



EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION IMPLEMENTING DECISION (EU) .../...

of **XXX**

postponing the expiry date of the approval of alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride for use in biocidal products of product-type 8 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 products¹, and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council² as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it is therefore considered approved under that Regulation subject to the conditions set out in Annex I to Directive 98/8/EC.
- (2) The approval of alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride for use in biocidal products of product-type 8 ('the approval') is to expire on 31 January 2025. On 28 July 2023, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride for use in biocidal products of product-type 8 ('the application').
- (3) On 11 April 2024, the evaluating competent authority of Italy informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

¹ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528>.

² 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, ELI: <http://data.europa.eu/eli/dir/1998/8>).

- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and the time needed for the Commission to decide whether to renew the approval of alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride for use in biocidal products of product-type 8, the expiry date should be postponed to 31 July 2027.
- (7) After the postponement of the expiry date of the approval, alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride remains approved for use in biocidal products of product-type 8 subject to the conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride for use in biocidal products of product-type 8 set out in Annex I to Directive 98/8/EC is postponed to 31 July 2027.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN