



Brussels, **XXX**  
SANTE/12067/2017 CIS  
(POOL/E4/2017/12067/12067-EN  
CIS.doc)  
[...](2018) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**approving penflufen as an active substance for use in biocidal products of product-  
type 8**

(Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

## 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<sup>1</sup>, 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<sup>2</sup>.
- (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<sup>3</sup>, treated articles

---

<sup>1</sup> OJ L 167, 27.6.2012, p. 1.

<sup>2</sup> 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.

<sup>3</sup> 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).

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.

*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,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*