EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

approving alkyl (C_{12-16}) dimethylbenzyl 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 alkyl (C_{12-16}) dimethylbenzyl 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 alkyl (C_{12-16}) dimethylbenzyl ammonium chloride (ADBAC/BKC (C_{12}-C_{16})) to be renamed for the purposes of this Regulation as alkyl (C_{12-16}) dimethylbenzyl ammonium chloride as a result of its evaluation.

(2) Alkyl (C_{12-16}) dimethylbenzyl 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 Chemical 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 alkyl (C_{12-16}) dimethylbenzyl ammonium chloride may be expected to satisfy the

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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 alkyl(C_{12-16}) dimethylbenzyl ammonium chloride; Product types: 3 and 4; ECHA/BPC/267/2020 and ECHA/BPC/268/2020, adopted on 6 October 2020.

requirements laid 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 alkyl (C12-16) dimethylbenzyl 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

Alkyl (C_{12-16}) dimethylbenzyl 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

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ANNEX

ANNEXES

to the

Commission Implementing Regulation (EU).../...

approving alkyl (C_{12-16}) dimethylbenzyl ammonium chloride as an active substance for use in biocidal products of product-types 3 and 4

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride	IUPAC name: not applicable EC No: 270-325-2 CAS No: 68424-85-1	Minimum purity of the active substance evaluated: 972 g/kg dry weight	1 November 2022	31 October 2032	3	The authorisation of biocidal products is subject to the following conditions: (a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. (b) In the light of the outcome of the risk assessment for the uses assessed, the product assessment shall pay particular attention to: (1) professional users; (2) sediment following disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment; (3) soil following disinfection of vehicles used for animal transport, footwear disinfection and disinfection in hatcheries after fogging treatment. (c) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[2] or Regulation (EC)

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated. 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.

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p.11).

						No 396/2005 of the European Parliament and of the Council[3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					4	The authorisation of biocidal products is subject to the following conditions: (a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. (b) In the light of the outcome of the risk assessment for the uses assessed, the product assessment shall pay particular attention to: (1) professional users; (2) sediment and soil following disinfection in slaughterhouses and butcheries. (c) For products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. (d) Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride shall not be incorporated in materials and articles intended to come into contact with food falling within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[4],

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

[4] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

						unless the Commission has established specific limits on the migration of alkyl (C_{12-16}) dimethylbenzyl ammonium chloride into food or it has been established pursuant to that Regulation that such limits are not necessary.