Commission Implementing Regulation (EU) No 408/2014 of 23 April 2014 approving synthetic amorphous silicon dioxide as an existing active substance for use in biocidal products for product-type 18 (Text with EEA relevance)

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approving synthetic amorphous silicon dioxide 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 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 silicon dioxide.

(2) Silicon dioxide has been evaluated in accordance with Article 11(2) of Directive 98/8/EC 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) The data submitted for the purpose of the evaluation allowed conclusions to be drawn only regarding a certain form of silicon dioxide, i.e. synthetic amorphous silicon dioxide described as wet silica CAS No 112926-00-8. The evaluation did not allow conclusions to be drawn regarding any other substance complying with the definition of silicon dioxide CAS No 7631-86-9 in the abovementioned list of active substances in Regulation (EC) No 1451/2007. Therefore, only synthetic amorphous silicon dioxide should be covered by the approval.

(4) France was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 16 April 2009 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 in an assessment report reviewed within the Standing Committee on Biocidal Products on 13 March 2014.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 408/2014. (See end of Document for details)*

(6) According to that assessment report, biocidal products used for product-type 18 and containing synthetic amorphous silicon dioxide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions relating to its use are satisfied.

(7) It is therefore appropriate to approve synthetic amorphous silicon dioxide for use in biocidal products for product-type 18 subject to compliance with such specifications and conditions.

(8) Since synthetic amorphous 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.

(9) 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.

(10) 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

Synthetic amorphous silicon dioxide shall be 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, 23 April 2014.

For the Commission

The President

José Manuel BARROSO