EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10274/2022
(POOL/E4/2022/10274/10274-EN.docx)
[…](2022) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving didecyldimethylammonium chloride as an active substance for use in biocidal products of product-types 1 and 2 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 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 didecyldimethylammonium chloride.

(2) Didecyldimethylammonium chloride has been evaluated for use in biocidal products of product-type 1 (human hygiene biocidal products) and product-type 2 (private area and public health area disinfectants and other biocidal products), as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council[3], which correspond respectively to product-types 1 and 2 as described in Annex V to Regulation (EU) No 528/2012.

(3) Italy was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 10 September 2012. After the submission of the assessment report, discussions took place in technical meetings organised by the Commission and, after 1 September 2013, by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2) of Regulation (EU) 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be evaluated in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1) of Regulation (EU) No 528/2012, the Biocidal Products Committee prepares the opinion of the Agency regarding the applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the

[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).

Agency[4] on 2 December 2021, having regard to the conclusions of the evaluating competent authority.

(6) According to those opinions biocidal products of product-types 1 and 2 containing didecyldimethylammonium chloride may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d), read in conjunction with Article 10(1) of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.

(7) Taking into account the opinions of the Agency, it is appropriate to approve didecyldimethylammonium chloride as an active substance for use in biocidal products of product-types 1 and 2 subject to compliance with certain conditions.

(8) 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.

(9) 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

Didecyldimethylammonium chloride is approved as an active substance for use in biocidal products of product-types 1 and 2 subject to the 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
Ursula VON DER LEYEN

[4] Biocidal Products Committee Opinions on the applications for approval of the active substance didecyldimethylammonium chloride; Product-types: 1 and 2; ECHA/BPC/311/2021 and ECHA/BPC/312/2021, adopted on 2 December 2021.