COMMISSION IMPLEMENTING REGULATION (EU) No 438/2014

of 29 April 2014

approving cyproconazole as an existing active substance for use in biocidal products for product-type 8

(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 cyproconazole.

(2) Cyproconazole has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to that Directive, which corresponds to product-type 8 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Ireland was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 30 May 2012 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 in an assessment report reviewed within the Standing Committee on Biocidal Products on 13 March 2014.

(5) According to that assessment report, biocidal products used for product-type 8 and containing cyproconazole may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain specifications and conditions relating to its use are satisfied.

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

(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) The report concludes that cyproconazole meets the criteria for being classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]), and for being very persistent (vP) and toxic (T) according to Annex XIII to Regulation (EC) No 1907/2006. Notwithstanding the fact that the existing harmonised classification of cyproconazole should be revised pursuant to Article 37 of Regulation (EC) No 1272/2008, those intrinsic properties should be taken into account for the purpose of determining the period of approval.

(9) Since the conditions of the first subparagraph of Article 90(2) of Regulation (EU) No 528/2012 are not met, the current practice under Directive 98/8/EC should be followed. The period of approval should therefore be five years.

(10) However, for the purpose of authorising products in accordance with Article 23 of Regulation (EU) No 528/2012, cyproconazole shall be considered as a candidate for substitution pursuant to Article 10(1)(a) and (d) of that Regulation.

([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).
([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).

(11) 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.

(12) 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

Cyproconazole shall be approved as an active substance for use in biocidal products for product-type 8, 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, 29 April 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)
Cyproconazole	IUPAC Name: (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol EC No: N/A CAS No: 94361-06-5 Cyproconazole has two diastereomers. Diastereomer A: enantiomeric pair, where the 2-hydroxy group and the 3-hydrogen are located on the same side (2S, 3S and 2R, 3R). Diastereomer B: enantiomeric pair, where the 2-hydroxy group and 3-hydrogen are located on opposite sides (2R, 3S and 2S, 3R). Technical cyproconazole is ca 1:1 mixture of the two diasteriomers, each of which is exactly a 1:1 mixture of the enantiomers.	940 g/kg Cyproconazole has two diastereomers (Diastereoisomer A: 430-500 g/kg, Diastereoisomer B: 470-550 g/kg).	1 November 2015	31 October 2020	8	Cyproconazole is considered a candidate for substitution in accordance with Article 10(1)(a) and (d) of Regulation (EU) No 528/2012. 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 conditions: (1) For industrial 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) Products shall not be authorised for industrial use by double vacuum impregnation, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate 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)
						(3) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: a. 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 hard standing, 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. b. Products shall not be authorised for industrial treatment of wood that will be exposed to weathering, or for treatment of wood that will be used for outdoor constructions, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.

(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.