EUROPEAN
COMMISSION

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ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) …/...

approving Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid as an existing active substance for use in biocidal products of product-types 2, 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
Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid	IUPAC Name: Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid EC No: N/A CAS No: 139734-65-9	The theoretical calculated dry weight specification: 1000 g/kg (100,0 %, by wt). The active substance as manufactured is an aqueous solution of 160-220 g/kg of Amines, N-C10–C16-alkyltrimethylenedi-, reaction products with chloroacetic acid (16-22 %, by wt).	1 January 2018	31 December 2027	2	The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: a) professional users; b) children for products used in institutional areas; c) surface water and sediment for products used in industrial or institutional areas; d) soil for products used in industrial areas.
					3	The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: a) professional users; b) surface water and sediment for products used for : i)

[1] The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 89(1) of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

						the disinfection of animal housing; ii) the disinfection of vehicles used for animal transport; iii) the disinfection of footwear and animals' hooves; c) soil for products used for the disinfection of vehicles used for animal transport; d) micro-organisms of the sewage treatment plant for products used for the disinfection of footwear and animals' hooves. 3) 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) 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 authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: a) professional users; b) surface water and sediment for products used in: i) food, drink and milk industry sites; ii) milking parlours; iii) slaughterhouses and butcheries and iv)

[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).

[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).

						large scale catering kitchens and canteens; c) soil for products used in i) food, drink and milk industry sites; ii) slaughterhouses and butcheries and iii) large scale catering kitchens and canteens. 3) 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 or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. 4) Products shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of peracetic acid into food or it has been established pursuant to that Regulation that such limits are not necessary.