Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Active chlorine generated from sodium chloride by electrolysis

Product type: 3

ECHA/BPC/196/2018

Adopted

25 April 2018

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

on the application for approval of the active substance active chlorine generated from sodium chloride by electrolysis for product type 3

In accordance with Article 89 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:	**Active chlorine generated from sodium chloride by electrolysis[1]**
Chemical name:	**not applicable**
EC No.:	**not applicable**
CAS No.:	**not applicable**
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 an application by PuriCore Europe Limited subsidiary of Realm Therapeutics PLC and Aqualution Systems Ltd on 31 July 2007, the evaluating Competent Authority Slovak Republic submitted an assessment report and the conclusions of its evaluation to the Commission on 19 November 2010. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the Technical Meeting (TM-I-2012), BPC (BPC-25) and its Working Groups (WG-IV-2017, WG-I-2018). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

[1] as in CA-March15-Doc.5.1-Final, Revised on 23 June 2015, Annex I

Adoption of the BPC opinion

Rapporteur: Slovak Republic

The BPC opinion on the approval of the active substance active chlorine generated from sodium chloride by electrolysis in product type 3 was adopted on 25 April 2018.

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 active chlorine generated from sodium chloride by electrolysis 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 active chlorine generated from sodium chloride by electrolysis in product type 3.

Specification is established for the precursor sodium chloride according to the specification of the European Pharmacopeia 9.0. No reference sources have been set for sodium chloride and no assessment of technical equivalence is required for sodium chloride. Active chlorine is formed in aqueous solution by the electrolysis of sodium chloride to produce an aqueous solution containing approximately 300 mg available Cl_2/L. Active chlorine is a mixture of three species collectively known as available chlorine (chlorine + hypochlorous acid + hypochlorite anion). It is not possible to isolate active chlorine from the aqueous solution. Active chlorine as generated in solution cannot be isolated in its pure form without drastically altering its composition. On this basis, most physico-chemical properties of active chlorine cannot be investigated due to not being technically feasible. In summary, the physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use. Water used for the generation of active chlorine from sodium chloride should be highly purified.

Validated analytical methods are not available for the active substance. Not sufficient quantitative compositional information on the technical active substance generated in situ was included in the CAR for the approval of the active substance. This information should be included in application for product authorisation.

Since in aqueous solution active chlorine is generated from sodium chloride by electrolysis to give an equilibrium of chlorine, hypochlorous acid and hypochlorite anion, which is pH and temperature dependent, classification for active chlorine is not feasible.

b) Intended use, target species and effectiveness

In PT 3, active chlorine generated from sodium chloride by electrolysis is used as disinfection of cow´s teats (professional use, 200-300 mg/L active chlorine), disinfection of animal feet in footbaths in animal houses (professional use, 35 mg/L active chlorine) and disinfection of areas in which animals are housed by spraying (professional use, 200-300 mg/L active chlorine). The data on active chlorine generated from sodium chloride by electrolysis and the representative biocidal product have demonstrated sufficient efficacy against the target species. Active chlorine generated from sodium chloride by electrolysis acts by non-specific oxidising mode of action.

The biocidal product represents equilibrium of hypochlorous acid, chlorine gas and sodium hypochlorite depending on the pH value and temperature.

Active chlorine has bactericidal, fungicidal, yeasticidal, sporicidal and virucidal activity.

The resistance of pathogens to active chlorine is not very probable. Resistance of pathogens to active chlorine is not higher than that of other active substances with a general mode of action (oxidation). There is no need for specific resistance management strategies for active chlorine based disinfectants. They do not differ from those that have already been proposed for other disinfectants with general mode of action, i.e. strict respect for recommended concentration use, strict respect for expiration time period, rotation of disinfectants.

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

Human health

The toxicological profile of active chlorine (as an equilibrium of chlorine, hypochlorous acid and sodium hypochlorite) generated through electrolysis is linked to that of sodium hypochlorite, hypochlorous acid and chlorine gas. Based on the available toxicological data covering the standard information requirements for biocides and some observational human data it was concluded that the only evident toxicological concern is the eye, skin and respiratory tract irritating potential of sodium hypochlorite solutions. Consequently the exposure and risk assessment is carried out for local effects only, as potential local irritating effects would be dominant compared to potential systemic effects. As the relevant use concentrations are below the reference values for local dermal effects and local oral effects, risks via the dermal and oral route can be excluded independent from use pattern. However, potential repiratory exposure depends on the use pattern. Respective exposure estimates are provided and compared to the established acceptable exposure concentration (AEC). Assuming the intended uses as described within this report the risk appears acceptable for all scenarios without specific risk mitigation measures.

A preliminary risk assessment for potential disinfection by-products (DBP) is based on chlorate as representative potentially critical DBP. This assessment indicates an acceptable risk if just the concentration of chlorate as given in the identity of the substance is considered. However, assuming that all of the active chlorine is converted to chlorate (as representative DBP) it would lead to a borderline to acceptable human worker health risk for the animal foot/hoof bath applications or unacceptable risk for all other scenarios. Consequently, more data and a refined assessment are necessary at product authorisation stage.

Only professional exposure may occur during the preparation of the precursor fluid. Solid sodium chloride as the precursor cannot be absorbed via the skin and the crystal is very unlikely to be respired. Oral uptake during professional work is also very unlikely to significantly increase the daily amount consumed via regular diet. The solid salt may cause irritation with daily exposure and therefore gloves are recommended for professionals handling solid salt.

A risk assessment for dietary exposure to chlorate as stable metabolite of hypochlorite is based on an EFSA agreed MRL of 0.01 mg/kg food for chlorate and available BPC draft guidance for dietary risk assessment. Considering just the concentration of chlorate as given in the substance identity, the exposure is likely to remain below the MRL. However considering full conversion of available chlorine to chlorate, MRLs above the EFSA agreed value of 0.01 mg/kg food commodity would result from all scenarios.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Teat disinfection	Primary inhalation and dermal exposure while cleaning cow teats by spraying with active chlorine solution (50 mL) each time the teat cup is removed from the teat.	Professional users	Acceptable
Disinfection of animal feet in foot baths	Active chlorine solution (50 mL) is dosed automatically into the water supply to give a 35 mg/L solution. Primary inhalation and dermal exposure while This solution is then transferred to the footbath	Professional users	Acceptable
Spraying of animal houses	Primary inhalation and dermal exposure while active chlorine solution is sprayed by the professional using a lance	Professional users	Acceptable
Exposure to IBC containing b.p.	Primary inhalation and dermal exposure during mixing and loading	Professional users	Acceptable
Bystanders	Secondary inhalation exposure of bystanders exposed to active chlorine when they are present during use under PT3.	Bystander	Acceptable
Exposure to precursor solid sodium chloride, during the preparation of the precursor fluid	Primary dermal exposure to solid sodium chloride; Skin irritation with daily exposure to solid salt may be considered, therefore gloves are recommended for professionals	Professional users	Acceptable with gloves

Secondary (indirect) exposure to children and adults can occur from touching freshly treated surfaces after spraying of an animal house. However, the exposure concentrations are 0.03% which is below the dermal reference value of 1%. Consequently, there is no concern for the child from indirect exposure (touching freshly treated surfaces after disinfection of an animal house) to available chlorine. Potential bystander exposure would be lower compared to the primary exposure and is therefore also considered acceptable.

Environment

The sum of the hypochlorite ion, hypochlorous acid and chlorine is defined as active chlorine or available chlorine. For the chemical reactivity in an aqueous solution with the same active chlorine concentrations and the same pH conditions, it is irrelevant whether active chlorine is generated from either chlorine gas, calcium hypochlorite, sodium hypochlorite, or from sodium chloride by electrolysis. Therefore, all studies investigating hypochlorite aqueous solutions were used for the evaluation and assessment of active chlorine generated from sodium chloride by electrolysis. For the water component algae were the most sensitive species in long term testing. No toxicity data were available for sediment and soil organisms, so the thresholds for these comparments were calculated from data for aquatic organisms using the equilibrium partitioning method. Active chlorine is highly reactive: it

reacts rapidly with organic matter in the sewer, sewage treatment plant (STP), surface water and soil. Where organic matter is present, it acts as a highly reactive oxidizing agent. Subseqently, active chlorine degrades rapidly in all compartments. Degradation was taken into account between release to the facility drain and inflow into the STP and in the STP. Degradation during the disinfection process and after release of effluent from the STP was not taken into account when calculating emissions. Aggregated risk assessment has been performed and no unacceptable risk was identified. Degradation was considered for the compartments surface water, sediment and soil.

Disinfection by-products are formed due to the use of active chlorine, for example in the STP. The risk to the environment from exposure to disinfection by-products was not evaluated due to the absence of guidance.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Disinfectant for animal housing	Terminal disinfection of animal housing with emission *via* waste water to Sewage Treatment Plant (STP) and to manure. Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable
Disinfectant for teat-dips	Disinfection of cow teat-dips with emission *via* waste water to Sewage Treatment Plant (STP) and to manure. Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable
Disinfectant for animal feet	Disinfection of footwear and animal feet with emission *via* waste water to Sewage Treatment Plant (STP) and to manure. Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable

While degradation was assumed in the sewer the risks for surface water and sediment were acceptable. No unacceptable risks were identified for the soil compartment and for groundwater. For the air compartment the volatilisation of hypochlorite from the STP was considered. As the predicted concentrations were very low the risks for air were considered acceptable.

Emission and exposure to the precursor sodium chloride resulting from all stages of the life-cycle of active chlorine released from active chlorine released by electrolysis from sodium chloride have been assessed in the exposure and risk assessments. Chloride is the only component of the precursor relevant for the environmental assessment. There was no unacceptable risk identified for STP, air, surface water, sediment, soil and groundwater.

Overall conclusion

The risk from the use of the biocidal product for professionals and for the environment is acceptable for all intended use scenarios. However, the exposure to the precursor solid sodium chloride during the preparation of the precursor fluid is only considered acceptable when gloves are worn while handling the salt.

More data and a refined risk assessment for disinfection by-products needs to be provided at product authorisation stage. The MRL setting and dietary risk assessment needs to be reviewed at product authorisation stage.

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	Active chlorine generated from sodium chloride by electrolysis 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 applicable	Active chlorine generated from sodium chloride by electrolysis 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 applicable	
	Toxic (T)	not applicable	
Endocrine disrupting properties	An assessment according to the latest ED criteria[2] has not been undertaken. However, there was no evidence of specific effects on endocrine tissues and organs. A decision on whether or not active chlorine generated from sodium chloride by electrolysis fulfils criterion (d) of Article 5(1) cannot be made.		

[2] Regulations, Commission delegated regulation (EU) 2017/2100 of September 2017 setting out criteria for determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

Respiratory sensitisation properties	No classification required. Active chlorine generated from sodium chloride by electrolysis does not fulfil criterion (b) of Article 10(1)
Concerns linked to critical effects	Active chlorine generated from sodium chloride by electrolysis does not fulfil criterion (e) of Article 10(1)
Proportion of non-active isomers or impurities	Active chlorine generated from sodium chloride by electrolysis does not fulfil criterion (f) of Article 10(1)

Consequently, the following is concluded:

Active chlorine generated from sodium chloride by electrolysis does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Active chlorine generated from sodium chloride by electrolysis 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. 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" and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR" agreed at the 54th and 58th 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). However, the exclusion criteria were not assessed in line with the criteria laid down in the Annex of Regulation (EU) No 2017/2100 which apply as of 7 June 2018.

2.2.2. POP criteria

POP criteria are not applicable to inorganic substances, such as active chlorine generated from sodium chloride by electrolysis.

2.3. BPC opinion on the application for approval of the active substance active chlorine generated from sodium chloride by electrolysis in product type 3

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

1. The specification for active chlorine generated in situ is based on the precursor sodium chloride. The minimum purity of the precursor sodium chloride is 99.0% to 100.5% (dried substance), set according to the specification of the European Pharmacopeia 9.0 for sodium chloride.

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. 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 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.

As classification of active chlorine generated from sodium chloride by electrolysis is not feasible, it is not possible to conclude, if the criteria according to Article 28 (2) (a) are met.

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. It was agreed that sodium chloride can be supplied by open sources. Hence, no reference sources are set for sodium chloride and no assessment of technical equivalence is required for sodium chloride in this case.

    b. Disinfection by-products (DBPs) are formed as a consequence of the use of active chlorine. An assessment of the risks of DBPs will be performed at product authorisation stage.

    c. The EFSA Panel on Contaminants in the Food Chain identified a potential concern related to exposure of infants and young children to chlorate *via* food and drinking water (EFSA Scientific Opinion on “Risks for public health related to the presence of chlorate in food”; EFSA Journal 2015; 13:4135). The Commission is considering approaches to address chlorate residues in food in the context of the legislation on drinking water and/or food hygiene. Any action proposed by the Commission should be taken into account at product authorisation.

    d. 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.

    e. Sufficient quantitative compositional information on the technical active substance generated in situ should be included in application for product authorisation.

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 active chlorine generated from sodium chloride by electrolysis.

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