Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Active chlorine released from hypochlorous acid

Product type: 4

ECHA/BPC/202/2018

Adopted

25 April 2018

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance active chlorine released from hypochlorous acid for product type 4

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) and its Working Groups (WG-IV-2017, WG-I-2018). 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 4 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 released from hypochlorous acid in product type 4 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 4. 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 product[1].

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.

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 4, active chlorine released from hypochlorous acid is used as hard surface disinfection/disinfection in food and feed industry (professional use, 200-300 mg/L active chlorine) and cleaning in place/cleaning in food and beverage industry (professional use, 200-300 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.

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

[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 conclude 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.

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 unacceptable risk for all scenarios. Consequently, more data and a refined assessment are necessary at product authorisation stage.

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 extimate for table surface cleaing is likely to remain borderline or 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 this scenario. For the risk assessment “cleaning in place” an EFSA CONTAM panel assessment is available concluding “that chronic exposures are of concern in particular in younger age groups with mild or moderate iodine deficiency”. Follow up work is under consideration by EC.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios					
Scenario	**Primary exposure and description of scenario**			**Exposed group**	**Conclusion**
	Route of exposure	**Reference value (local effects)**	**Potential exposure to concentration of available Cl**		
Spraying of tables in restaurants	Primary inhalation and dermal exposure while spraying active chlorine solution onto hard surface or cloth and cleaning surfaces.			Professional users	Acceptable
Filling of trigger sprayer	Primary inhalation and dermal exposure while filling sprayer with active chlorine solution			Professional users	Acceptable
Use of generator in Cleaning-in-place	Primary inhalation and dermal exposure while active chlorine solution is produced by electrolysis of the precursor in a generator and dosed into lines and vessels.			Professional users	Acceptable
Bystanders	Secondary inhalation exposure of bystanders exposed to active chlorine when they are present during use under PT4.			Bystander	Acceptable

Secondary (indirect) exposure to children and adults can occur from touching freshly disinfected tables. 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 tables in restaurants) 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. 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.

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 slaughterhouses/ butcheries	Surface disinfection by spraying of slaughterhouse/butchery with emission via waste water to Sewage Treatment Plant (STP). Compartments assessed: STP, air, surface water, sediment, soil and groundwater	Acceptable
Disinfectant for large catering kitchen	Surface disinfection by spraying of large scale catering kitchen with 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.

Overall conclusion

The risk from the use of the biocidal product for professionals and for the environment is acceptable for the use scenario.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>no classification required</td><td rowspan="3">Active chlorine released from hypochlorous acid does not fulfil criterion (a), (b) and (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>no classification required</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>no classification required</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>not applicable</td><td rowspan="3">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)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>not applicable</td></tr>
<tr><td>Toxic (T)</td><td>not applicable</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">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 released from hypochlorous acid fulfils criterion (d) of Article 5(1) cannot be made.</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Active chlorine released from hypochlorous acid does not fulfil criterion (b) of Article 10(1)</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Active chlorine released from hypochlorous acid does not fulfil criterion (e) of Article 10(1)</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">Active chlorine released from hypochlorous acid does not fulfil criterion (f) of Article 10(1)</td></tr>
</table>

[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

Consequently, the following is concluded:

Active chlorine released from hypochlorous acid does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Active chlorine released from hypochlorous acid 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 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 4

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.

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.

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. 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.

    b. 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.

    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.

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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