbonate, and in particular Appendices I and II thereto, shall be taken into account.
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▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
▼ M373						
33	<i>Bacillus amyloliquefaciens</i> AH2	n.a.	The nominal content of <i>Bacillus amyloliquefaciens</i> AH2 in the technical product and formulation is $1,0 \times 10^{11}$ CFU/L (range 7×10^{10} – 7×10^{11}). No relevant impurities	27 September 2021	27 September 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Bacillus amyloliquefaciens</i> AH2 and in particular Appendices I and II thereof, shall be taken into account.
▼ M377						
34	<i>Purpureocillium lilacinum</i> strain PL11	Not applicable	No relevant impurities	25 January 2022	24 January 2037	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Purpureocillium lilacinum</i> strain PL11 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: a) the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾ ; b) the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
▼ M381						
35	<i>Bacillus amyloliquefaciens</i> IT-45	n.a.	The nominal content of <i>Bacillus amyloliquefaciens</i> IT-45 in the technical product and formulation is: minimum: 2×10^{13} CFU/kg, maximum: 6×10^{14} CFU/kg. No relevant impurities	27 February 2022	27 February 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus amyloliquefaciens</i> IT-45 shall be taken into account.
▼ M383						
36	<i>Metarhizium brunneum</i> strain Ma 43	Not applicable	No relevant impurities	1 May 2022	30 April 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on <i>Metarhizium brunneum</i> strain Ma 43, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that microorganisms are as such considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.
▼ M387						
37	<i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004	Not applicable	The content of the virus in the technical grade active ingredient, produced as an isolated technical material, must be at least $2,0 \times 10^{11}$ occlusion bodies/g.	18.4.2022	18.4.2037	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus (SeMNPV), isolate BV-0004, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (⁵),

▼ **M387**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the protection of operators and workers, taking into account that microorganisms are <i>per se</i> considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M397**

38	Straight Chain Lepidopteran Pheromones (acetates)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	1 September 2022	30 August 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M399**

39	Sheep fat CAS No: 98999-15-6 CIPAC No: 919	Sheep fat	Minimum purity of sheep fat: 100 % No relevant impurity	1 November 2022	30 October 2037	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on sheep fat, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
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▼ **M403**

40	Heptamaloxyloglucan CAS No: 870721-81-6 CIPAC No: 851	α -L-fucopyranosyl-(1→2)- β -D-galactopyranosyl- (1→2)- α -D-xylopyranosyl-(1→6)-[α -D-xylopyranosyl-(1→6)- β -D-glucopyranosyl-(1→4)]- β -D-glucopyranosyl-(1→4)-D-glucitol	≥ 780 g/kg The following impurity is of toxicological and environmental concern and must not exceed the following levels in the technical material: - Patulin, max. 50 µg/kg	1 March 2023	28 February 2038	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on heptamaloxyloglucan, and in particular Appendices I and II thereto, shall be taken into account.
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▼ **M401**

41	Fish oil CAS No: 8016-13-5 CIPAC No: 918	Not applicable	Minimum purity of the active substance as manufactured: Fish oil 100 % Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured: Maximum levels according to Commission Directive 2002/32/EC (⁶) for the following impurities, proportionate to a fish oil with a moisture content of 12 %:	1 March 2023	28 February 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on fish oil, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M401**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
			5 ng/kg of sum of polychlorinated dibenzo-pardioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) (⁷) 20 ng/kg of sum of polychlorinated dibenzo-pardioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin like polychlorinated biphenyls (PCBs) (⁷) 0,5 mg/kg of mercury 2 mg/kg of cadmium 10 mg/kg of lead 175 µg/kg of non-dioxin-like PCBs			

▼ **M410**

42	<i>Trichoderma atroviride</i> AGR2	n.a.	The nominal content of <i>Trichoderma atroviride</i> AGR2 in the technical product and formulation is Minimal: 5 x 10¹¹ CFU/kg Nominal: 1 x 10¹² CFU/kg Maximal: 1 x 10¹³ CFU/kg No relevant impurities	22 February 2023	21 February 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> AGR2 and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites;
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▼ **M410**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						— the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be recommended to reduce dermal and inhalation exposure.

▼ **M409**

43	<i>Trichoderma atroviride</i> AT10	n.a.	The nominal content of <i>Trichoderma atroviride</i> AT10 in the technical product and formulation is Minimal: 1 x 10¹¹ CFU/kg Nominal: 5 x 10¹¹ CFU/kg Maximal: 1 x 10¹² CFU/kg No relevant impurities	20 February 2023	20 February 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Trichoderma atroviride</i> AT10 and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured used in plant protection products, including full characterisation of relevant secondary metabolites; — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers. Use of PPE/RPE might be considered to reduce dermal and inhalation exposure.
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▼ **M431**

44	Quartz sand (there is no ISO common name) (1) 7631-86-9 (CAS) (2) 14808-60-7 (CAS) 855 (CIPAC)	(1) Silicon dioxide (2) Quartz	915 g/kg The impurity crystalline silica with a particle diameter ≤ 10 µm is of toxicological concern and shall not exceed a level of 0,1 % of particles in the technical material.	1 September 2023	31 August 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on quartz sand, and in particular Appendices I and II thereof, shall be taken into account.
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▼ **M431**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
	[<i>So far they have been indicated as:</i> CAS No: 14808-60-7 CIPAC No: not allocated]					Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M432**

45	Fat distillation residues CAS No not available 915 (CIPAC No)	Not available	≥ 400 g/kg of cleaved fatty acids (free/ester bonded) palmitic acid min 19 % of cleaved fatty acids stearic acid min 18 % of cleaved fatty acids oleic acid min 37 % of cleaved fatty acids acid value min 70 mg KOH/g The following impurity is of toxicological concern and shall not exceed the following levels in the technical material: nickel max 0,1 g/kg	1 November 2023	31 October 2038	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on fat distillation residues, and in particular Appendices I and II thereof, shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M136**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
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▼ **M433**

46	<i>Cydia pomonella</i> granulovirus (CpGV)	Not applicable	<i>Bacillus cereus</i> : < 1 × 10 ⁷ CFU/g in the formulated products.	1 November 2023	31 October 2038	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Cydia pomonella</i> granulovirus (CpGV), and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (⁵), — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M445**

47	Hydrolysed proteins CAS No: Not applicable CIPAC No: 901	Not available	Hydrolysed proteins. <i>Animal tissues hydrolysate excluding ruminants hides and skins</i> (no ISO common name): — 708 g/kg on a dry weight basis [range in TK (technical concentrate) 400-434 g/kg]. Hydrolysed proteins. <i>Urea enriched beet molasses, hydrolysed</i> (no ISO common name):	1 May 2024	30 April 2039	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on hydrolysed proteins, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material for '<i>hydrolysed proteins-urea enriched beet molasses, hydrolysed</i>' as commercially manufactured on the basis of an analysis of at least five representative batches. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M445**

	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
			— 110 g/kg on a dry weight basis [range in TK (technical concentrate) 90-110 g/kg]. Hydrolysed Proteins. <i>Collagen protein Hydrolysate</i> (no ISO common name): — 582 g/kg on a dry weight basis [range in TK (technical concentrate) 249-262 g/kg]. Lead, cadmium, arsenic, mercury and biuret in accordance with Regulation (EU) 2019/1009 on fertilising products. Formaldehyde below 1 g/kg.			

▼ **M446**

48	Urea CAS No: 57-13-6 CIPAC No: 913	Urea	980 g/kg The following impurities were considered of toxicological concern and a maximum level is established of: Biuret: < 12 g/kg Formaldehyde: < 0,5 g/kg Cadmium: < 1 mg/kg Mercury: < 0,1 mg/kg	1 May 2024	30 April 2039	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on urea, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured on the basis of an analysis of at least five representative batches. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M446**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
			Lead: < 1 mg/kg Arsenic: < 1 mg/kg			

▼ **M470**

49	<i>Betabaculovirus phoperculellae</i>	Not applicable	No relevant impurities	12 February 2025	12 February 2040	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Betabaculovirus phoperculellae</i>, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that all microorganisms are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use; — the guarantee by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the adherence of the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 ⁽⁸⁾. Conditions of use shall include risk mitigation measures, where appropriate.
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▼ **M471**

50	<i>Bacillus subtilis</i> RTI477	Not applicable	No relevant impurities	12 February 2025	12 February 2040	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus subtilis</i> RTI477, and in particular Appendices I and II thereto, shall be taken into account.
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▼ **M471**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that microorganisms per se are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use, — the strict maintenance by the producer of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the adherence to the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 ⁽⁹⁾ Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M472**

51	<i>Bacillus velezensis</i> RTI301	Not applicable	No relevant impurities	12 February 2025	12 February 2040	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <i>Bacillus velezensis</i> RTI301, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use;
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▼ **M472**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						— the strict maintenance by the producer of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the adherence to the limits on microbiological contamination as set in the OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No 65 ⁽⁹⁾. Conditions of use shall include risk mitigation measures, where appropriate.

▼ **M136**

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

► **M292** ⁽²⁾ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-an_a_microbial-contaminant-limits.pdf ◀

► **M326** ⁽³⁾ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127). ◀

► **M351** ⁽⁴⁾ The concerned active substance was initially approved as *Verticillium lecanii*, but later, for scientific reasons, its name was changed to *Lecanicillium muscarius* strain Ve6, which was later changed again to the name under which the approval was renewed, *Akanthomyces muscarius* strain Ve6. ◀

► **M387** ⁽⁵⁾ https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_phys-chem-ana_micro_bial-contaminant-limits.pdf ◀

► **M401** ⁽⁶⁾ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

⁽⁷⁾ Expressed in World Health Organisation (WHO) toxic equivalents. ◀

⁽⁸⁾ Organisation for Economic Cooperation and Development (2014), OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products, Series on Pesticides and Biocides, No 65, OECD Publishing, Paris, <https://doi.org/10.1787/9789264221642-en>.

⁽⁹⁾ Organisation for Economic Cooperation and Development (OECD): <https://doi.org/10.1787/9789264221642-en>.

PART E

Candidates for substitution

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
1	Flumetralin CAS No 62924-70-3 CIPAC No 971	<i>N</i> -(2-chloro-6-fluorobenzyl)- <i>N</i> -ethyl- α,α,α -trifluoro-2,6-dinitro- <i>p</i> -toluidine	980 g/kg The impurity Nitrosamine (calculated as nitroso-dimethylamine) shall not exceed 0,001 g/kg in the technical material.	11 December 2015	► M466 15 January 2025 ◀	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on flumetralin, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; (c) the risk to herbivorous mammals; (d) the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production); 2. the compliance of the toxicity batches with the confirmed technical specification. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in points 1 and 2 by 11 June 2016.

▼ **M166**▼ **M162**▼ **M169**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
2	Esfenvalerate CAS No: 66230-04-4 CIPAC No: 481	(α S)- α -cyano-3-phen-oxybenzyl (2S)-2-(4-chlorophenyl)-3-methylbutyrate	830 g/kg The impurity toluene shall not exceed 10 g/kg in the technical material.	1 January 2016	► M440 31 May 2026 ◀	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on esfenvalerate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk from esfenvalerate and the 2S α R-isomer of fenvalerate to aquatic organisms including the risk for bio-accumulation through the food chain, — the risk to honeybees and non-target arthropods, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate.
3	Metsulfuron-methyl CAS No 74223-64-6 CIPAC No 441.201	Methyl 2-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsul-famoyl)benzoate	967 g/kg	1 April 2016	► M444 31 August 2026 ◀	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metsulfuron-methyl, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of consumers, — the protection of groundwater, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority by 30 September 2016 confirmatory information as regards the genotoxic potential of the metabolite triazine-amine (IN-A4098) to confirm that this metabolite is not genotoxic and not relevant for risk assessment.

▼ **M166**▼ **M172**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
4	Benzovindiflupyr CAS No: 1072957-71-1 CIPAC No: not available	<i>N</i> -[(1 <i>RS</i> ,4 <i>SR</i>)-9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide	960 g/kg (50/50) racemate	2.3.2016	► M444 2 August 2026 ◀	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on benzovindiflupyr, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities; (2) the compliance of the toxicity and ecotoxicity batches with the confirmed technical specification; (3) the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. The applicant shall submit to the Commission, the Member States and the Authority the information requested under points (1) and (2) by 2 September 2016 and the information requested under point (3) within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M166**▼ **M170**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
5	Lambda-Cyhalothrin CAS No 91465-08-6 CIPAC No 463	A 1:1 mixture of: (R)- α -cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate or of (R)- α -cyano-3-phenoxybenzyl (1S)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-3-phenoxybenzyl (1R)-cis-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate	900 g/kg	1 April 2016	► M444 31 August 2026 ◀	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on lambda-cyhalothrin, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the: (a) protection of operators, workers and bystanders; (b) metabolites potentially formed in processed commodities; (c) risk to aquatic organisms, mammals and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate. The applicants shall submit confirmatory information as regards: 1. a systematic review to assess the evidence available as regards potential sperm effects linked to exposure to lambda-cyhalothrin using guidance available (e.g. EFSA GD on Systematic Review methodology, 2010); 2. toxicological information to assess the toxicological profile of the metabolites V (PBA) and XXIII (PBA(OH)). The applicants shall submit those information to the Commission, the Member States and the Authority by 1 April 2018.

▼ **M166**▼ **M205**▼ **M227**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
6	Prosulfuron CAS No 94125-34-5 CIPAC No 579	1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea	950 g/kg The impurity 2-(3,3,3-trifluoro-propyl)-benzene sulphonamide shall not exceed 10 g/kg in the technical material.	1 May 2017	► M449 15 June 2026 ◀	► M358 For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfuron including its addendum, and in particular Appendices I and II thereto, shall be taken into account. In that overall assessment Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of consumers, taking into account exposure to metabolites of prosulfuron; — the risk to non-target terrestrial and aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. ◀
7	Pendimethalin CAS No 40487-42-1 CIPAC No 357	N-(1-ethylpropyl)-2,6-dinitro-3,4-xylylene	900 g/kg 1,2-dichloroethane ≤ 1 g/kg Total N-Nitroso compounds: max 100 ppm, of which N-Nitroso-pendimethalin: < 45 ppm.	1 September 2017	► M460 15 January 2027 ◀	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pendimethalin, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers

▼ **M227**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						shall be compared and verified against the specification of the technical material, — the protection of operators, — the protection of birds, mammals and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. In particular, personal protective equipment such as gloves, coverall and sturdy footwear has to be worn to ensure that the AOEL is not exceeded for the operator. The applicant shall submit confirmatory information to the Commission, the Member States and the Authority as regards: 1. the potential for bioaccumulation, in particular a reliable BCF value for bluegill sunfish (<i>Lepomis macrochirus</i>); 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. The applicant shall submit the confirmatory information requested under point 1 by 31 December 2018. The applicant shall submit the confirmatory information requested under point 2 within a period of two years of the publication by the Commission of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M239**

8

Imazamox
CAS No 114311-32-9
CIPAC No 619

2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid

≥ 950 g/kg

The impurity cyanide ion (CN⁻) shall not exceed 5 mg/kg in the technical material.

1 November 2017

► **M468** 30 June 2027 ◀

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on imazamox, and in particular Appendices I and II thereto, shall be taken into account.

▼ **M239**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						In this overall assessment Member States shall pay particular attention to: — the protection of consumers; — the protection of aquatic plants and of non-target terrestrial plants; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programs shall be initiated to verify potential groundwater contamination from imazamox and metabolites CL 312622 and CL 354825 in vulnerable zones, where appropriate.

▼ **M260**

9	Propyzamide CAS No 23950-58-5 CIPAC No 315	3,5-dichloro- <i>N</i> -(1,1-dimethylprop-2-ynyl) benzamide	920 g/kg	1 July 2018	► M475 30 November 2027 ◀	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on propyzamide and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of operators, — the protection of groundwater in vulnerable areas, — the protection of birds, mammals, non-target plants, soil and aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. In particular, personal protective equipment such as gloves, coverall and sturdy footwear has to be worn to ensure that the AOEL is not exceeded for the operator. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:
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▼ **M260**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						1. the completion of assessment of toxicological profile of metabolites identified in significant concentration in primary and rotational crops; 2. the soil degradation of major metabolite RH- 24580; 3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. The applicant shall submit the information mentioned under point (1) by 31 October 2018 and the information mentioned under point (2) by 30 April 2019. The applicant shall submit the confirmatory information mentioned in point (3) within two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater be made public by the Commission.

▼ **M288**

10	Copper compounds: Copper hydroxide CAS No 20427-59-2 CIPAC No 44.305 Copper oxychloride CAS No 1332-65-6 or 1332-40-7 CIPAC No 44.602 Copper oxide CAS No 1317-39-1 CIPAC No 44.603 Bordeaux mixture CAS No 8011-63-0 CIPAC No 44.604 Tribasic copper sulphate CAS No 12527-76-3 CIPAC No 44.306	Copper (II) hydroxide Dicopper chloride trihydroxide Copper oxide Not allocated Not allocated	≥ 573 g/kg ≥ 550 g/kg ≥ 820 g/kg ≥ 245 g/kg ≥ 490 g/kg	1 January 2019	31 December 2025	Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the conclusions of the review report on copper compounds and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the operator, worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment and other mitigation measures as appropriate; — the protection of water and non-target organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate;
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▼ **M288**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
			The following impurities shall not exceed the following levels: Arsenic max. 0,1 mg/g Cu Cadmium max. 0,1 mg/g Cu Lead max. 0,3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg			— the amount of active substance applied and ensure that the authorised amounts, in terms of rates and number of applications, do not exceed the minimum necessary to achieve the desired effects and do not cause any unacceptable effect on the environment taking into account background levels of copper at the application site, and, where the information is available, copper input from other sources. Member States may in particular decide to set a maximum annual application rate not exceeding 4 kg/ha of copper.

▼ **M293**

11	Methoxyfenozide CAS No 161050-58-4 CIPAC No 656	N-tert-Butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide	≥ 970 g/kg The following impurities must not exceed the following levels in the technical material: Tert-butylhydrazine < 0,001 g/kg RH-116267 < 2 g/kg	1 April 2019	31 March 2026	Only uses in greenhouses shall be authorised. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on methoxyfenozide, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the risk of accumulation in soil; — the protection of non-target arthropods, sediment dwelling and aquatic organisms; Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. a comparative in vitro metabolism study on methoxyfenozide, by 1 April 2020;
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▼ **M293**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water, within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. The applicant shall also provide an updated assessment of the information submitted and, where relevant, further information to confirm the absence of thyroid endocrine activity in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ⁽²⁾ by 1 February 2021.

▼ **M361**

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▼ **M347**

13	etoxazole CAS No 153233-91-1 CIPAC No 623	(RS)-5-tert-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro-1,3-oxazol-4-yl]phenetole	≥ 948 g/kg	1 February 2021	31 January 2028	Only uses on ornamental plants in permanent greenhouses shall be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on etoxazole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to:
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▼ **M347**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						— possible uptake of persistent soil metabolites in rotational crops; — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. The applicant shall submit to the Commission, the Member States and the Authority by 5 January 2023 confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, including an updated assessment of the information already submitted and, where relevant, further information.

▼ **M374**

14	Cypermethrin CAS No 52315-07-8 CIPAC No 332	(RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate or (RS)-α-cyano-3-phenoxybenzyl-(1RS)-cis-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate	920 g/kg cis:trans: 40/60 to 60/40 The following impurities are of toxicological concern and must not exceed the following levels in the technical material: hexane: 5g/kg	1 February 2022	31 January 2029	Authorisations shall be limited to professional users. When authorising plant protection products containing cypermethrin for spray applications outdoors, in order to ensure the protection of non-target organisms, in particular aquatic organisms and non-target arthropods, including bees: — risk mitigation measures achieving reduction of drift shall be required that lead to exposure $\leq 5,8$ mg a.s./ha in off-crop areas and, in addition, for spring applications to concentrations in water bodies $\leq 0,0038$ μg a.s./L, — only uses outside flowering of the crop and when no flowering weeds are present may be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on cypermethrin, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention to: — the protection of aquatic organisms, non-target arthropods, including bees;
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▼ M374

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
					— consumer risk assessment; — the technical specification of the active substance used in plant protection products. Where considered appropriate, Member States shall set monitoring requirements when granting authorisations in accordance with Article 6(i) of the Regulation (EC) No 1107/2009, in order to complement the monitoring under Directives of the European Parliament and of the Council 2000/60/EC ⁽³⁾ and 2009/128/EC ⁽⁴⁾. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the toxicological profile of the metabolites bearing the 3-phenoxybenzoyl moiety; 2. the relative toxicity of individual cypermethrin isomers, in particular the enantiomer (1S cis αR); 3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water. 4. Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 The applicant shall submit: — the information referred to in point 1 by 15 December 2022; — the information referred to in point 2 by 15 December 2023; and — the information referred to in point 3 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

▼ **M374**

	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
						As regards Points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity shall be submitted by 15 December 2023.

▼ **M455**

15	metconazole CAS No: 125116-23-6 (unstated stereochemistry) CIPAC No: 706	(1RS,5RS:1RS,5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	≥ 940 g/kg (sum of cis- and trans-isomers), with cis-metconazole (CL 354801) level not less than 800 g/kg and not more than 950 g/kg The following impurities shall not exceed the following levels in the technical material: — toluene: 2 g/kg — ethylcyclohexane: 2 g/kg	1 September 2024	31 August 2031	Use shall be limited to professional users. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on metconazole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the consumer exposure assessment with regards to residues that may be present in the primary crops and succeeding crops grown in rotation; — the protection of operators and bystanders/residents; — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water;
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▼ **M455**

	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
						2. the general toxicity profile of the metabolites M11 and M21 should be further investigated in order to confirm the appropriate toxicological reference values applicable to them. Moreover, confirmation of the presence of M11 and M21 and their ratio among the monohydroxylated metconazole compounds in crops, in order to confirm the residue definition for risk assessment. The applicant shall submit the confirmatory information referred to in point 1 by 15 July 2026 and in point 2 by 15 July 2026 to the Commission, Member States and the Authority.

▼ **M166**

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

► **M293** ⁽²⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33). ◀

► **M374** ⁽³⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁽⁴⁾ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of EN 5 EN pesticides (OJ L 309, 24.11.2009, p. 71). ◀