# Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

**Active chlorine released from sodium hypochlorite**

**Product type: 1**

ECHA/BPC/127/2016

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 1**

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 1 of the following active substance:

| | |
|---|---|
| **Common name:** | **active chlorine released from sodium hypochlorite*** |
| **Chemical name of the releaser:** | **sodium hypochlorite** |
| **EC No. of the releaser:** | **231-668-3** |
| **CAS No. of the releaser**: | **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 1 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 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 released from sodium hypochlorite in product type 1. 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 chlorate, a relevant metabolite, a validated analytical method is required for drinking water but not available (see section 2.5).

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. H 314<br>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<br>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 %<br>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<br>Aquatic Acute 1 H400<br>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<br>H400 Very toxic to aquatic life<br>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 %<br>M = 10 (acute) and 1 (chronic)<br>Note B |
| **Justification for the proposal** | |
| - | |

**b) Intended use, target species and effectiveness**

Active chlorine has strong bactericidal, fungicidal, sporicidal and virucidal activity. In PT 1, active chlorine released from sodium hypochlorite is used for skin disinfection of the hands and lower forearms by professionals in healthcare and non-professionals (1000 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 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 (at high doses) 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) 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** |
| Skin disinfection | Primary exposure; skin disinfection in healthcare and non-professional uses at home using a 0.1% ready-to-use solution and handling empty containers. | Professional users and non-professional users | Acceptable |
| Bystanders | Secondary inhalation exposure of bystanders exposed to sodium hypochlorite when they are present during skin disinfection. | Bystanders | Acceptable |

The semi-quantitative and qualitative risk assessments showed no unacceptable risk for the use of the ready-to-use disinfectant for hand disinfection in healthcare or at home. Exposure of professional and non-professional users as well as bystanders is acceptable without the need for any risk mitigation measure.

Due to absence of guidance, disinfection-by-products were not evaluated.

**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, active chlorine degrades rapidly in all compartments. Degradation was taken into account during the disinfection process, between release to the facility drain and inflow into the STP, in the STP and after release of the effluent or sludge from the STP to the environment. 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. 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** |
| Skin 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 |
| Skin disinfection: non-professional use | Emission via waste water to Sewage Treatment Plant. Compartments assessed: STP, air, surface water, sediment and soil | Acceptable |

Both for the professional and non-professional use scenario risks were identified for surface water and sediment when no degradation in the sewer was assumed. If 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**

Acceptable risks were identified for all scenarios for human health and 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) |
| | Bioaccumulative (B) or very Bioaccumulative | not B or vB | |

| | | | |
|---|---|---|---|
| | (vB) | | of Article 5(1) and does not fulfil criterion (d) of Article 10(1) |
| | 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).

### 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 1

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] 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)

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.

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. 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.

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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