Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

didecyldimethylammonium chloride

Product type: 3

ECHA/BPC/265/2020

Adopted

6 October 2020

Opinion of the Biocidal Products Committee

on the application for approval of the active substance didecyldimethylammonium chloride for product type 3

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 3 of the following active substance:

Common name:	**Didecyldimethylammonium chloride**
Chemical name:	**N,N-Didecyl-N,N-dimethylammonium chloride**
EC No.:	**230-525-2**
CAS No.:	**7173-51-5**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of two separate applications by Lonza AG & Stepan Europe & Mason Europe Ltd (US DDAC Issues Steering Committee, US ISC) and by Nouryon (ex Akzo Nobel) and Thor (European Quat Consortium, EQC) on 31 July 2007, the evaluating Competent Authority Italy submitted an assessment report and the conclusions of its evaluation to the Commission on 10 September 2012.

The assessment for endocrine disruption properties of didecyldimethylammonium chloride was submitted to ECHA on 21 November 2019. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-28 and BPC-36) and its Working Group (WG V 2017 and WG II 2020). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Italy

The BPC opinion on the approval of the active substance didecyldimethylammonium chloride in product type 3 was adopted on 6 October 2020.

The BPC opinion was adopted by consensus.The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the didecyldimethylammonium chloride in product type 3 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of didecyldimethylammonium chloride in product type 3. The active substance is already approved for product type 8 (Directive 2013/4/EU). Didecyldimethylammonium chloride was notified as an existing active substance, separately by Lonza AG & Stepan Europe & Mason Europe Ltd (US DDAC Issues Steering Committee, US ISC) and by Nouryon (ex Akzo Nobel) and Thor (European Quat Consortium, EQC).

Didecyldimethylammonium chloride is a cationic surfactant-type active substance, which is not manufactured solvent-free, but in process solvents as technical concentrate (in water or water/alcohol). Specifications for the reference sources are established.

The physico-chemical properties of the active substance and biocidal products have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal products.

Validated analytical methods are available for the active substance as manufactured and for the significant impurities. Validated analytical methods are available for the relevant matrices soil, water, food of plant origin and milk. For additional matrices of animal origin, *e.g.* meat, fully validated analytical methods are missing and additional validation data are required at product authorisation (see section 2.5).

Didecyldimethylammonium chloride is currently classified according to Regulation (EC) No 1272/2008 (CLP Regulation).

The classification and labelling for didecyldimethylammonium chloride according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 4 Skin Corr. 1B
	H302 H314
Labelling	
Pictogram Codes	GHS05, GHS07
Signal Word	Danger
Hazard Statement Codes	H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage.

On the basis of the results from the studies presented by US ISC and EQC in their respective dossiers, classification of didecyldimethylammonium chloride was proposed according to principles detailed in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation with amendments and adaptations).

The proposed classification and labelling for didecyldimethylammonium chloride according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 3 Skin Corr.1B STOT SE 3 Aquatic Acute 1 Aquatic Chronic
	H301 H314 H335 H400 H411
Labelling	
Pictogram Codes	GHS05, GHS06, GHS09
Signal Word	Danger
Hazard Statement Codes	H301: Toxic if swallowed. H314: Causes severe skin burns and eye damage. H335: May cause respiratory irritation. H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long lasting effects.
Specific Concentration limits, M-Factors	M factor=10 (Acute)

b) Intended use, target species and effectiveness

Products based on didecyldimethylammonium chloride are disinfectants to be used in areas in which animals are housed, kept or transported. Possible applications include animal house disinfection, including disinfection in hatcheries, animal transport vehicles and footbaths. The in-use concentration can vary, depending on the area and circumstances, *e.g.* frequency of use, level of soiling etc.

Like other quaternary ammonium substances, didecyldimethylammonium chloride is a membrane active agent with a target site predominantly at the cytoplasmic (inner) membrane in bacteria or the plasma membrane in yeasts, leading to membrane disorganization, followed by leakage of the intracellular substance with release of K^+ ions and other cytoplasmic constitutes, and precipitation of cell content leading to cell death.

The assessment of the biocidal activity of the active substance demonstrates that didecyldimethylammonium chloride has a sufficient level of efficacy against the target organisms bacteria and fungi.

Quaternary ammonium compounds have been in use for many years, with no indication that their efficacy in use is diminishing over time. Nevertheless, occasional increase in tolerance has been reported in the literature. The development of resistance is possible for such uses, therefore, at the stage of product authorization, strategies of resistance management will be reviewed if needed.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

The main critical effects associated with didecyldimethylammonium chloride are due to its corrosive properties. The active substance induces severe erythema, desquamation and corrosive eschar in the rabbit skin, and therefore it is classified as corrosive to skin. According

to the available studies on toxicokinetics and metabolism as well as to the toxicity study package, no systemic effects in the absence of local effects were observed in any of those studies. Therefore, only a local risk assessment was considered necessary for the use of didecyldimethylammonium chloride.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary exposure and description of scenario**	**Exposed group**	**Conclusion**
Animal house disinfection	Mixing and loading: dilution of concentrate b.p. (containing 15% or 50% of didecyldimethylammonium chloride) to the in-use concentration (0.4% or 0.5%). PPE for mixing and loading: gloves, goggles, protective coveralls. Spraying: Disinfection of areas in which animals are housed (both coarse and trigger spray application).	Professional users	Acceptable with PPE (PPE needed for mixing and loading, only)
Animal transport disinfection	Mixing and loading (M&L): dilution of concentrate b.p. (containing 15% of didecyldimethylammonium chloride) to the in-use concentration (0.4%). PPE for mixing and loading: gloves, goggles, protective coveralls. Spraying: Disinfection in means of animal transport (both coarse and trigger spray application).	Professional users	Acceptable with PPE (PPE needed for mixing and loading, only)
Egg wash house disinfection (Disinfection of fertilised eggs in hatcheries)[1]	Mixing and loading: dilution of concentrate b.p. (containing 15% of didecyldimethylammonium chloride) to the in-use concentration (0.04%). PPE for mixing and loading: gloves, goggles, protective coveralls. Dipping: Disinfection in hatcheries by dipping.	Professional users	Acceptable with PPE (PPE needed for mixing and loading, only)
Footbaths	Mixing and loading: dilution of concentrate b.p. (containing 15% or 50% of didecyldimethylammonium chloride) to the in-use concentration (3.5% or 0.5%). PPE for mixing and loading: gloves, goggles, protective coveralls. Dipping: Disinfection of human and animal feet by dipping.	Professional users	Acceptable with PPE (PPE needed for mixing and loading, only)

When appropriate risk mitigation measures are in place, including appropriate exposure control measures like PPEs, the potential risks associated with local effects were acceptable for all uses.

[1] Disinfection of fertilised eggs: these are breeding eggs so this scenario is not relevant for consumer exposure via food.

In-use concentrations do not trigger any classification for local effects, so that no qualitative local risk assessment has been performed for inhalation and dermal route. Nevertheless, for primary exposure a semi-quantitative local risk assessment has been conducted.

No exposure is expected via inhalation route due to the dimensions of the particle sizes generated during the coarse trigger spray application. In fact, the assessed product is not volatile and care should be taken that the application process does not result in the forming and exposure of inhalable aerosols. In case of spraying, only coarse sprays (trigger spray) with big droplets are recommended. Coarse sprays with droplets ≥ 40 µm are not inhaled (TGD, EN 481 and WHO classification droplet sizes). Consequently, systemic effects do not occur and exposure/local effect potential is controlled or eliminated based on application equipment (which produces non-respirable particles), use patterns, and/or PPE. In conclusion, no unacceptable risks were highlighted due to the direct applications of the diluted solutions.

Since the in-use dilutions are of low concentration as well as the a.s. has a low volatility, for secondary exposure dermal and inhalation exposure were considered negligible.

Indirect exposure via food

A preliminary livestock exposure for didecyldimethylammonium chloride in PT 3 has been performed according to the available draft guidance. According to this assessment, based on a worst-case consumer exposure, the exposure estimate is below 30% of the ADI and therefore no unacceptable risks are identified from indirect exposure to residues via food ingestion.

Environment

Didecyldimethylammonium chloride is readily biodegradable, and the substance is neither persistent nor problematic metabolites are produced. The substance is hydrolytically stable, and hydrolytic processes do not contribute to its degradation in the environment. Didecyldimethylammonium chloride is neither volatile nor is it expected to be present in the air. Didecyldimethylammonium chloride can be considered immobile in soil and its degradation in soil has been demonstrated by reading across with a soil degradation study carried out on a similar substance (Bardap 26). The potential for bioaccumulation is low.

Among pelagic organisms, *Daphnia magna* and algae have the highest and equivalent sensitivity to other similar compounds; the risk assessment to the pelagic aquatic compartment is driven by the chronic toxicity to algae (lowest absolute endpoint value). For the organisms in sediment compartment, the PNEC derived with the EPM method is used in the risk assessment, as being more conservative than that derived experimentally. The soil characteristics influence the toxicity of the active to terrestrial organisms by modulating its bioavailability. The chronic toxicity to microorganisms (most sensitive organisms in chronic tests) drives the risk assessment. The evaluation of secondary poisoning via aquatic food chain is based on short-term dietary toxicity data on birds and from a 90 days oral repeated dose study with dog retrieved from the human health section and using the fish experimental BCF.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Animal house disinfection (breeding pigs)	Environmental compartments: surface water, sediment, STP and soil	Acceptable
Disinfection of vehicles used for animal transport	Environmental compartments: soil, surface water, sediment and STP	Acceptable for surface water and STP Not acceptable for sediment and soil
Footwear	Environmental compartments: soil, groundwater, surface water, sediment and STP	Acceptable
Animal's feet	Environmental compartments: soil, groundwater, surface water, sediment and STP	Acceptable
Disinfection in hatcheries	Environmental compartments: soil, surface water, sediment and STP	Acceptable for fumigation treatment Not acceptable for sediment and soil after fogging treatment

For the aquatic compartment (surface water, sediment and STP), PEC/PNEC ratios are less than one, demonstrating that the risks to aquatic organisms and to the functioning of sewage treatment plants are acceptable. For sediment only, in disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment the risks are not acceptable. For the terrestrial compartment, the risks to soil dwelling organisms following the uses of didecyldimethylammonium chloride are acceptable, except in disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment.

Overall conclusion

Acceptable risks were identified for all the scenarios for human health, when appropriate RMMs are in place for mixing and loading to prevent local effects.

For the environment, acceptable risks were identified for the animal house, footwear, animal's feet disinfection and disinfection in hatcheries after fumigation treatment. In disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment, for sediment and soil unacceptable risks are demonstrated. There are sufficient safe uses, but RMM are required to prevent unacceptable risks, e.g. waste water treatment prior to discharge to the municipal sewer, reduce the amount applied per square meter and/or reduce to RTU-products intended to disinfect small surfaces.

In conclusion, safe uses covering both the human health and the environment have been identified.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria.

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	Didecyldimethylammonium chloride does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P	Didecyldimethylammonium chloride does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B	
	Toxic (T)	Not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	Didecyldimethylammonium chloride does not fulfil criterion (d) of Article 5(1) No conclusion can be drawn whether didecyldimethylammonium chloride fulfils criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn based on the available data.	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	Didecyldimethylammonium chloride does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Didecyldimethylammonium chloride does not fulfil criterion (e) of Article 10(1)		
Proportion of non-active isomers or impurities	As the proportion of impurities is below 20%, didecyldimethylammonium chloride does not fulfil criterion (f) of Article 10(1)		

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[2] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[3] and with "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[4] agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

Consequently, the following is concluded: didecyldimethylammonium chloride does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012. Didecyldimethylammonium chloride does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, properties of didecyldimethylammonium chloride have been sufficiently investigated and based on the available evidence, the substance does not meet the ED criteria for human health according to the criteria laid down in Regulation (EU) No 2017/2100. With respect to non-target organisms, in relation to the criteria set out in section B of Regulation (EU) No 2017/2100 no conclusion can be drawn based on the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of didecyldimethylammonium chloride for PT 3 was submitted before 1 September 2013.

2.2.2. POP criteria

Didecyldimethylammonium chloride does not meet the PBT criteria. No potential for long-range environmental transport is expected, either. Subsequently, it is concluded that didecyldimethylammonium chloride is not expected to meet the POP criteria.

2.3. BPC opinion on the application for approval of the active substance didecyldimethylammonium chloride in product type 3

In view of the conclusions of the evaluation, it is proposed that didecyldimethylammonium chloride shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 908 g/kg dry weight

[2] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[3] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

4 See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

2. The authorisations of biocidal products are subject to the following condition(s):
    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 view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
        i. Professionals;
        ii. Sediment following disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment;
        iii. Soil following disinfection of vehicles used for animal transport 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[5] or Regulation (EC) No 396/2005[6] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Didecyldimethylammonium chloride meets the criteria for classification according to Regulation (EC) 1272/2008 as skin corrosive of category 1B and aquatic acute category 1. The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

1. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
    a. If an unacceptable risk is identified for industrial and/or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
    b. An assessment of the risk during spraying may be required at product authorisation where use of the product may lead to inhalable aerosol formation (droplets < 40 µm).
    c. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.
    d. Unacceptable risks are identified for sediment and soil following disinfection of vehicles used for animal transport and disinfection in hatcheries after fogging treatment. If the risks cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

[5] Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11
[6] Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of didecyldimethylammonium chloride.

However, as regards the analysis of didecyldimethylammonium chloride residues in various matrices of animal origin (*e.g.* meat), additional validation data should be provided. These data must be provided as soon as possible but not later than 6 months before the date of approval to the eCA (Italy).

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