COMMISSION IMPLEMENTING REGULATION (EU) 2016/1087

of 5 July 2016

approving tolylfluanid as an existing active substance for use in biocidal products of 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 tolylfluanid.

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

(3) Finland was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 17 March 2015.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 9 December 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 7 and containing tolylfluanid 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.

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

(7) Since tolylfluanid 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 ([3]), treated articles treated with or incorporating tolylfluanid 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,

([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 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

Tolylfluanid is approved as an active substance for use in biocidal products of 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, 5 July 2016.

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
Tolylfluanid	IUPAC Name: N-(Dichlorofluoro-methylthio)-N′,N′-di-methyl-N-p-tolylsulfa-mide EC No: 211-986-9 CAS No: 731-27-1	96 % w/w	1 January 2018	31 December 2027	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: a) industrial or professional users; b) non-professional users of treated paints containing tolylfluanid as a film preservative; c) surface water, soil and ground water, including the risk from degradation products. 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 tolylfluanid 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 used for the evaluation made in accordance with Article 89(1) 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.