COMMISSION IMPLEMENTING REGULATION (EU) 2017/795

of 10 May 2017

approving pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide as an existing active substance for use in biocidal products of 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 silicon dioxide (as a nanomaterial formed by aggregates and agglomerates), to be renamed pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide, as the result of its evaluation.

(2) Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide has been evaluated for use in products of product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as evaluating competent authority and submitted the assessment report together with its recommendations on 18 December 2015.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinion of the European Chemicals Agency was formulated on 11 October 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, biocidal products of product-type 18 containing pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide 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.

(6) It is therefore appropriate to approve pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide for use in biocidal products of product-type 18, subject to compliance with certain specifications and conditions.

(7) Since pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide as evaluated is a nanomaterial, the approval should cover such nanomaterials pursuant to Article 4(4) of Regulation (EU) No 528/2012 provided that certain specifications and conditions relating to their use are satisfied.

(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.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

[2] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide is approved as an active substance for use in biocidal products of 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, 10 May 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Reference structural characteristics (2)	Date of approval	Expiry date of approval	Product type	Specific conditions
Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	IUPAC Name: Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica EC No: 272-697-1 CAS No: 68909-20-6	998 g/kg (purity of core measured after ignition).	— Carbon content: 3,0-4,0 %; — Primary particle size: 6,9-8,6 nm; — Specific surface area: 217-225 m^2/g; — Size of stable aggregated particles: > 70 nm; — Surface treatment: with > 90 % of the surface surface-treated with hexamethylsilazane (CAS 999-97-3)	1 November 2018	31 October 2028	18	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 use 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 professional users; (3) for products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (3) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (4) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 89(1) 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 to be technically equivalent to the evaluated active substance.

(2) The structural characteristics indicated in this column were the ones of the active substance used for the evaluation made in accordance with Article 89(1) of Regulation (EU) No 528/2012.

(3) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(4) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).