

Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Active chlorine released from hypochlorous acid

Product type: 2

ECHA/BPC/256/2020

Adopted

16 June 2020

Opinion of the Biocidal Products Committee

on the application for approval of the active substance active chlorine released from hypochlorous acid for product type 2

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 2 of the following active substance:

Common name:	Active chlorine released from hypochlorous acid
Chemical name of the releaser:	Hypochlorous acid
EC No. of the releaser:	232-232-5
CAS No. of the releaser:	7790-92-3
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, BPC-35) and its Working Groups (WG-IV-2017, WG-I-2018, WG-I-2020). During the peer review the common name of the biocide was changed from 'Active Chlorine: manufactured by the reaction of hypochlorous acid and sodium hypochlorite produced *in situ*' to 'Active chlorine released from hypochlorous acid'. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Slovak Republic

The BPC opinion on the approval of the active substance active chlorine released from hypochlorous acid in product type 2 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.

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 released from hypochlorous acid in product type 2 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 released from hypochlorous acid (HOCl) in product type 2. The active substance is generated by electrolysis of a diluted aqueous solution of sodium chloride, by which chlorine is formed and undergoes rapid hydrolysis to hypochlorous acid. The generated solution is bottled and forms the product¹.

Hypochlorous acid is very weak acid. Hypochlorous acid is known only in aqueous solution, formed by the action of water on chlorine. Hypochlorous acid cannot be isolated in its pure form and it is technically not feasible to determine most of the physico-chemical properties.

Data on hypochlorous acid are mainly based on data of recently performed studies on a 24% available chlorine solution (chlorine + hypochlorous acid + hypochlorite anion) and on literature data, which also addresses those physical-chemical parameters which are meaningful for hypochlorous acid. Specification for the reference source is established. One relevant impurity is present: sodium chlorate ($\leq 0.0007\%$ w/w of available chlorine).

In summary, the physico-chemical properties of the releaser and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the releaser hypochlorous acid and for the active substance as manufactured.

Hypochlorous acid is not currently listed in Annex VI of Regulation 1272/2008. A classification proposal is currently not available. Consequently, the submission of a CLH dossier is required. However, it needs to be taken into account that hypochlorous acid cannot be isolated in its pure form.

b) Intended use, target species and effectiveness

In PT 2, active chlorine released from hypochlorous acid is used as hard surface disinfection (professional use, 200-300 mg/L active chlorine) and disinfection of dental lines² (professional use, 5 mg/L active chlorine). The data on active chlorine released from hypochlorous acid and the representative biocidal product have demonstrated sufficient efficacy against the target species. Active chlorine released from hypochlorous acid acts by non-specific oxidising mode of action.

¹ Originally, the dossier for active chlorine released from hypochlorous acid was submitted under the Biocidal Products Directive as part of the dossier on active chlorine generated from sodium chloride by electrolysis. During the peer review it was concluded however that these are distinct active substances. Consequently, the original dossier was split in two: active chlorine generated from sodium chloride by electrolysis and active chlorine released from hypochlorous acid.

² Although the use disinfection of dental lines was included in the evaluation, it should be noted that this use falls under Directive 93/42/EEC concerning medical devices.

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 irritation 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 respiratory exposure depends on the use pattern. Respective exposure estimates are provided and compared to the established acceptable exposure concentration. Assuming the intended uses as described within this report the risk appears acceptable for all scenarios except for “hard surface disinfection” for floor surfaces, e.g. *via* mopping. The exposure estimate is about 14 fold above the AEC short and long term value of 0.5 mg/m³. Therefore, this use is not supported.

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 acceptable risk just for the patient exposure to in use solutions with dental lines, but none of the other exposure scenarios. Consequently, more data and a refined assessment are necessary at product authorisation stage.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	Primary and secondary exposure and description of scenario	Exposed group	Conclusion
Hard surface disinfection – manual, mopping and wiping (PT 2.01)	Primary inhalation and dermal exposure while pouring product directly onto hard surface or cloth and cleaning surface.	Professional users	Inhalation exposure: Not acceptable
			Dermal exposure: Acceptable
Hard surface disinfection – trigger sprayer (PT 2.01)	Primary inhalation and dermal exposure while spraying product directly onto hard surface or cloth and cleaning surface (1.25 mL per spray)	Professional users	Acceptable
Dental line disinfection (PT 2.01) ²	Primary inhalation and dermal exposure; dental line – handled by dental nurse using up to 0.03% solution	Professional users	Acceptable

Child patient at dentist drinking water treated with active chlorine	Secondary dermal and oral exposure to a patient drinking water.	General public	Acceptable
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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. 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
Disinfectant for hard surfaces	Disinfection of rooms, furniture and objects with emission <i>via</i> waste water to Sewage Treatment Plant (STP). Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable
Disinfectant for equipment	Disinfection of dental lines with emission <i>via</i> 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 and acceptable risks identified.

Overall conclusion

The primary and secondary exposure risk for human health is acceptable for the intended use scenarios, except for “hard-surface disinfection – manual”. A label is required: “Must not be used for large floor surface disinfection indoors.”

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

Acceptable risks were identified for all scenarios for the environment.

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 released from hypochlorous acid 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 released from hypochlorous acid 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 released from hypochlorous acid 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 released from hypochlorous acid does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Active chlorine released from hypochlorous acid does not fulfil criterion (e) of Article 10(1)		
Proportion of non-active isomers or impurities	Active chlorine released from hypochlorous acid 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”³, with “Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR”⁴ and with “Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment”⁵ 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 released from hypochlorous acid 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

³ 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>)

⁴ 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))

⁵ 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>)

active chlorine released from hypochlorous acid for PT 2 was submitted before 1 September 2013, no conclusion is drawn whether active chlorine released from hypochlorous acid meets the conditions laid down in Article 5(1)(d) based on the available data.

Active chlorine released from hypochlorous acid 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 released from hypochlorous acid for PT 2 was submitted before 1 September 2013, no conclusion is drawn whether active chlorine released from hypochlorous acid meets the conditions laid down in Article 10(1)(a and e) based on the available data.

2.2.2. POP criteria

POP criteria are not applicable to inorganic substances, such as active chlorine released from hypochlorous acid.

2.3. BPC opinion on the application for approval of the active substance active chlorine released from hypochlorous acid in product type 2

In view of the conclusions of the evaluation, it is proposed that active chlorine released from hypochlorous acid shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification established for hypochlorous acid (as dry weight min 90.87% w/w) releasing active chlorine, which is placed on the market as biocidal product (bottled). Hypochlorous acid is the predominant species at pH 3.0 - 7.4. Sodium chlorate (relevant impurity): $\leq 0.0007\%$ w/w of available chlorine.
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. professional users for hard surface disinfection via mopping or wiping

Since no CLP proposal is available, it cannot be concluded, if the active substance fulfils the criteria according to Article 28 (1) to enable inclusion in Annex I of Regulation (EU) No 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. An unacceptable risk for professional users is identified for hard surface disinfection of large surfaces, e.g. via mopping and wiping. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures, this use should not be authorised.
 - b. Disinfectant by-products are formed as a consequence of the use of active chlorine. An assessment of the risks of disinfectant by-products will be performed at product authorisation stage.

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 released from hypochlorous acid.

However, further study is required:

- A new 5-batch analysis of the company Aqualution Systems Ltd should be provided to the evaluating Competent Authority (Slovakia) as soon as possible but not later than 6 months before the date of approval of the active substance.

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