COMMISSION IMPLEMENTING REGULATION (EU) No 1039/2013

of 24 October 2013

modifying the approval of nonanoic acid as an existing active substance for use in biocidal products for product-type 2

(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 nonanoic acid.
- (2) Nonanoic acid has been included into Annex I to Directive 98/8/EC for use in product-type 2 through Commission Directive 2012/41/EU (4), and is therefore considered as approved for that product-type by virtue of Article 86 of Regulation (EU) No 528/2012.
- (3) Furthermore, nonanoic acid has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 10, masonry preservatives, as defined in Annex V to that Directive. The evaluation covered use as an algaecide for the curative treatment of construction materials. That specific use is now covered by product-type 2 as defined in Annex V to Regulation (EU) No 528/2012.
- (4) Austria was designated as Rapporteur Member State and submitted the competent authority report, together with

a recommendation, to the Commission on 3 April 2012 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

- (5) 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, within the Standing Committee on Biocidal Products on 27 September 2013, in an assessment report.
- (6) It appears from that report that biocidal products used as an algaecide for the curative treatment of construction materials and containing nonanoic acid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC.
- (7) The existing approval of nonanoic acid for product-type 2 does not cover the conditions resulting from the evaluation of products used as an algaecide for the curative treatment of construction materials. It is therefore appropriate to complement that existing approval with those conditions. For the purpose of allowing all interested parties to prepare themselves to meet the new requirements following from the recent redefinition of biocidal product-types, it is furthermore appropriate to modify the date of approval originally provided for by Directive 2012/41/EU.
- (8) Since the evaluation did not address nanomaterials, the approval should not cover such materials pursuant to Article 4(4) of Regulation (EU) No 528/2012.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Nonanoic acid shall be approved as an active substance for use in biocidal products for product-type 2, subject to the specifications, the new conditions and the new date of approval set out in the Annex.

Article 1

(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 (OLL 123, 24.4.1998, p. 1)

⁽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).

the market (OJ L 123, 24.4.1998, p. 1).

(4) Commission Directive No 2012/41/EU of 26 November 2012 amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance nonanoic acid to product type 2 (OJ L 327, 27.11.2012, p. 28).

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, 24 October 2013.

For the Commission The President José Manuel BARROSO

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)
Nonanoic acid, Pelargonic acid	IUPAC Name: Nonanoic acid EC No: 203-931-2 CAS No: 112-05-0	896 g/kg	1 October 2015	30 September 2025	2	The product assessment shall pay particula 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 conditions: 1. Unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means, authorisation shall be subject to the following conditions: (a) Instructions for use informing on how to minimize aerosol exposure. (b) Authorisation of products for non professional users are subject to the packaging being designed to minimise user exposure. 2. Authorisation of products used a algaecide for outdoor remedial treatment of construction materials shall be subject to safe operating procedures and risk mitigation measures in order to protect the environment.

ANNEX

⁽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