

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Active chlorine generated from sodium chloride by electrolysis

Product type: 1

ECHA/BPC/250/2020

Adopted

16 June 2020

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 1

In accordance with Article 90(2) 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 1 of the following active substance:

Common name:	Active chlorine generated from sodium chloride by electrolysis¹
Chemical name:	not applicable
EC No.:	not applicable
CAS No.:	not applicable

Existing active substance submitted under Article 11 of the Biocidal Products Directive 98/8/EC

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 BPC-35) and its Working Groups (WG-IV-2017, WG-I-2018 and WG-I-2020). 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 1 was adopted on 16 June 2020.

Due to the entry into force of Regulation (EU) 2017/2100 the Commission returned the BPC opinion to ECHA on 18 June 2018 with the request to revise the opinion already adopted by the Biocidal Products Committee (BPC), related to the application of the criteria for endocrine disrupting properties as laid down in this regulation.

In addition, the Commission requested to ECHA for an opinion on sodium chloride specification and water quality for the generation of active chlorine by electrolysis pursuant to Article 75(l)(g) of Regulation (EU) No 528/2012. This request was based on the industry's concerns that they would not be able to meet the specification for sodium chloride and water as adopted in the BPC opinion of 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 1 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 1.

The specification is established for the precursor sodium chloride as follows: sodium chloride can be supplied from the sources which comply with the norms NF Brand, EN 973 A, EN 973 B, EN 14805 Type 1, EN 14805 Type 2, EN 16370 Type 1, EN 16370 Type 2, EN 16401 Type 1, EN 16401 Type 2, CODEX STAN 150-1985 and European Pharmacopoeia 9.0. The Certificates of analysis to confirm one of the norms should be provided at the product authorization stage. No reference sources have been set for sodium chloride and no assessment of technical equivalence is required for sodium chloride.

To address differences among the standards and to ensure a consistent level of purity of the generated active chlorine, the specification of the generated active chlorine is set according to European Standard on EN 901:2013 including the maximum content of the relevant impurities sodium chlorate of $\leq 5.4\%$ w/w of available chlorine and sodium bromate of $\leq 0.5\%$ w/w of available chlorine, but excluding the heavy metals. The compliance with this specification has to be demonstrated when submitting an application for product authorisation.

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.

If the water quality used for the generation of active chlorine has an impact on the composition of the generated active chlorine this should be considered during the assessment of disinfection by-products (DBPs) at product authorisation stage.

Validated analytical methods are not available for the active substance. Not sufficient quantitative compositional information regarding the active substance generated in situ, which would confirm the specification according to the standard EN 901:2013 was included in the application for 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 1, active chlorine generated from sodium chloride by electrolysis is used as hand wash/skin disinfection in healthcare (professional and non-professional use, 200-300 mg/L active chlorine) and foot wash/skin disinfection in healthcare (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 table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	Primary exposure and description of scenario	Exposed group	Conclusion
Hand washing from dispenser	Primary inhalation and dermal exposure; skin disinfection in healthcare, including medical personnel, patients and hospital visitors using up to 0.03% ready-to-use solution.	Professional users and non-professional users	Acceptable
Feet-treatment	Primary inhalation and dermal exposure; skin disinfection in healthcare, professionals using a 0.03% ready-to-use solution.	Professional users	Acceptable
Filling of foot baths and dispensers	Primary inhalation and dermal exposure; Mixing and loading in healthcare, professionals using a 0.03% ready-to-use solution	Professional users	Acceptable
Bystanders	Secondary inhalation exposure of bystanders exposed to active chlorine when they are present during skin disinfection.	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
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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 irritation effects would be dominant compared to potential systemic effects. As the 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. Moreover the oral route does not appear relevant for PT 1. In contrast, respiratory exposure is potentially relevant and depends on the use pattern. Respective exposure estimates are provided and compared to the established acceptable exposure concentration (AEC). Assuming ventilation rates in a usual hospital situation also these estimates indicate acceptable risks for local respiratory effects.

Potential bystander exposure would be lower compared to the primary exposure and is therefore also considered acceptable.

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 an unacceptable risk. 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.

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 compartments 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.

Subsequently, 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.

Disinfectant 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
Hand disinfection in hospitals: professional and non-professional use	Emission via waste water to sewage treatment plant (STP). Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable
Feet disinfection in hospitals: professional use	Emission via waste water to sewage treatment plant (STP). 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 non-professionals (only hand washing) and for the environment is acceptable for the 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. A refined risk assessment for disinfection by-products needs to be provided 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	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No conclusion can be drawn based on the available data.	No conclusion can be drawn whether Active chlorine generated from sodium chloride by electrolysis fulfils criterion (d) of Article 5(1) and/or 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	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 other than those related to endocrine disrupting properties	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)

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, 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:

Active chlorine generated from sodium chloride by electrolysis does not meet the exclusion criteria laid down in Article 5(1)(a, b, c and e) of Regulation (EU) No 528/2012. For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, the necessary data was not submitted and no conclusion can be drawn based on the available data. The EFSA Scientific Opinion “Risks for public health related to the presence of chlorate in food”; (EFSA Journal 2015; 13:4135) suggests that chlorate may disrupt the thyroid hormone homeostasis. An assessment of the endocrine-disrupting properties of chlorate was not performed and no conclusion can be drawn based on the available data. According to the CA meeting note mentioned above, for reports submitted before 1 September 2013, the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant. In case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. As the evaluation of active chlorine generated from sodium chloride by electrolysis for PT 1 was submitted before 1 September 2013, no conclusion is drawn whether active chlorine generated from sodium chloride by electrolysis meets the conditions laid down in Article 5(1)(d) based on the available data.

Active chlorine generated from sodium chloride by electrolysis does not meet the conditions laid down in Article 10(1)(b, c, d and f) of Regulation (EU) No 528/2012. As the evaluation of active chlorine generated from sodium chloride by electrolysis for PT 1 was submitted before 1 September 2013, no conclusion is drawn whether active chlorine generated from sodium chloride by electrolysis meets the conditions laid down in Article 10(1)(a and e) based on the available data.

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](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 (available from <https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details>)

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 1

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 norms NF Brand, EN 973 A, EN 973 B, EN 14805 Type 1, EN 14805 Type 2, EN 16370 Type 1, EN 16370 Type 2, EN 16401 Type 1, EN 16401 Type 2, CODEX STAN 150-1985 and European Pharmacopoeia 9.0 can be used.
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.

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. Confirmation with the accepted norms (NF Brand, EN 973 A, EN 973 B, EN 14805 Type 1, EN 14805 Type 2, EN 16370 Type 1, EN 16370 Type 2, EN 16401 Type 1, EN 16401 Type 2, CODEX STAN 150-1985 and European Pharmacopoeia 9.0) has to be demonstrated at product authorization stage by submitting certificates of analysis.
 - 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. It should be demonstrated that the active substance generated in situ complies with the specification according to the standard EN 901:2013 including the maximum content of the relevant impurities sodium chlorate of $\leq 5.4\%$ w/w of available chlorine and sodium bromate of $\leq 0.5\%$ w/w of available chlorine, but excluding the heavy metals. The compliance with the specification of the active substance has to be demonstrated when submitting an application for product authorisation, according to the revised Recommendation of the BPC Working Groups "In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ, their precursors and biocidal products".

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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