



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10785/2016
(POOL/E4/2016/10785/10785-EN.doc)
[...](2016) **XXX** draft

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

of **XXX**

**approving calcium magnesium oxide (burnt dolomitic lime) as an existing active
substance for use in biocidal products of product-types 2 and 3**

(Text with EEA relevance)

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

of **XXX**

approving calcium magnesium oxide (burnt dolomitic lime) as an existing active substance for use in biocidal products of product-types 2 and 3

(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 calcium magnesium oxide (burnt dolomitic lime).
- (2) Calcium magnesium oxide (burnt dolomitic lime) has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council³ for use in products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, and product-type 3, veterinary hygiene, as described in Annex V to that Directive, which correspond to product-types 2 and 3 respectively, as described in Annex V to Regulation (EU) No 528/2012.
- (3) The United Kingdom was designated as evaluating competent authority and submitted the assessment reports together with its recommendations on 19 September 2011.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 14 April 2016 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2 and 3 and containing calcium magnesium oxide (burnt dolomitic lime) may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.
- (6) It is therefore appropriate to approve calcium magnesium oxide (burnt dolomitic lime) for use in biocidal products of product-types 2 and 3, subject to compliance with certain specifications and conditions.

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).

³ 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).

- (7) 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.
- (8) 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

Calcium magnesium oxide (burnt dolomitic lime) is approved as an active substance for use in biocidal products of product-types 2 and 3, 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