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[...] (2023) **XXX** draft

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

of **XXX**

**approving Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆))
as an existing active substance for use in biocidal products of product-type 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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approving Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆)) as an existing active substance for use in biocidal products of product-type 2 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(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 products¹, and in particular Article 89(1), third subparagraph, thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆)) for product-type 2 (CAS No: 68424-85-1).
- (2) Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆)) has been evaluated for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council³, which corresponds to product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, 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 European Chemicals Agency ('the Agency').
- (4) It follows from Article 90(2), first subparagraph, of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 are to be assessed in accordance with Directive 98/8/EC.

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).

- (5) In accordance with Article 75(1), second subparagraph, point (a), 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 read in conjunction with Article 75(1) and (4) of Regulation (EU) No 528/2012, the Biocidal Products Committee adopted the opinion of the Agency on 2 December 2021⁴, having regard to the conclusions of the evaluating competent authority. In its opinion, the Agency concluded that Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆)) may be approved as an active substance, but three members of the Biocidal Products Committee provided minority opinions expressing concern for a possible risk for the soil compartment.
- (6) The Commission initiated a further consultation of Member States on the matter in the Standing Committee on Biocidal Products, where it was decided that further discussion was needed at technical level regarding the risk for the soil compartment. Subsequently, a request for an opinion was submitted to the Agency in accordance with Article 75(1), point (g), of Regulation (EU) No 528/2012. The Biocidal Products Committee adopted a revised opinion of the Agency on 7 June 2023⁵, concluding that the risk for the soil compartment is acceptable. According to that opinion of the Agency, the biocidal products of product-type 2 containing Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆)) may be expected to satisfy the requirements laid down in Article 5(1), points (b), (c) and (d), of Directive 98/8/EC, provided that certain requirements concerning their use are complied with.
- (7) Taking into account the opinion of the Agency, it is appropriate to approve Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆)) as an active substance for use in biocidal products of product-type 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

Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride (ADBAC/BKC (C₁₂-C₁₆)) is approved as an active substance for use in biocidal products of product-type 2, subject to the conditions set out in the Annex.

⁴ Biocidal Products Committee Opinion on the application for approval of the active substance Alkyl(C₁₂₋₁₆) dimethylbenzyl ammonium chloride; Product-type: 2; ECHA/BPC/310/2021, adopted on 2 December 2021.

⁵ Biocidal Products Committee Opinion on the application for approval of the active substance Alkyl(C₁₂₋₁₆) dimethylbenzyl ammonium chloride; Product-type: 2; ECHA/BPC/387/2023, adopted on 7 June 2023.

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