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ANNEX

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to the

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

**approving alkyl (C₁₂₋₁₆) 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	<p>The authorisation of biocidal products is subject to the following conditions:</p> <p>(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.</p> <p>(b) In the light of the outcome of the risk assessment for the uses assessed, the product assessment shall pay particular attention to:</p> <ol style="list-style-type: none"> (1) professional users; (2) sediment and soil following disinfection in slaughterhouses and butcheries. <p>(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.</p> <p>(d) Alkyl (C₁₂₋₁₆) 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 Council⁴,</p>

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.
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