Commission Implementing Regulation (EU) 2018/1292 of 25 September 2018 approving cyphenothrin as an existing active substance for use in biocidal products of product-type 18 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1292

of 25 September 2018

approving cyphenothrin 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 cyphenothrin.

(2) Cyphenothrin 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 a rapporteur Member State and its evaluating competent authority submitted the assessment report together with its recommendations on 11 April 2013.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 14 December 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority[(4)].

(5) 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 evaluated while taking into account the conditions set out in Article 5 of Directive 98/8/EC. Following the opinion of the European Chemicals Agency, biocidal products of product-type 18 containing cyphenothrin may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

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

(7) The opinion of the European Chemicals Agency concludes that cyphenothrin meets the criteria for being a persistent (P) and toxic (T) substance in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5].

(8) For the purposes of Regulation (EU) No 528/2012, cyphenothrin meets the conditions set out in point (d) of Article 10(1) of Regulation (EU) No 528/2012 and should be therefore considered a candidate for substitution. The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, should perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing cyphenothrin.

(9) 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 terms of Directive 98/8/EC, the period of approval should be 10 years, in accordance with the practice established under that Directive.

(10) 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.

(11) 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

Cyphenothrin 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, 25 September 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1292. (See end of Document for details)*

ANNEX

Common Name	IUPAC NameIdentification Numbers	Minimum degree of purity of the active substance[a]	Date of approval	Expiry date of approval	Product type	Specific conditions
Cyphenothrin	IUPAC Name: (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate EC No: 254-484-5 CAS No: 39515-40-7	92 % w/w (total isomers)	1 February 2020	31 January 2030	18	Cyphenothrin is considered a candidate for substitution in accordance with point (d) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks

a 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.

b 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).

c 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).

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1292. (See end of Document for details)*

						2)	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. In view of the risks identified for the uses assessed, the product assessment shall pay particular

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b 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).

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