EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11135/2016
(POOL/E4/2016/11135/11135-EN.doc)
[…](2016) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving L(+) Lactic acid as an active substance for use in biocidal products of product-type 1

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving L(+) Lactic acid as an active substance for use in biocidal products of product-type 1

(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 Article 90(2) thereof,

Whereas:

(1) Germany received on 29 August 2013 an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council[2], for the inclusion of the active substance L(+) Lactic acid in Annex I to that Directive for use in products of product-type 1, human hygiene, as described in Annex V to that Directive, which correspond to product-type 1 as described in Annex V to Regulation (EU) No 528/2012.

(2) Germany submitted the assessment report together with its recommendations on 5 February 2015 in accordance with Article 90(2) of Regulation (EU) No 528/2012.

(3) The opinion of the European Chemicals Agency was formulated on 10 December 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(4) According to that opinion, biocidal products of product-type 1 and containing L(+) Lactic acid 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.

(5) It is therefore appropriate to approve L(+) Lactic acid for use in biocidal products of product-type 1, subject to compliance with certain specifications and conditions.

(6) 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.

(7) 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] 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

L(+) Lactic acid is approved as an active substance for use in biocidal products of product-type 1, 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