COMMISSION IMPLEMENTING REGULATION (EU) 2017/2003

of 8 November 2017

approving fludioxonil as an active substance for use in biocidal products of product-types 7, 9 and 10

(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 9(1)(a) thereof,

Whereas:

(1) Denmark received on 8 October 2014 an application for the approval of the active substance fludioxonil for use in biocidal products of product-type 7, film preservatives, product-type 9, fibre, leather, rubber and polymerised materials preservatives, and product-type 10, construction material preservatives, as described in Annex V to Regulation (EU) No 528/2012.

(2) Denmark submitted the assessment reports together with its recommendations on 5 April 2016 in accordance with Article 8(1) of Regulation (EU) No 528/2012.

(3) The opinions of the European Chemicals Agency were formulated on 2 March 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(4) According to those opinions, biocidal products of product-types 7, 9 and 10 and containing fludioxonil 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 fludioxonil for use in biocidal products of product-types 7, 9 and 10, subject to compliance with certain specifications and conditions.

(6) Since fludioxonil meets the criteria laid down in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]) for being very persistent, treated articles treated with or incorporating fludioxonil should be appropriately labelled when placed on the market.

(7) 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.

(8) 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

Fludioxonil is approved as an active substance for use in biocidal products of product-types 7, 9 and 10, 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*.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) 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).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 November 2017.

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
Fludioxonil	IUPAC Name: 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile EC No: Not available CAS No: 131341-86-1	950 g/kg	1 April 2018	31 March 2028	7	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 industrial and professional users. 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 fludioxonil shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					9	The authorisations of biocidal products are subject to the following condition: 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. 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 fludioxonil shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

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
					10	The authorisations of biocidal products are subject to the following condition: 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. 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 fludioxonil shall ensure that the label of that treated article provides the information listed 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 evaluated. 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.