Commission Implementing Regulation (EU) 2016/1933 of 4 November 2016 approving calcium magnesium tetrahydroxide (hydrated 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) 2016/1933

of 4 November 2016

approving calcium magnesium tetrahydroxide (hydrated 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 products[(1)], and in particular the third subparagraph of 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 calcium magnesium tetrahydroxide (hydrated dolomitic lime).

(2) Calcium magnesium tetrahydroxide (hydrated dolomitic lime) has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council[(3)] 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 tetrahydroxide (hydrated 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1933. (See end of Document for details)*

(6) It is therefore appropriate to approve calcium magnesium tetrahydroxide (hydrated dolomitic lime) for use in biocidal products of product-types 2 and 3, subject to compliance with certain specifications and conditions.

(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 tetrahydroxide (hydrated 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, 4 November 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1933. (See end of Document for details)*

ANNEX

Common Name	IUPAC NameIdentification Numbers	Minimum degree of purity of the active substance[a]	Date of approval	Expiry date of approval	Product type	Specific conditions
Calcium magnesium tetrahydroxide (hydrated dolomitic lime)	IUPAC Name: Calcium magnesium tetrahydroxide EC No: 254-454-1 CAS No: 39445-23-3	800 g/kg (The value provides the content of Ca and Mg expressed as $Ca(OH)_2$ and $Mg(OH)_2$. Typical values for $Mg(OH)_2$ in hydrated dolomitic lime are in the range of 15 %-40 %)	1 May 2018	30 April 2028	2	The authorisations of biocidal products are subject to the following conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment

a The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 89(1) of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.