



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/11719/2016
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[...](2016) **XXX** draft

COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

not approving PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-type 5

(Text with EEA relevance)

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(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 PHMB (1600; 1.8).
- (2) PHMB (1600; 1.8) has been evaluated for use in products of product-type 5, drinking water, as defined 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 23 November 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 12 October 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products used for product-type 5 and containing PHMB (1600; 1.8) may not be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012. For that product-type, the scenarios evaluated in the environmental risk assessments identified unacceptable risks.
- (6) It is therefore not appropriate to approve PHMB (1600; 1.8) for use in biocidal products for product-type 5.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

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 DECISION:

Article 1

PHMB (1600; 1.8) (EC No : n.a. , CAS No 27083-27-8 and 32289-58-0) is not approved as an active substance for use in biocidal products for product-type 5.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER