



Brussels, **XXX**
SANTE/11721/2016 Rev. 1
(POOL/E4/2016/11721/11721R1-
EN.doc)
[...](2017) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**approving pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated as an
existing active substance for use in biocidal products of product-type 18**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

approving pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated 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 products¹, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated.
- (2) Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated 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 silicon dioxide, nano, surface treated 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 silicon dioxide, nano, surface treated for use in biocidal products of product-type 18, subject to compliance with certain specifications and conditions.
- (7) Since pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated as evaluated is a nanomaterial, the approval should cover such nanomaterials pursuant to

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).

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,

HAS ADOPTED THIS REGULATION:

Article 1

Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated 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,

For the Commission
The President
Jean-Claude JUNCKER