EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12666/2021 CIS
(POOL/E4/2021/12666/12666-EN
CIS.docx)
[…](2021) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving didecyldimethyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving didecyldimethyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4

(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 didecyldimethyl ammonium chloride (DDAC) to be renamed for the purposes of this Regulation as didecyldimethyl ammonium chloride as a result of its evaluation.

(2) Didecyldimethyl ammonium chloride has been evaluated for use in biocidal products of product-type 3, veterinary hygiene biocidal products and product-type 4, food and feed area disinfectants, 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 3 and 4 as defined 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.

(4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the European Chemicals Agency[4] ('the Agency') on 6 October 2020, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products of product-types 3 and 4 containing didecyldimethyl ammonium chloride may be expected to satisfy the requirements laid

---

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).

4 Biocidal Products Committee Opinions on the applications for approval of the active substance didecyldimethylammonium chloride; Product-types: 3 and 4; ECHA/BPC/265/2020 and ECHA/BPC/266/2020, adopted on 6 October 2020.

down in Article 5(1)(b), (c) and (d) of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.

(6) Taking into account the opinions of the Agency, it is appropriate to approve didecyldimethyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4 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

Didecyldimethyl ammonium chloride is approved as an active substance for use in biocidal products of product-types 3 and 4 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
Ursula VON DER LEYEN