# Commission Implementing Regulation (EU) 2015/1982 of 4 November 2015 approving hexaflumuron as an existing active substance for use in biocidal products for product-type 18 (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) 2015/1982

of 4 November 2015

approving hexaflumuron as an existing active substance for use in biocidal products for product-type 18

(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 hexaflumuron.

(2) Hexaflumuron has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council[(3)] for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive, which corresponds to product-type 18, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Portugal was designated as evaluating competent authority and submitted the assessment report, together with its recommendations, to the Commission on 11 July 2011 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007[(4)].

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 3 December 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products used for product-type 18 and containing hexaflumuron may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC provided that certain conditions concerning its use are complied with.

(6) It is therefore appropriate to approve hexaflumuron for use in biocidal products for product-type 18 subject to compliance with certain specifications and conditions.

(7) The opinion concludes that the characteristics of hexaflumuron render it very persistent (vP), very bioaccumulative (vB) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5].

(8) Since, pursuant to Article 90(2) of Regulation (EU) No 528/2012, substances for which the Member States' evaluation has been completed by 1 September 2013 should be approved in accordance with Directive 98/8/EC, the period of approval should be 5 years in accordance with the practice established under that Directive.

(9) For the purposes of Article 23 of Regulation (EU) No 528/2012 however, hexaflumuron meets the conditions of Article 10(1)(a) and (d) of that Regulation and should therefore be considered a candidate for substitution.

(10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities should also evaluate whether the conditions of Article 5(2) can be satisfied to decide if a biocidal product containing hexaflumuron can be authorised or not.

(11) Since hexaflumuron meets the criteria for being very persistent (vP), very bioaccumulative (vB) and toxic (T) in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006, treated articles treated with or incorporating hexaflumuron should be appropriately labelled when placed on the market.

(12) 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.

(13) 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*

Hexaflumuron is approved as an active substance for use in biocidal products for product-type 18, 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, 4 November 2015.

*For the Commission*

*The President*

Jean-Claude JUNCKER

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1982. (See end of Document for details)*

ANNEX

| Common Name | IUPAC NameIdentification Numbers | Minimum degree of purity of the active substance[a] | Date of approval | Expiry date of approval | Product type | Specific conditions |
|---|---|---|---|---|---|---|
| Hexaflumuron | IUPAC Name: 1-[3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea EC No: 401-400-1 CAS No: 86479-06-3 | 984 g/kg | 1 April 2017 | 31 March 2022 | 18 | Hexaflumuron 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. In addition, |

**a** 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 16(2) of Directive 98/8/EC. 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.

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|---|---|---|---|---|---|---|
| | | | | | | pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. The authorisations of biocidal products are subject to the following conditions. (1) Products shall only be authorised for use in Member States where at least one of the conditions set in Article |

**a** 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 16(2) of Directive 98/8/EC. 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.