Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Active chlorine released from chlorine

Product type: 2

ECHA/BPC/136/2016

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 chlorine for product type 2

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 2 of the following active substance:

Common name:	**active chlorine released from chlorine***
Chemical name of the releaser:	**chlorine**
EC No. of the releaser:	**231-959-5**
CAS No. of the releaser:	**7782-50-5**
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 Chlorine 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 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 chlorine in product type 2 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 chlorine 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 chlorine in product type 2. Active chlorine is efficacious chlorine or available/releasable chlorine that is disinfectant, algaecide, fungicide and microbiocide. Upon use chlorine releases active chlorine by reacting in water to hypochlorous acid and hydrochloric acid. Further, hypochlorous acid partially dissociates to the hypochlorite anion. The ratio of chlorine, hypochlorous acid and the hypochlorite anion in the equilibrium aqueous solution is pH and temperature dependent. The evaluation is based on the assessment of the releaser: chlorine (a gas at room temperature and ambient pressure), 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.

Validated analytical methods are available for chlorine as manufactured and for the active substance. Validated analytical methods are required for the relevant matrices air and 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 chlorine 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 chlorine according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Press. Gas Ox. Gas 1 H270 Acute Toxicity (inhalation) 3 * H331 Skin Irrit. H315 Eye Irrit. 2 H319 STOT SE 3 H335 Aquatic Acute 1 H400
Labelling	
Pictogram codes	GHS03, GHS04, GHS06 and GHS09
Signal Word	Danger
Hazard Statement Codes	H270: May cause or intensify fire; oxidiser

	H331: Toxic if inhaled H315: Causes skin irritation H319: Causes serious eye irritation H335: May cause respiratory irritation H400: Very toxic to aquatic life
Specific Concentration limits, M-Factors	M = 100 Not U
Justification for the proposal	
-	

Based on the results of the evaluation it is proposed to amend the classification for acute toxicity via inhalation. The proposed classification and labelling for the releaser chlorine according to Regulation (EC) No 1272/2008 (CLP Regulation) by the evaluating Competent Authority (eCA; Italy) is:

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Press. Gas Ox. Gas 1 H270 Acute Tox. 2 H330 H315: Causes skin irritation Eye Irrit. 2 H319 STOT SE 3 H335 Aquatic Acute 1 H400
Labelling	
Pictogram codes	GHS03, GHS04, GHS06 and GHS09
Signal Word	Danger
Hazard Statement Codes	H270: May cause or intensify fire; oxidiser H330: Fatal if inhaled H315: Causes skin irritation H319: Causes serious eye irritation H335: May cause respiratory irritation H400: Very toxic to aquatic life
Specific Concentration limits, M-Factors	M = 100 Note U
Justification for the proposal	
-	

b) Intended use, target species and effectiveness

Active chlorine has strong bactericidal, fungicidal, sporicidal and virucidal activity. In PT 2, active chlorine released from chlorine is used for the protection of humans from pathogenic organisms which may result in spreading of contagious diseases due to contact with contaminated water (e.g. swimming pool). The uses evaluated are: i) treatment of sewage and waste water (including municipal waste water): before receiving the waste water plant (pre-chlorination) and after the waste water plant (5-40 mg/L active chlorine); ii) treatment of public swimming pools: continuous flow and shock dosing using 3 and 50 mg/L active chlorine, respectively. Active chlorine is used by professionals only in PT 2.

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

Chlorine gas is handled exclusively in closed systems and an exposure to the gas is only accidental. Due to its gaseous aggregate state, inhalation is the only possible exposure route. In water, chlorine forms hypochlorous acid, which is in equilibrium with the hypochlorite ion characterised by irritating/corrosive effects, and chlorine. In biological systems, characterised by pH values in the range 6-8, the most abundant species is hypochlorous acid. At alkaline pH values, the hypochlorite anion is predominant, whilst chlorine is the main species only below pH 4.

Human health effects are primarily due to the local mode of action of chlorine gas and potential systemic effects are secondary to its direct irritating reactivity. Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. oral, 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**
Disinfection of sewage/waste water before and after the waste water plant	Primary exposure including mixing and loading, application and post application (maintenance) tasks	Professional users	Acceptable with automated dosing systems.
Disinfection of public swimming pools	Primary exposure including mixing and loading, application and post application	Professional users	Acceptable with automated dosing systems.
Bystanders exposure during M&L tasks	Secondary inhalation exposure of professional bystanders during M&L tasks	Professional bystanders	Acceptable
Swim instructors	Secondary inhalation exposure of swim instructors	General public: swim instructors	Acceptable
Swimming	Secondary oral, dermal and inhalation exposure of swimming pool users	General public: baby, child, adult	Acceptable

For the intended uses of chlorine gas in PT2, automated dosing systems are designated. During exchange of chlorine containers, empty containers are closed, and the pressure of the connecting circuit is lowered until a low-pressure is achieved. It is only allowed to change the cylinder/drum when the system is under low-pressure in order to avoid any chlorine emission. The new cylinder/drum is connected to the system with a flexible, stainless steel pipe. The new cylinder/drum is checked for possible leaks with an ammonia "detector". During these tasks, RPE is at hand and alarm systems are placed in the area where the vessels are connected to the system. In case of a leak, the presence of chlorine in the atmosphere is detected, turning red light and buzzer are switched on and operators shall wear the appropriate RPE.

For the primary exposure scenario's automated dosing systems were considered. Thus, exposure to chlorine gas can occur only during mixing and loading, i.e. during connecting/disconnecting chlorine containing vessels to a dosing system. The uses are acceptable provided safety procedures and the use of appropriate protective equipment is applied to limit the exposure to chlorine to accidental events.

All secondary exposure scenarios are considered acceptable for the exposed groups.

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, in 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 sewage / waste water in the primary settler of the Sewage Treatment Plant (STP): pre-chlorination	Sewage Treatment Plant, air, surface water, sediment, soil and groundwater	Acceptable
Disinfection of sewage / waste water in the effluent stream of the Sewage Treatment Plant: post-chlorination	Sewage Treatment Plant, air, surface water, sediment, soil and groundwater	Acceptable with the condition that a STP must have technical systems (e.g. labyrinths and/or a longer release pipe) leading to a residence time of more than 30 minutes or a faster reduction of active chlorine before the effluent is discharged into the surface water
Disinfection of public swimming pools	Sewage Treatment Plant, air, surface water, sediment, soil and groundwater	Acceptable

Acceptable risks were identified for all compartments for disinfection of sewage / waste water in the primary settler of the STP for the pre-chlorination scenario. For the other scenarios risks were identified for surface water, and sediment when no degradation in the sewer was assumed.

For disinfection of sewage / waste water (pre-chlorination) and disinfection of public swimming pools, if degradation was assumed in the sewer (considering a realistic worst-case approach with respect to the value for the residence time), the risks for surface water and sediment were acceptable.

For disinfection of sewage / waste water in the effluent stream of the STP (post-chlorination) obviously there is no degradation in the sewer system. In the risk assessment a residence time of 30 minutes is assumed before the effluent is discharged into the surface water. Technical systems (e.g. labyrinths and longer release pipes) may exist which allow a longer residence time or a faster reduction in the effluent of the STP. Furthermore, post-chlorination disinfection is only required if a high load with e.g. *E. coli* occurs. Therefore, it could be expected that organic material is still available which would result in a higher degradation rate compared to the one used in the risk assessment.

No unacceptable risks were identified for the soil and groundwater compartment for all scenarios. 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 when appropriate RMMs are in place. Special attention is needed for the handling of chlorine containers. Acceptable risks were identified for all scenarios for the environment, with the exception of the post-chlorination disinfection of STPs. This scenario is acceptable with the condition that a STP

has labyrinths and/or a release pipe leading to a residence time of more than 30 minutes or a faster reduction of active chlorine before the effluent is discharged into the surface water.

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 chlorine 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 P or vP</td><td rowspan="3">Active chlorine released from chlorine 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 B or vB</td></tr>
<tr><td>Toxic (T)</td><td>T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Active chlorine released from chlorine is not considered to have endocrine disrupting properties. Active chlorine released from chlorine does not fulfil criterion (d) of Article 5(1).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Active chlorine released from chlorine 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 chlorine 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 chlorine does not fulfil criterion (f) of Article 10(1).</td></tr>
</table>

Consequently, the following is concluded:

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

Active chlorine released from chlorine 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 not applicable to inorganic substances, such as active chlorine released from chlorine.

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

In view of the conclusions of the evaluation, it is proposed that active chlorine released from chlorine 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 chlorine: ≥ 995 g/kg (i.e. ≥ 99.5% w/w);
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;
        ii. Surface water and sediment for disinfection of sewage / waste water in the effluent stream of the Sewage Treatment Plant (post-chlorination).

Chlorine is classified for acute toxicity (inhalation) category 2, STOT SE 3 and aquatic acute category 1. The active substance does fulfil the criteria according to Article 28(2)(a) and therefore active chlorine released from chlorine 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:

[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)

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. Particular attention should be paid to the prevention and handling of accidental release of chlorine gas in chlorination facilities. National or other local provisions may be applicable.

c. An unacceptable risk for surface water and sediment is identified for disinfection of sewage / waste water in the effluent stream of the Sewage Treatment Plant (post-chlorination). If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means products should not be authorised or labels and where provided Safety Data Sheets should indicate that the residence time before the effluent is discharged into the surface water of the treated STP needs to be more than 30 minutes.

d. Disinfectant by-products are formed as a consequence of the use of active chlorine released from chlorine. 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 assessment 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 chlorine.

However, further studies are required:

- a new test on oxidising gases according to the UN Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria, to confirm the oxidising properties of chlorine;
- 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).

o0o