COMMISSION IMPLEMENTING REGULATION (EU) No 955/2013

of 4 October 2013

to approve propiconazole as an existing active substance for use in biocidal products for product-type 9

(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 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 [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 propiconazole.

(2) Pursuant to Regulation (EC) No 1451/2007, propiconazole has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 9, fibre, leather, rubber and polymerised materials preservatives, as defined in Annex V to that Directive, which corresponds to product-type 9 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Finland was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 11 February 2011 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 12 July 2013, in an assessment report.

(5) It appears from the assessment report that biocidal products used for product-type 9 and containing propiconazole may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC.

(6) It is therefore appropriate to approve propiconazole for use in biocidal products for product-type 9.

(7) Since the evaluation did not address nanomaterials, the approval 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 Member States, interested parties, and the Commission where appropriate, to prepare themselves to meet the new requirements entailed.

(9) 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

Propiconazole shall be approved as an active substance for use in biocidal products for product-type 9, subject to the specifications and conditions set out in the Annex to this Regulation.

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, 4 October 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 167, 27.6.2012, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.
[3] OJ L 123, 24.4.1998, p. 1.

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)
Propiconazole	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	930 g/kg	1 June 2015	31 May 2025	9	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. Authorisations are subject to the following condition: 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. Where a treated article has been treated with or intentionally incorporates propiconazole, and where necessary due to the possibility of skin contact as well as the release of propiconazole under normal conditions of use, the person responsible for placing the treated 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/comm/environment/biocides/index.htm