COMMISSION IMPLEMENTING REGULATION (EU) 2018/1130

of 13 August 2018

approving cypermethrin as an existing active substance for use in biocidal products of product-type 18

(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 the third subparagraph of Article 89(1) 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 cypermethrin.

(2) Cypermethrin has been evaluated for use in products of product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to Regulation (EU) No 528/2012.

(3) Belgium was designated as a rapporteur Member State and its evaluating competent authority submitted the assessment report together with its recommendations on 15 April 2015.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 5 May 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority ([3]).

(5) According to that opinion, biocidal products of product-type 18 containing cypermethrin may be expected to satisfy the criteria of Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.

(6) It is therefore appropriate to approve cypermethrin for use in biocidal products of product-type 18, subject to compliance with certain specifications and conditions.

(7) Furthermore, a need to further investigate the endocrine disrupting potential of cypermethrin has been identified in a screening study carried out in preparation of the impact assessment conducted by the Commission on various options to set criteria to identify endocrine disruptors ([4]). An assessment of the potential endocrine disrupting properties of cypermethrin will also be conducted in the context of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([5]), and the conclusions thereof are expected before the end of 2018. Depending on the outcome of that assessment, the Commission will consider the need to review the approval of cypermethrin as active substance for use in biocidal products in accordance with Article 15 of Regulation (EU) No 528/2012.

(8) 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.

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

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([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 (BPC) Opinion on the application for approval of the active substance Cypermethrin, Product type: PT 18, ECHA/BPC/153/2017, Adopted on 5 May 2017
([4]) COM(2016) 350 final.
([5]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Cypermethrin is approved as an active substance for use in biocidal products of product-type 18, subject to the specifications and 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, 13 August 2018.

For the Commission
The President
Jean-Claude JUNCKER

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
Cypermethrin	IUPAC Name: Cypermethrin *cis:trans* 40:60; (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate EC No: 257-842-9 CAS No: 52315-07-8	≥ 92 % w/w Isomeric ratio: *cis:trans* 40:60	1 June 2020	31 May 2030	18	The authorisations of biocidal products are 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. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: a) professional users; b) secondary exposure of infants and toddlers; c) surface water for: i) surface application indoors; and ii) outdoor wall and perimeter applications in urban areas; d) soil for: i) surface application indoors; ii) outdoor wall applications in urban and rural areas; and iii) perimeter applications in rural areas; e) sediment for: i) surface application, chemical barrier and crack and crevice treatment indoors; and ii) outdoor wall and perimeter applications in urban areas; f) groundwater for outdoor wall and perimeter applications in urban areas.

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
						3. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) 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) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

(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).