Commission Implementing Regulation (EU) 2016/2289 of 16 December 2016 approving epsilon-Momfluorothrin as an active substance for use in biocidal products of product-type 18 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/2289

of 16 December 2016

approving *epsilon*-Momfluorothrin as an 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 Article 90(2) thereof,

Whereas:

(1) The United Kingdom received on 29 May 2013 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[(2)], for the inclusion of the active substance *epsilon*-Momfluorothrin, in Annex I to that Directive for use in products of product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to that Directive, which correspond to product-type 18 as described in Annex V to Regulation (EU) No 528/2012.

(2) The United Kingdom submitted the assessment report together with its recommendations on 6 October 2015 in accordance with Article 90(2) of Regulation (EU) No 528/2012.

(3) The opinion of the European Chemicals Agency was formulated on 16 June 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(4) According to that opinion, biocidal products of product-type 18 and containing *epsilon*-Momfluorothrin 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.

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

(6) 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.

(7) 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

epsilon-Momfluorothrin 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, 16 December 2016.

For the Commission

The President

Jean-Claude JUNCKER

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
epsilon-Momfluorothrin	IUPAC Name: All isomers: 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (EZ)-(1RS,3RS;1SR,3SR)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate RTZ isomer: 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl (Z)-(1R,3R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate EC No: none CAS No: All isomers: 609346-29-4 RTZ isomer: 1065124-65-3	All isomers: 93 % w/w RTZ isomers: 82,5 % w/w	1 July 2017	30 June 2027	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 use 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 surface water, sediment and soil for products used (i) indoors as a space spray; and (ii) outdoors as a surface spray.
					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[b] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[c] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the

						applicable MRLs are not exceeded.

a The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012. 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).

(**1**) OJ L 167, 27.6.2012, p. 1.

(**2**) 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).

Status:
Point in time view as at 16/12/2016.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/2289.