COMMISSION IMPLEMENTING REGULATION (EU) No 406/2014

of 23 April 2014

to approve ethyl butylacetylaminopropionate as an existing active substance for use in biocidal products for product-type 19

(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 Regulation (EC) No 1451/2007 ([2]) establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council ([3]). That list includes ethyl butylacetylaminopropionate.

(2) Ethyl butylacetylaminopropionate has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 19, repellents and attractants, as defined in Annex V to that Directive, which corresponds to product-type 19 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Belgium was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 5 November 2009 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated in an assessment report reviewed within the Standing Committee on Biocidal Products on 13 March 2014.

(5) According to that assessment report, biocidal products used for product-type 19 and containing ethyl butylacetylaminopropionate may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that the certain specifications and conditions relating to its use are satisfied.

(6) It is therefore appropriate to approve ethyl butylacetylaminopropionate for use in biocidal products for product-type 19 subject to compliance with such specifications and conditions.

(7) Since the evaluation did not address nanomaterials, the approval should not cover such materials in accordance with Article 4(4) of Regulation (EU) No 528/2012.

(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 laid down.

(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 Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Ethyl butylacetylaminopropionate shall be approved as an active substance for use in biocidal products for product-type 19, 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, 23 April 2014.

For the Commission
The President
José Manuel BARROSO

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 (2)
Ethyl butylacetylaminopropionate	IUPAC Name: 3-(N-acetyl-N-butyl) aminopropionic acid ethyl ester EC no: 257-835-0 CAS no: 52304-36-6	990 g/kg	1 November 2015	31 October 2025	19	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. Authorisations are subject to the following condition: Primary exposure of humans to the product shall be minimized by considering and applying appropriate risk mitigation measures, including, where applicable, instructions on the amount and the frequency with which the product may be applied to human skin.

(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 8 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.

(2) For the implementation of the common principles of Annex VI to Regulation (EU) No 528/2012, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm