COMMISSION IMPLEMENTING REGULATION (EU) 2015/1609

of 24 September 2015

approving propiconazole as an existing active substance for use in biocidal products for product-type 7

(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 propiconazole.

(2) Propiconazole has been evaluated for use in product-type 7, film preservatives, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Finland was designated as evaluating competent authority and submitted the assessment report, together with its recommendations on 6 November 2013.

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 4 December 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products used for product-type 7 and containing propiconazole may be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012, provided that certain conditions concerning its use are complied with.

(6) It is therefore appropriate to approve propiconazole for use in biocidal products for product-type 7 subject to compliance with certain specifications and conditions.

(7) Since propiconazole meets the criteria for being very persistent (vP) according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]), and meets the criteria for classification as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]), treated articles treated with or incorporating propiconazole should be appropriately labelled when placed on the market.

(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]) 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).

([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Propiconazole is approved as an active substance for use in biocidal products for product-type 7, 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, 24 September 2015.

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
Propiconazole	IUPAC Name: 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	960 g/kg	1 December 2016	30 November 2026	7	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. The authorisations of biocidal products are subject to the following conditions: (1) For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks to the soil compartment, labels and, where provided, safety data sheets of products shall indicate that measures shall be taken to protect the soil during the outdoor application of the preserved mixtures to prevent losses and minimise emissions to the environment, unless it can be demonstrated that risks can be reduced to an acceptable level by other means. (3) In view of the risks to the aquatic compartment, products shall not be authorised for preservation of mixtures used for outdoor application on mineral surfaces, unless it can be demonstrated that risks can be reduced to an acceptable level. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating propiconazole shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the 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 16(2) of Directive 98/8/EC. 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.