Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE NATIONAL AUTHORISATION APPLICATION**



**Biocidal chlor**

Product type

2 (Disinfectants and algaecides not intended for direct application to humans or animals),

5 (disinfection of drinking water for both human and animals)

Active chlorine released from chlorine

Case Number in R4BP:

Evaluating Competent Authority: PL

# Table of Contents

[Table of Contents 2](#_Toc76024842)

[1 Conclusion 2](#_Toc76024843)

# CONCLUSION

The biocidal product Biocidal chlor is identical to the biocidal product Arche Chlorine already authorised in Poland as a union authorisation (Case Number in R4BP: BC-UQ045679-98, Asset Number in R4BP: EU-0026816-0000, Authorisation Number: EU-0026816-0000).

Arche Chlorine contains active chlorine released from chlorine as the active substance included in the Union list of approved active substances referred to in Article [9(2)](https://lexparency.org/eu/32012R0528/ART_9/#2) of Regulation [(EU) No 528/2012](https://lexparency.org/eu/32012R0528/) for product-types 2 and 5.

Based on the physical, chemical and technical characteristics of the already authorised product – Arche chlorine, PLCA considers the product as sufficiently described to fulfil the conditions for granting an authorization.

Authorization of Arche chlorine is granted in Poland as a product type 2 or 5 disinfectant. Based on the efficacy studies it can be concluded that the product is sufficiently efficacious against vegetative bacteria (including *Legionella pneumophila*) and viruses, relevant to the products’ areas of use and in-use conditions. The biocidal product Arche Chlorine is used in dedicated, often large-scale, installations, and only handled by professionals. It is to be used to disinfect waste water by shock dosing, disinfect drinking water suppliers, disinfect water in reservoirs and tanks, disinfect water in collective drinking water systems, disinfect drinking water (origin of water: tap water) for animals.

Biocidal chlor 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.

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**.”

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**.”

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

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”. 9 (10) 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”.**

Based on Article 1 of Regulation (EU) No 414/2013 the applicant submitted an application for authorisation of the same product indicating the proposed differences between the same product and the related reference product. The differences include name of the biocidal product,the address of the authorisation holder and addition of formulators of biocidal product (see the supporting document for details). Those differences fulfil the requirements of administrative changes as described in Section 2 of Annex 1 of Regulation (EU) No 354/2013.

Changes introduced in Summary of product characteristics for Biocidal chlorcovering the range of biocidal activity of the product do not fulfil the requirements described in Regulation (EU) No 414/2013.

For the full report and details of the product assessment please see the documentation recorded in R4BP under the Belgium Asset Number: EU-0026816-0000.

**Conditions for the authorization of the biocidal product Biocidal chlor in Poland:**

The authorization of the biocidal product can be granted according to Article 19(1) of the BPR. The assessment presented in the Product Assessment Report has shown that the Biocidal chlor may be authorized for use as a product-type 2 (Disinfectants and algaecides not intended for direct application to humans or animals) and product-type 5 (disinfection of drinking water for both human and animals).

Based on the performed assessment, following risk mitigation measures is included in the proposed label:

For use #1

* 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.
* Regular water quality assessment should be performed to ensure the effluent meets all required quality standards

For uses #2, #3, #4:

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

Detailed description of the conditions for the authorization of this biocidal product is presented in the summary of product characteristics (SPC) and includes Poland’s national requirements.