Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

Arche Chlorine

ECHA/BPC/281/2021

Adopted

16 June 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of the biocidal product

Arche Chlorine

In accordance with Article 44(3) 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, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the the biocidal product:	**Arche Chlorine**
Authorisation holder:	**Arche Consortia**
Active substance(s) common name:	**Active chlorine released from chlorine (CAS number chlorine 7782-50-5)**
Product type(s):	**2 and 5**

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 7 December 2018**,** recorded in R4BP3 under case number BC-UQ045679-98, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 3 November 2020. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-39) and its Working Groups (WG-I-2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the Union authorisation of the biocidal product/biocidal product family was reached on 16 June 2021.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority positions including their grounds are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the single biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, as defined in Article 3(r).

The single biocidal product meets meet the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion.

The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of **Arche Chlorine** referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

General

The biocidal product “Arche Chlorine” is used as a water disinfectant for product type (PT) 2 or PT 5 in dedicated, often large-scale, installations, and only handled by (trained) professionals:

Use code	Use
Use # 1	PT2: Disinfection of waste water after the waste-water plant: - Disinfection of waste water after the waste-water plant, by shock dosing (in case of contamination).
Use # 2	PT5: Disinfection of drinking water at drinking water suppliers: - Disinfection at the drinking water suppliers and their water distribution systems, by continuous dosing.
Use # 3	PT5: Disinfection of water in reservoirs: - Disinfection of water (origin of water: tap water) stored in reservoirs/large tanks by continuous dosing.
Use # 4	PT5: Disinfection of water in collective systems: - Disinfection of drinking water in collective drinking water systems (in public institutions, healthcare facilities), by continuous dosing.
Use # 5	PT5: Disinfection of drinking water for animals: - Disinfection of drinking water (origin of water: tap water) for animals (in agricultural areas), by continuous dosing.

Arche Chlorine contains ≥99.5% w/w of active chlorine released from chlorine as active substance. No substance of concern has been identified in the biocidal product.

Physico-chemical properties

The product in this dossier is identical to the active substance releaser chlorine described in the Assessment Report (AR) prepared under the approval process. Arche Chlorine is a greenish-yellow gas with a characteristic stringent odour. The density of compressed liquid chlorine is reported in the AR to be 1.411 kg/dm^3 (20 °C, 10 kg/cm^2 pressure). The density

of chlorine varies with temperature and pressure and is not a constant value under the storage and use conditions of this product. Based on the chemical and technical properties of the product and the safety regulations in place for the transport, handling and storage of chlorine, the stability of the product is ensured. Exposure to elevated temperatures (max. 50 °C) or direct sunlight during storage is not allowed. The product is not intended to be used in combination with other products. The surface tension is 18.2 mN/m and the viscosity at 20 °C is $13.3x10^{-3}$ Pa.s. Due to its chemical and physical properties, chlorine gas is always stored in dedicated carbon/steel recipients with special, dedicated valves. Chlorine packages for use within the EU should be constructed and labelled according to the Transportable Pressure Equipment Directive (TPED) and ADR. Maximum filling 1.25 kg/l (80% of volume approximately).

The product has the following physical hazard classification: Oxidising Gas 1 and Press. Gas (Liq. Gas).

Analytical methods for monitoring and detection are available.

Efficacy

The target organisms include vegetative bacteria (including *Legionella pneumophila*) and viruses, relevant to the products' areas of use and in-use conditions.

Detailed function, field of use, application rates and contact times of the authorised products are described in the Efficacy part of the PAR and described in the section *# 2.1.4." Authorized use(s)"* but also summarised just below:

- Disinfection of waste water (post-STP) by shock dosing in case of contamination (use #1): active against bacteria and viruses with 477 mg/L Active Chlorine in 30 min contact time in dirty conditions.
- Disinfection of drinking water suppliers (use #2): by continuous dosing: Active against bacteria and viruses with 0.5 mg/L Active Chlorine (as residual concentration in the system).
- Disinfection of water in reservoirs and tanks (origin of water: tap water) (use #3): by continuous dosing (in the inlet of the reservoir in order to assure proper distribution of the disinfectant in the water): active against bacteria and viruses with 0.5 mg/L Active Chlorine (as residual concentration in the system).
- Disinfection of water in collective drinking water systems (use #4): by continuous dosing active against bacteria (including *Legionella pneumophila*) and viruses with 1 mg/L Active Chlorine (as residual concentration in the system).
- Disinfection of drinking water (origin of water: tap water) for animals (use #5): by continious dosing active against bacteria and viruses with 0.5 mg/L Active Chlorine (as residual concentration in the system).

Human health

Arche Chlorine is classified as follows according to the harmonized classification of active substance as:

- Acute Toxicity (inhal.) 3;
- Eye Irritation 2;
- STOT SE 3;
- Skin Irritation 2.

Only local exposure for the risk assessment is 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.

Dermal exposure: for the dermal route of exposure, a semi-quantitative (Tier-1) assessment has been performed (in case of the dermal NOAEC is exceeded in Tier-1, a qualitative assessment will be performed).

Oral exposure: for the oral route of exposure, a semi-quantitative (Tier-1) assessment has been performed (in case of the oral NOAEC is exceeded in Tier-1, a qualitative assessment will be performed).

Inhalation exposure: for the inhalation route of exposure, a quantitative assessment has been performed (in case of the inhalation AEC is exceeded in Tier-1, Tier-2 with RPE). Exposure towards aerosol (NaOCl as avCl) and vapour (HClO as avCl) is conceivable

Primary exposure:

The professional users may be exposed by inhalation route to the gaseous product (Cl_2) when connecting and disconnecting the canisters and during maintenance process (e.i. repair broking dosing system).

According to the local risk assessment, the risk is acceptable for the professional user.

For connecting or disconnecting the product containers as well as for maintenance or repair of the gas pipe system, the following risk mitigation measures (RMMs) are mandatory:

- an alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m^3) is in place with initiates safety procedures like wearing RPE (EN141B);
- application of LEV (according to the national legislation) and low-pressure/vacuum are in place to avoid chlorine emission;
- the electrochemical sensors used for measurements detect various chlorinated species additional to chlorine itself;
- sensors are measuring exposure also when the operators are using RPE (EN141B).

Secondary exposure:

A local exposure by oral, dermal and inhalation route with sanitazing solution is considered for the general public taking a shower.

An oral exposure of general public via drinking water consumption is also considered.

According to the local risk assessment, the risk is acceptable for the general public.

In order to inform the user, the following risk mitigation measure is to be added for uses #2, #3, #4:

“Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limits before consumption.”

Dietary risk assessment:

It was considered that at this stage the necessary information about the chlorate measurements generated from the use of the product is not available to carry out the dietary risk assessment.

According to the agreement reached at WG-I-2021, the dietary risk assessment should not be conducted, but the following RMMs are to be added to the product label to reduce the risk for the consumers:

For use #2, 3 and 4: *“Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Directive 2020/2184.”*

For use #5: "For *food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Reg. 2020/749."*

Disinfection by-products (DBP) risk assessment:

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out.

The current guidance (Volume V, Guidance on Disinfection By-Products) should be completed in order to be applicable during the active substance renewal. ECHA and the member states will work actively to address these issues (e.g. data lacking and harmonised toxicological reference values.).

Animal health:

The product is not used on animals directly. Animals can come into contact with residues of the products as the products are used for the disinfection of animal drinking water. The following argument is included in the Assessment Report of the active substance:

"Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly (decomposition to physiological sodium and chloride). Hence, residue formation is assumed to be negligible for aqueous solutions of chlorine. Finally, no systemic assessment is required for substances such as chlorine which act by a local mode of action only."

Therefore, no effects of the active substance on animals are expected. Furthermore, the risk of local exposure is covered by the human risk assessment.

During disinfection, chlorate can be formed, an oral exposure of animals via drinking water consumption is possible.

However, at this stage the necessary information about chlorate measurements generated from the use of the product "Arche Chlorine" is not available in order to carry out the animal risk assessment following the disinfection of drinking water.

Environment

The product has the following environmental hazard classification: Aquatic Acute 1.

The effect of the use of chlorine for the disinfection of water on the environment is assessed. Due to its high reactivity with organic matter, chlorine will rapidly degrade in the soil, in the sewer system and in the STP. For uses with release to the STP or direct release to soil, only negligible levels of active chlorine reach the concerned environmental compartments and hence these uses do not result in unacceptable risk to the environment:

- Use#2: PT5: "Disinfection of drinking water at drinking water suppliers";
- Use#3: PT5: "Disinfection of water in reservoirs";
- Use#4: PT5: "Disinfection of water in collective systems";
- Use#5: PT5: "Disinfection of drinking water for animals".

In case chlorine is used for the disinfection of waste water effluent, direct release to surface water could lead to unacceptable risk for the aquatic compartment for Use#1: PT2: "disinfection of waste water after the waste-water plant".

Therefore, risk mitigation measures are proposed for this use:

- "*Reduce residual concentrations of active chlorine by active carbon filtration or addition of reducing agents (e.g. ascorbic acid or sodium ascorbate) before discharging the wastewater to surface water. Alternatively, the water should be retained in a buffer after disinfection.*"
- "*Regular water quality assessment should be performed to ensure the effluent meets all required quality standards*".

Disinfection by-products (DBP) risk assessment:

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out. the current 'guidance' (Volume V, Guidance on Disinfection By-Products) covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.

Overall Conclusion

It is concluded that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the product "Arche Chlorine".

When using the product "Arche Chlorine" according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health or to the environment.

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance **Active chlorine released from chlorine** contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s) in the biocidal product are met.

The physico-chemical properties of the biocidal product are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
    - the fate and distribution of the biocidal product in the environment,
    - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
    - the impact of the biocidal product on non-target organisms,
    - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product

As the conditions of Article 19(1) are met it is proposed that the single biocidal product shall be authorised for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

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