Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Active chlorine released from sodium hypochlorite

Product type: 5

ECHA/BPC/131/2016

Adopted

14 December 2016

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 released from sodium hypochlorite for product type 5

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 5 of the following active substance:

Common name:	**active chlorine released from sodium hypochlorite***
Chemical name of the reelaser:	**sodium hypochlorite**
EC No. of the reelaser:	**231-668-3**
CAS No. of the reelaser:	**7681-52-9**
Existing active substance	

*as in *CA-March15-Doc.5.1-Final, Revised on 23 June 2015, Annex II – Releasers*

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 Euro Chlor Sodium Hypochlorite Registration Group on 31 July 2007, the evaluating Competent Authority Italy submitted an assessment report and the conclusions of its evaluation to the Commission on 17 May 2010. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Commission organised consultations via the Technical Meetings (TM-I-2012 and TM-II-2012) and the Agency organised consultations via the BPC (BPC-18) and its Working Groups (WG-II-2016, WG-III-2016 and WG-IV-2016). 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 active chlorine released from sodium hypochlorite in product type 5 was adopted on 14 December 2016.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage:

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 active chlorine released from sodium hypochlorite in product type 5 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 sodium hypochlorite in product type 5. Active chlorine is efficacious chlorine or available/releasable chlorine that is disinfectant, algaecide, fungicide and microbiocide. Upon use sodium hypochlorite releases active chlorine by hydrolysing in water to hypochlorous acid, which can react to chlorine depending on pH. The ratio of chlorine, hypochlorous acid and hypochlorite anion in the equilibrium aqueous solution is pH and temperature dependent. The evaluation is based on the assessment of the releaser: sodium hypochlorite, and of the active substance: active chlorine, being the equilibrium aqueous solution. Specifications for the reference sources are established.

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 releaser and biocidal product.

A validated analytical method is available for sodium hypochlorite as manufactured and for the active substance. No validated analytical methods are available for the relevant impurity sodium chlorate and some other impurities (see section 2.5). A validated analytical method is required for the relevant matrix drinking water. However, for drinking water a validated analytical method is missing and required at product authorisation (see section 2.5). For food and feed in principle validated analytical methods are required for the active substance. However, as active chlorine released from sodium hypochlorite degrades rapidly in contact with food and feed matrices, no methods are to be submitted. For chlorate, a relevant metabolite, validated analytical methods are required for drinking water and food and feed, but not available.

An opinion adopted by the EFSA Panel on Contaminants in the Food Chain of 2015 on chlorate is available. This opinion was used in the dietary risk assessment on chlorate, a metabolite of active chlorine.

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

The harmonised classification and labelling for the releaser "sodium hypochlorite … %Cl active" according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Skin Corr. 1B H 314 Aquatic Acute 1 H400
Suppl. Hazard statement code	EUH031
Labelling	
Pictogram codes	GHS05 and GHS09
Signal Word	Danger
Hazard Statement Codes	H314 Causes severe skin burns and eye damage H400 Very toxic to aquatic life
Suppl. Hazard statement code	EUH031 Contact with acids liberates toxic gas
Specific Concentration limits, M-Factors	EUH031 C ≥ 5 % Note B
Justification for the proposal	
-	

The proposed classification and labelling for the releaser "sodium hypochlorite, solution … %Cl active" according to Regulation (EC) No 1272/2008 (CLP Regulation) was adopted by the Risk Assessment Committee (RAC) in June 2016:

Classification according to the CLP Regulation adopted by RAC	
Hazard Class and Category Codes	Skin Corr. 1B H 314 Aquatic Acute 1 H400 Aquatic Chronic 1 H410
Suppl. Hazard statement code	EUH031
Labelling	
Pictogram codes	GHS05 and GHS09
Signal Word	Danger
Hazard Statement Codes	H314 Causes severe skin burns and eye damage H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long-lasting effects
Suppl. Hazard statement code	EUH031 Contact with acids liberates toxic gas
Specific Concentration limits, M-Factors	EUH031 C ≥ 5 % M = 10 (acute) and 1 (chronic) Note B
Justification for the proposal	
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b) Intended use, target species and effectiveness

Active chlorine has strong bactericidal, fungicidal, sporicidal and virucidal activity. In PT 5, active chlorine released from sodium hypochlorite is used by professionals for the disinfection of drinking water for human consumption (0.5 mg/L active chlorine).

The efficacy depends on the active chlorine concentration and decreases with an increase in pH and vice versa, which is parallel to the concentration of hypochlorous acid. The efficacy is strongly reduced by the presence of organic load and in general by the presence of

particles. Sufficient information for the active substance is available to conclude that biocidal products may be expected to be efficacious against the target organisms.

Although different species vary in their sensitivity to active chlorine, development of acquired resistance is not expected since its multiple molecular sites of attack on the surface and within the microbial cells. For the same reasons cross-resistance is not to be expected, nor has it been observed.

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

Human health

The primary mode of action of active chlorine released from sodium hypochlorite in aqueous solutions is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity. Any systemic effects seen in animal studies are considered to be secondary to local irritation/corrosion. Consequently, only a local risk assessment was performed for all relevant routes of exposure to active chlorine (i.e. dermal, inhalation and where relevant oral) which is considered to also cover the risk resulting from potential systemic effects.

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**
Drinking water disinfection	Primary exposure. Large scale disinfection of drinking water where exposure is possible: - mixing and loading (M&L) (disconnection/connection of containers; PPE: gloves, goggles, protective clothing, closed footwear, RPE10) - post-application (handling of containers) - maintenance of the pumping system (PPE: gloves, goggles, protective clothing, closed footwear) - maintenance of the circuit system	Professional users	Acceptable with PPE/RPE
Bystanders	Secondary exposure. exposure of bystanders present during or following the use of biocidal product. During mixing and loading RPE10.	Bystanders	Acceptable with RPE
Showering	Secondary exposure to aqueous solutions by oral, dermal and inhalation route during showering with chlorinated water.	General public	Acceptable
Consumption of chlorinated drinking water	Secondary oral exposure of the general public to aqueous solutions during consumption of chlorinated drinking water.	General public	Acceptable

For primary exposure scenarios, a local risk assessment (quantitative and/or qualitative as appropriate) was performed considering dermal and inhalation exposures. Primary exposure

during human drinking water disinfection is acceptable without PPE for tasks with exposure to the in-use dilution (i.e. maintenance of the circuit system), and for tasks where exposure to the concentrated product is possible (i.e. mixing and loading, maintenance of pumping system) with PPE/RPE (gloves, goggles, protective clothing, closed footwear and for M&L RPE10).

Due to the high reactivity of chlorine species such as hypochlorite, residues on surfaces degrade rapidly. Moreover, in-use dilutions are of low concentration. Thus secondary exposure via dermal route is considered negligible, and only indirect inhalation exposure is assessed. Due to the rapid chemical degradation and the local mode of action, only acute secondary scenarios are considered relevant. The secondary exposures are acceptable, provided that during the mixing and loading tasks only professional bystanders wearing RPE may be present.

Indirect exposure via food Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly. Hence, residue formation is assumed to be negligible for aqueous solutions of chlorine. Conversely, chlorate residues, a stable metabolite that can be formed from hypochlorite in aqueous chlorine solutions, are considered relevant for dietary exposure from the uses of active chlorine as drinking water and/or food area disinfectant.

Active chlorine is widely used for disinfection of surfaces and equipment in food and feed processing areas as well as for disinfection of drinking water, and thus, chlorate residues can be carried-over into food and feed during cleaning, washing and processing steps.

The EFSA CONTAM Panel carried out a comprehensive dietary exposure and risk assessment for chlorate residues in food and drinking water based on occurrence data (EFSA Scientific Opinion of the on "Risks for public health related to the presence of chlorate in food" (EFSA Journal 2015; 13:4135). It considered chlorate contamination in food to be most likely derived from biocidal uses of active chlorines. Accordingly, CONTAM Panel assumed that chlorate residues in food result mainly form the use of chlorinated water for food processing (e.g. washing) and from the disinfection of surfaces and food processing equipment coming into contact with food. In addition, one of the main average contributors to the chronic dietary exposure to chlorate was 'Drinking water'. A potential concern was identified based on current occurrence data for chronic exposure of infants, toddlers and in some cases in other children groups. The CONTAM Panel identified the need for further information related to the hazards, occurrence and impact of food processing related to chlorate in food. In addition, it was recommended that efforts to reduce chlorate residues in food should take into account whether these would have an impact on microbiological food safety. Overall, the potential concern for chlorate residues in food has to be addressed in the context of the legislation on drinking water and/or food hygiene.

In addition, a preliminary livestock exposure assessment to chlorate was performed based on draft guidance. The preliminary assessment, based on worst-case consumer exposure the acceptable daily intake is below 30% and no MRL setting is required according to EMA Guidance on MRL setting.

In the absence of guidance, no assessment of disinfectant-by-products has been performed.

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 or sodium hypochlorite. Therefore, all studies investigating hypochlorite aqueous solutions were used for the evaluation and assessment of active chlorine released from any of the three substances. For the water compartment 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, in all compartments active chlorine degrades rapidly. Degradation was taken into account during the disinfection process, between release to the facility drain to the STP and inflow, into the STP and after release of the effluent or sludge from the STP to the environment in the compartments surface water, sediment and soil.

Disinfectant by-products are formed due to the use of active chlorine, for example in the STP. This 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**
Disinfection of drinking water for human consumption: large scale chlorination	Emission to Sewage Treatment Plant (STP) via waste water. Emission to surface water, sediment, soil and groundwater via STP. Compartments assessed: STP, air, surface water, sediment, soil and groundwater.	Acceptable

No unacceptable risks were identified for any of the compartments. For the air compartment the volatilisation of hypochlorite from the STP was considered for the scenario. As the predicted concentrations were very low the risks for air was considered acceptable.

Overall conclusion

Acceptable risks were identified for all scenarios for human health when appropriate RMMs are in place to prevent local effects. 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 sodium hypochlorite
	Mutagenicity (M)	no classification	

		required	does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Toxic for reproduction (R)	no classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	Active chlorine released from sodium hypochlorite 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 or vB	
	Toxic (T)	T	
Endocrine disrupting properties	Active chlorine released from sodium hypochlorite is not considered to have endocrine disrupting properties. Active chlorine released from sodium hypochlorite does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Active chlorine released from sodium hypochlorite does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects	Active chlorine released from sodium hypochlorite does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Active chlorine released from sodium hypochlorite does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Active chlorine released from sodium hypochlorite 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"[1] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[2] 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).

[1] 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)

[2] 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)

2.2.2. POP criteria

POP criteria are non applicable to inorganic substances, such as active chlorine released from sodium hypochlorite.

2.3. BPC opinion on the application for approval of the active substance active chlorine released from sodium hypochlorite in product type 5

In view of the conclusions of the evaluation, it is proposed that active chlorine released from sodium hypochlorite 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 releaser sodium hypochlorite: aqueous solution with an active chlorine concentration ≤180 g/kg (i.e. ≤18% w/w). Sodium chlorate (relevant impurity): ≤5.4% of the active 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. Professionals.
    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 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.

Sodium hypochlorite is classified for skin corrosion category 1B and aquatic acute category 1. The active substance does fulfil the criteria according to Article 28(2)(a) and therefore active chlorine released from sodium hypochlorite cannot be included in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

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 professional users, safe operational procedures and appropriate organizational 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. 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.

d. Disinfectant by-products are formed as a consequence of the use of active chlorine released from sodium hypochlorite. Due to the absence of guidance, which is under development, an assessment of the risks of disinfectant by-products could not be performed. When guidance becomes available this will have to be performed.

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 sodium hypochlorite.

However, further studies are required:

- a new test for oxidising liquids and a new test for explosives (at the maximum available concentration of sodium hypochlorite in water) according to the UN Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria, in order to investigate the oxidising and explosive properties, respectively, of sodium hypochlorite as manufactured;
- validated analytical methods for impurities (including sodium chlorate) in sodium hypochlorite as manufactured;
- validated analytical methods for active chlorine residues and for the relevant metabolite chlorate in drinking water;
- validated analytical methods for residues of the relevant metabolite chlorate in food and feed.

These studies must be provided as soon as possible but no later than 6 months before the date of approval to the eCA (Italy).

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