EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10788/2016 ANNEX
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ANNEX 1

**ANNEX**

**to the**

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

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

# ANNEX

| Common Name | IUPAC Name<br>Identification Numbers | Minimum degree of purity of the active substance[1] | Date of approval | Expiry date of approval | Product type | Specific conditions |
|---|---|---|---|---|---|---|
| Calcium magnesium tetrahydroxide (hydrated dolomitic lime) | IUPAC Name:<br>Calcium magnesium tetrahydroxide<br><br>EC No: 254-454-1<br>CAS No: 39445-23-3 | 800 g/kg<br>(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:<br>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 of the active substance.<br>2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to industrial and professional users. |
| | | | | | 3 | The authorisations of biocidal products are subject to the following conditions:<br>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 of the active substance.<br>2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users. |

[1] 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.