COMMISSION IMPLEMENTING REGULATION (EU) 2018/1131

of 13 August 2018

approving penflufen as an active substance for use in biocidal products of 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 Article 9(1)(a) thereof,

Whereas:

(1) The evaluating competent authority of the United Kingdom received on 7 July 2015 an application for the approval of the active substance penflufen for use in biocidal products of product-type 8, wood preservatives, as described in Annex V to Regulation (EU) No 528/2012.

(2) The evaluating competent authority of the United Kingdom submitted the assessment report together with its recommendations on 28 February 2017 in accordance with Article 8(1) of Regulation (EU) No 528/2012.

(3) The opinion of the European Chemicals Agency was formulated on 14 December 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority ([2]).

(4) According to that opinion, biocidal products of product-type 8 containing penflufen 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 penflufen for use in biocidal products of product-type 8, subject to compliance with certain specifications and conditions.

(6) Since the opinion of the European Chemical Agency concludes that penflufen meets the criteria for being very persistent (vP) in accordance with Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]), treated articles treated with or incorporating penflufen should be labelled appropriately 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

Penflufen is approved as an active substance for use in biocidal products of product-type 8, subject to the specifications and conditions set out in the Annex.

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

([2]) Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance Penflufen, Product type: 8, ECHA/BPC/184/2017, Adopted on 14 December 2017.

([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).

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, 13 August 2018.

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
Penflufen	IUPAC Name: 5-fluoro-1,3-dimethyl-N-{2-[(2RS)-4-methylpentan-2-yl]phenyl}-1H-pyrazole-4-carboxamide EC No: not available CAS No: 494793-67-8	980 g/kg (1:1 ratio (R:S) ratio of enantiomers)	1 February 2019	31 January 2029	8	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 uses 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 and professional users; (b) soil and groundwater for wood in service that will be exposed to frequent weathering. 3. In view of the risks identified for soil, labels, and, where provided, safety data sheets of product 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 hardstanding, 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. 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 penflufen 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.