Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Active chlorine released from sodium hypochlorite

Product type: 3

ECHA/BPC/129/2016

Adopted

14 December 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance active chlorine released from sodium hypochlorite for product type 3

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 3 of the following active substance:

Common name:	**active chlorine released from sodium hypochlorite***
Chemical name of the reelaser:	**sodium hypochlorite**
EC No. of the releaser:	**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 3 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 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 released from sodium hypochlorite in product type 3. Active chlorine is efficacious chlorine or available/releasable chlorine that is disinfectant, algaecide, fungicide and microbicide. 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 (see section 2.5).

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 3, active chlorine released from sodium hypochlorite is used for: i) disinfection of animal housing and of vehicles used for animal transport by low pressure spraying (2000 mg/L active chlorinte) by professionals, and ii) disinfection of cases and litter trays for pets by a trigger spray (30000 mg/L active chlorine) or by wiping and mopping (5000 mg/L active chlorine) by non-professionals.

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 (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**
Disinfection of animal houses	Primary exposure. Disinfection of areas in which animals are housed by spraying. PPE for mixing and loading: gloves, goggles, protective clothing, closed footwear.	Professional users	Acceptable with PPE
Disinfection of animal transportation	Primary exposure. Disinfection in means of animal transport by spraying. PPE for mixing and loading: gloves, goggles, protective clothing, closed footwear.	Professional users	Acceptable with PPE
Spraying pets cases and litter trays	Primary exposure. Disinfection of pets' cases and litter trays by spraying with ready-to-use trigger spray, assuming product integrated RMM to avoid dermal exposure during application.	Non-professional users	Acceptable with RMM
Wiping pets cases and litter trays	Primary exposure. Disinfection of pets' cases and litter trays by wiping. Product integrated RMMs are assumed to avoid exposure during mixing and loading.	Non-professional users	Acceptable with RMM
Bystanders during disinfection	Secondary inhalation exposure of bystanders during disinfection of - animal houses or - animal transportation vehicles - pets' cases and litter trays.	Bystanders	Acceptable

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

exposure scenarios were acceptable provided appropriate RMMs are in place. For the tasks carried out by professional users, where exposure to the solution causing corrosive/irritant effects is possible, the wearing of appropriate PPE (gloves, goggles, protective clothing, closed footwear), as well as other RMMs, including engineering controls, safe operational procedures and appropriate organizational measures is required. For non-professional users for the tasks where exposure to a solution triggering local effects is possible, i.e. adding the solution in a bucket by decanting or a dosing cap or during spray application of a ready-to-use product, adequate product integrated risk mitigation measures are required to limit dermal exposure to the solution. These measures may include engineering controls, like packaging, formulation controls etc.

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 was assessed. Due to the rapid chemical degradation and the local mode of action, only acute secondary scenarios were considered relevant. All secondary exposure scenarios are acceptable.

Indirect exposure via food In contrast to active chlorine, chlorate residues, a stable metabolite that can be formed from hypochlorite in aqueous chlorine solutions, are considered relevant for dietary exposure. A preliminary livestock exposure assessment to chlorate was performed based on draft guidance. The assessment was based on the concentration of chlorate according to the sodium hypochlorite specification; the potential generation of chlorate during or post application was not considered. According to the preliminary assessment, based on worst-case consumer exposure, the acceptable daily intake is below 30% and therefore in line with the *Guideline on risk characterisation and assessment of maximum residue limits (MRL) for biocides* of the European Medicines Agency the procedure for MRL assessment is not triggered.

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 animal housing	Veal calves, ducks and turkey in free range on litter floors. Emissions from spraying to slurry/manure. The slurry/manure will be spread on grassland or arable land and lead to exposure of soil and groundwater. Additionally, disinfection of turkey housings leads to emission to the sewer system. Compartments assessed: Sewage Treatment Plant (STP), air, surface water, sediment, soil and groundwater The scenarios for veal calves, ducks and turkey cover the other animal categories.	Acceptable
Disinfection of vehicles used for animal transport	Animal transport for cattle and poultry. Waste water emissions from spraying to the STP. Compartments assessed: Sewage Treatment Plant (STP), air, surface water, sediment, soi and groundwater	Acceptable

*Covering also disinfection of pet case and litter trays.

For both scenarios risks were identified for surface water and sediment when no degradation in the sewer or in manure/slurry was assumed, while for the soil compartment risks were identified only for the disinfection of animal housing. If degradation was assumed the risks were acceptable. No unacceptable risks were identified for the STP, the soil compartment and for groundwater. For the air compartment the volatilisation of hypochlorite during application was considered for both scenarios. As the predicted concentrations were very low the risks for air were 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 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 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

[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)

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).

2.2.2. POP criteria

POP criteria are not 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 3

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. Professional and non-professional users.
    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. If an unacceptable risk is identified for non-professional users due to exposure to the biocidal product triggering local effects, appropriate product integrated risk mitigation measures, like packaging and/or formulation controls, or other engineering controls shall be applied.

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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