COMMISSION IMPLEMENTING REGULATION (EU) No 1090/2014

of 16 October 2014

approving permethrin as an existing active substance for use in biocidal products for product-types 8 and 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 Regulation (EC) No 1451/2007 ([2]) establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council ([3]). That list includes permethrin.

(2) Permethrin has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 8, wood preservatives, and product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Ireland was designated as evaluating Competent Authority and submitted the assessment reports, together with its recommendations, to the Commission on 7 December 2010 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007.

(4) The opinion of the European Chemicals Agency was formulated on 8 April 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating Competent Authority.

(5) According to those opinions, biocidal products used for product-types 8 and 18 and containing permethrin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council provided that certain specifications and conditions relating to its use are satisfied.

(6) It is therefore appropriate to approve permethrin for use in biocidal products for product-type 8 and 18 subject to compliance with certain specifications and conditions.

(7) Since the evaluations did not address nanomaterials, the approvals should not cover such materials pursuant to Article 4(4) 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 laid down.

(9) 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 Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([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).

HAS ADOPTED THIS REGULATION:

Article 1

Permethrin shall be approved as an active substance for use in biocidal products for product-types 8 and 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 October 2014.

For the Commission
The President
José Manuel BARROSO

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 (2)
Permethrin	IUPAC Name: 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate EC No: 258-067-9 CAS No: 52645-53-1 The cis:trans ratio is 25:75.	930 g/kg	1 May 2016	30 April 2026	8	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. For biocidal products, authorisations are subject to the following conditions: (1) For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. (2) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. (3) Products shall not be authorised for wood that will be exposed to frequent weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 19 and Annex VI of Regulation (EU) No 528/2012, if necessary by the application of appropriate risk mitigation measures.

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)
						(4) Products shall not be authorized for treatment of outdoor constructions near or above water or for the treatment of wood that will be used for outdoor constructions near or above water, unless data are submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures. For treated articles, the following condition applies: Where a treated article has been treated with or intentionally incorporates permethrin, and where necessary due to the possibility of skin contact as well as the release of permethrin under normal conditions of use, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					18	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. For biocidal products, authorisations are subject to the following conditions: (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

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)
						(2) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. Labels and, where provided, safety data sheets of products authorised shall indicate such measures required. In particular, products authorised for the application to textile fibres or other materials to control insect damage shall indicate that freshly treated fibres and other appropriate materials shall be stored to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. For treated articles, the following condition applies: Where a treated article has been treated with or intentionally incorporates permethrin, and where necessary due to the possibility of skin contact as well as the release of permethrin under normal conditions of use, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

(1) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 8 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 technically equivalent with the evaluated active substance.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/chemicals/biocides/index_en.htm.