Official Journal
of the European Union

EN
L series

2025/2297

17.11.2025

COMMISSION IMPLEMENTING DECISION (EU) 2025/2297

of 13 November 2025

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Saltidin 20 % Outdoor in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2025) 7591)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 36(3) thereof,

Whereas:

(1) On 7 May 2021, the company Saltigo GmbH ('the applicant') submitted to the competent authorities of Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and Switzerland, an application for an authorisation granted by mutual recognition in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product Saltidin 20 % Outdoor ('the product'). The product is a repellent (product-type 19) in accordance with Annex V to Regulation (EU) No 528/2012, contains 20,6 % w/w of the active substance icaridin and is to be used by non-professionals on human skin to repel house mosquitoes. Belgium is the reference Member State responsible for the evaluation in accordance with Article 34(1) of Regulation (EU) No 528/2012.

(2) On 7 March 2024, Germany referred objections to the coordination group pursuant to Article 35(2) of Regulation (EU) No 528/2012, indicating that the product does not meet the conditions for authorisation laid down in Article 19(1), point (b)(iii) of that Regulation for adults and children older than 12 years. According to Germany, as the risk mitigation measure 'Wash hands before handling food' proposed by Belgium is not sufficient to exclude the risk of transferring the product to food, a quantitative dietary risk assessment has to be performed in line with Section 5.1 of the Guidance on the Biocidal Products Regulation Volume III Human Health, Assessment & Evaluation (Parts B+C) (version 4.0, December 2017) ([2]) ('Guidance on the Biocidal Products Regulation'). Germany shared its proposal for a dietary risk assessment that estimated an exposure above 10 % of the acceptable daily intake which, according to the Guidance on the Biocidal Products Regulation, would trigger the need for additional data to define the nature of the residues. Germany therefore considered that a nature-of-residue study (OECD guideline 507) should be provided by the applicant to assess the toxicity of the active substance and its metabolites.

(3) Belgium noted that that the 'Scenario to estimate the indirect exposure via food by using insect repellents' used by Germany for the dietary risk assessment and triggering the need for the applicant to provide the nature-of-residue study (OECD guideline 507) was not agreed or published at the time of the submission of the application for authorisation of the product. Consequently, Belgium considered that there was no requirement for the applicant to submit the study.

(4) As no agreement was reached in the coordination group on whether the biocidal product complies with the conditions for authorisation, on 4 September 2024, Belgium referred the unresolved objection to the Commission and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement in accordance with Article 36(1) of Regulation (EU) No 528/2012. That statement was forwarded to the Member States concerned and to the applicant.

([1]) OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.
([2]) biocides_guidance_human_health_ra_iii_part_bc_en.pdf.

(5) On 27 February 2025, the Commission requested an opinion from the European Chemicals Agency ('the Agency') in relation to the disagreement in accordance with Article 36(2) of Regulation (EU) No 528/2012. The Agency was asked to determine if additional data to define the nature of the residues (OECD guideline 507) according to the Guidance on the Biocidal Products Regulation is needed to assess the toxicity of the active substance and its break-down metabolites and if so, to ask the applicant to provide such data within six months from the request, taking into account that the concerned scenario from the Guidance on the Biocidal Products Regulation was not applicable at the time when the application for authorisation of the product was under evaluation by the reference Member State. Finally, the Agency was asked to determine if the product is considered to meet the condition in Article 19(1), point (b)(iii) of Regulation (EU) No 528/2012 for adults and children older than 12 years.

(6) On 16 May 2025, the Biocidal Products Committee of the Agency adopted its opinion ([3]). The Agency concluded that no additional data is needed to define the nature of the residues (OECD guideline 507) and to assess the toxicity of the active substance and its break-down metabolites. According to the Agency, there is not a sufficient level of concern to warrant the application of the draft 'Scenario to estimate the indirect exposure via food by using insect repellents' in order to perform a dietary risk assessment on the product. The Agency concluded that the product meets the condition in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 for adults and children older than 12 years, provided that the additional precautionary measure 'Wash hands thoroughly before handling or eating food' is included in the authorisation and on the label of the product.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product Saltidin 20 % Outdoor identified by the case number BC-PA066303-55 in the Register for Biocidal Products meets the condition for authorisation laid down in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 for adults and children older than 12 years, provided that the additional precautionary measure 'Wash hands thoroughly before handling or eating food' is included in the authorisation and on the label of the product.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 November 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission

([3]) https://echa.europa.eu/it/bpc-opinions-on-article-38.