

COMMISSION IMPLEMENTING DECISION (EU) 2018/619**of 20 April 2018****not approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products of product-types 1, 5 and 6****(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 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 PHMB (1415; 4.7) (EC No: n.a., CAS No: 32289-58-0 and 1802181-67-4).
- (2) PHMB (1415; 4.7) has been evaluated for use in products of product-type 1, human hygiene, 5, drinking water, and 6, preservatives for products during storage, as described in Annex V to Regulation (EU) No 528/2012.
- (3) France was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 13 December 2016.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 4 October 2017 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products used for product-types 1, 5 and 6 containing PHMB (1415; 4.7) may not be expected to satisfy the requirements laid down in Article 19(1)(b) of Regulation (EU) No 528/2012. For those product-types, the scenarios evaluated in the human health and environmental risk assessments identified unacceptable risks.
- (6) It is therefore not appropriate to approve PHMB (1415; 4.7) for use in biocidal products of product-types 1, 5 and 6.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

PHMB (1415; 4.7) (EC No: n.a., CAS No: 32289-58-0 and 1802181-67-4) is not approved as an active substance for use in biocidal products of product-types 1, 5 and 6.

⁽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 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, 20 April 2018.

For the Commission
The President
Jean-Claude JUNCKER
