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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2643

of 27 November 2023

approving formic acid as an existing active substance for use in biocidal products of product-types 2, 3, 4 and 5 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 89(1), third subparagraph, thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes formic acid for product-types 2, 3, 4 and 5.

(2) Formic acid has been evaluated for use in biocidal products of product-types 2 (disinfectants and algaecides not intended for direct application to humans or animals), 3 (veterinary hygiene), 4 (food and feed area) and 5 (drinking water), as described in Annex V to Regulation (EU) No 528/2012.

(3) Belgium was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment reports together with the conclusions of its evaluation to the European Chemicals Agency (the 'Agency') on 15 September 2021. The Agency discussed the assessment reports and the conclusions in technical meetings.

(4) In accordance with Article 75(1), second subparagraph, point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinions of the Agency ([3]) on 8 June 2022, having regard to the conclusions of the evaluating competent authority.

(5) In those opinions, the Agency concludes that biocidal products of product-types 2, 3, 4 and 5 containing formic acid may be expected to satisfy the criteria laid down in Article 19(1), point (b), of Regulation (EU) No 528/2012, provided that certain conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve formic acid as an active substance for use in biocidal products of product-types 2, 3, 4 and 5 subject to compliance with certain conditions.

(7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

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

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

([3]) Biocidal Products Committee Opinions on the application for approval of the active substance *formic acid*, Product-types 2, 3, 4 and 5; ECHA/BPC/325/2022, ECHA/BPC/326/2022, ECHA/BPC/327/2022 and ECHA/BPC/328/2022.

HAS ADOPTED THIS REGULATION:

Article 1

Formic acid is approved as an active substance for use in biocidal products of product-types 2, 3, 4 and 5, subject to the conditions set out in the Annex.

Article 2

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

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

Done at Brussels, 27 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
Formic acid	Methanoic Acid EC No: 200-579-1 CAS No: 64-18-6	99 % w/w	1 November 2024	31 October 2034	2	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to: (i) professional users; (ii) non-professional users; (iii) secondary exposure of the general public and children.
					3	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to professionals users; (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels ('MRLs') need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3), and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

					4	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to professional users; (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.
					5	The authorisation of biocidal products is subject to the following conditions: (1) the product assessment pays particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance; (2) the product assessment pays particular attention to: (i) professional users; (ii) the environment: soil compartment; (3) for products that may lead to residues in food or feed, it shall be assessed whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded.

ELI: http://data.europa.eu/eli/reg_impl/2023/2643/oj

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

(2) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(3) 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).