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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2576

of 2 October 2024

approving 2-methyl-4-oxo-3-(prop-2- ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropanecarboxylate (prallethrin) as an existing active substance for use in biocidal products of product-type 18 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 2-methyl-4-oxo-3-(prop-2-ynyl) cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate ('prallethrin') (CAS No: 23031-36-9) for product-type 18.

(2) Prallethrin has been evaluated for use in biocidal products of product-type 18 (insecticides, acaricides and products to control other arthropods), as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which corresponds to product-type 18 as described in Annex V to Regulation (EU) No 528/2012.

(3) Greece was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 9 April 2012. After the submission of the assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2), first subparagraph, of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the substantive conditions for approval laid down in Directive 98/8/EC.

(5) 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 opinion of the Agency on 26 February 2024 ([4]), having regard to the conclusions of the evaluating competent authority.

(6) In its opinion, the Agency concluded that biocidal products of product-type 18 containing prallethrin may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d), of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.

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

([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, ELI: http://data.europa.eu/eli/reg_del/2014/1062/oj).

([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1, ELI: http://data.europa.eu/eli/dir/1998/8/oj).

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance Prallethrin; Product-type: 18; ECHA/BPC/411/2024, adopted on 26 February 2024.

(7) Taking into account the opinion of the Agency, it is appropriate to approve prallethrin as an active substance for use in biocidal products of product-type 18 subject to compliance with certain conditions, including certain conditions for placing on the market of treated articles treated with or incorporating prallethrin.

(8) In its opinion, the Agency also concludes that prallethrin meets the criteria for being a very persistent and toxic substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([5]). Prallethrin therefore meets the condition laid down in Article 10(1), point (d), of Regulation (EU) No 528/2012 and should, therefore, for the purposes of Article 23(1) of that Regulation, be considered a candidate for substitution.

(9) In accordance with Article 23(1) of Regulation (EU) No 528/2012 the competent authorities of the Member States are to perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution.

(10) Since it can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved under the substantive conditions for approval laid down in Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.

(11) 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.

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

HAS ADOPTED THIS REGULATION:

Article 1

2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate ('prallethrin') is approved as an active substance for use in biocidal products of product-type 18, 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, 2 October 2024.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

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
prallethrin	IUPAC name: 2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate EC No: 245-387-9 CAS No: 23031-36-9	92,0 % weight per weight (w/w) *Note*: 1R-trans, S isomer are present at > 80 % (w/w)	1 March 2026	29 February 2036	18	Prallethrin is considered a candidate for substitution in accordance with Article 10(1), point (d), of Regulation (EU) No 528/2012. The authorisation of biocidal products containing prallethrin as an active substance is subject to the following conditions: (1) the product assessment shall pay 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 shall pay particular attention to: (a) children (toddlers); (b) surface water, sediment, soil and groundwater for products applied indoors by non-professional users by residual spraying (barrier treatment) in private households; (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 Regulations (EC) No 470/2009 [2] or (EC) No 396/2005 [3] of the European Parliament and of the Council, and any appropriate risk mitigation measures shall be taken to ensure that such MRLs are not exceeded. The placing on the market of treated articles is subject to the following conditions: (1) the person responsible for the placing on the market of a treated article treated with or incorporating prallethrin shall ensure that the label of that treated article provides the information listed in Article 58(3), second subparagraph, of Regulation (EU) No 528/2012;

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
						(2) Member States' competent authorities or, in the case of a Union authorisation the Commission, shall specify in the summary of the biocidal product characteristics of a biocidal product containing prallethrin the relevant instructions for use and precautions to be indicated on the label of the treated articles under Article 58(3), second subparagraph, point (e), of Regulation (EU) No 528/2012.

([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, ELI: http://data.europa.eu/eli/reg/2009/470/oj).

([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, ELI: http://data.europa.eu/eli/reg/2005/396/oj).

ELI: http://data.europa.eu/eli/reg_impl/2024/2576/oj