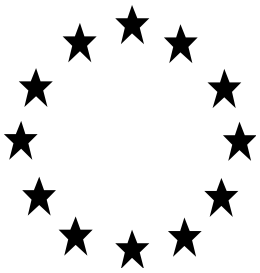
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the competent authority)



ARCHE Chlorine POOL

Product type(s)
2 - Disinfectants and algaecides not intended for direct application to humans or animals

Active chlorine released from chlorine as included in the Union list of approved active substances / Annex I of Regulation (EU) No 528/2012

Case Number in R4BP: BC-UM070195-21

Competent Authority: DE (BAuA)

Date: 12.04.2024

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Changes history table

Application type	refMS /eCA	Case number in the refMS	Decision date[1]	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	DE	BC-UM070195-21	01.06.2023	Initial assessment	
NA-AAT	DE	BC-YN094058-07	12.04.2024	Formal referral after disagreements on Mutual recognition (including the splitting of Use 1 into Use 1 and 3)	

[1] Date is entered when DE CA takes decision in R4BP

1 Conclusion

ARCHE Chlorine POOL is a(n) ready to use gaseous biocidal product containing Active chlorine released from chlorine as active substance. The product is used as a disinfectant and algaecide not intended for direct application to humans or animals (product-type 2) by professional users for the control of bacteria, Legionella and viruses in indoor and outdoor large-scale swimming pools, spas and hot tubs by continuous dosing or shock dosing in case of contamination.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for Disinfection of swimming pool water by continuous dosing, Disinfection of swimming pool water, spas and hot tubs operated with high hygienic requirements by continuous dosing and Disinfection of swimming pool water by shock dosing in case of contamination, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended use(s) of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

The biocidal product does not contain any non-active substance (so called "co-formulant") which is considered as a substance of concern.

The biocidal product should be considered not to have endocrine-disrupting properties.

The biocidal product contains the active substance Active chlorine released from chlorine, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100.

However, based on the available information, there are no indications for endocrine disrupting properties of this active substance.

The biocidal product does not contain any non-active substance.

More information is available in section 2.7 of the PAR and in the confidential annex.

The biocidal product contains active chlorine released from chlorine which does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for substitution.

Therefore, a comparative assessment of the biocidal product is not required.

Composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. As the biocidal product does not contain any non-active substance, this represents the full composition. The manufacturer of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance(s) in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.5 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

The following Physical hazards were identified: Ox Gas 1 (H270) and Liquefied gas under pressure (H280).More information is available in section 3.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of the active substance is available. More information on the analytical methods for the active substance is available in section 3.4 of the PAR.

Efficacy against target organisms

The biocidal product has been shown to be efficacious against bacteria, Legionella and viruses for the disinfection of swimming pool water, spas and hot tubs operated with high hygienic requirements by continuous dosing and to be efficacious against bacteria and viruses for disinfection of swimming pool water by continuous dosing. For the disinfection of swimming pool water by shock dosing in case of contamination, the biocidal product has been shown to be efficacious against bacteria and viruses. More information is available in section 3.5 of the PAR.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.6 of the PAR.

Since no substance of concern has been identified, the human health risk assessment is based on active chlorine releasen from chlorine.

Based on the risk assessment, it is unlikely that the intended use(s) cause(s) any unacceptable acute or chronic risk to professional users, and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the uses, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance(s) is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the use(s), exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 3.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on active chlorine released from chlorine.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed.

2 Information on the biocidal product

2.1 Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

Product type(s)	2 - Disinfectants and algaecides not intended for direct application to humans or animals
Type(s) of formulation	GA (gas)

2.2 Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

Use number	Use description	PT	Target organisms	Application method	Application rate (min-max)	User category	Conclusion (refMS)	Comment (eCA/refMS)
1	*Disinfection of swimming pool water, spas and hot tubs by continuous dosing*	*PT2*	*Bacteria* *Legionella pneumophila / Legionella** *Viruses*	*Closed system / Disinfection large-scale swimming pools, spas and hot tubs by continuous dosing. Chlorine containers are connected to an automated dosing system by professionals. PH and disinfectant levels are continuously monitored. Products are dosed via a reservoir or buffer tank using an automatic pumping system, or directly in the water stream. In all cases a mechanical filter is present to clean the water.*	*<u>Continuous dosing:</u>* *0.3-1,4 mg/L active chlorine (bacteria incl. Legionella, viruses)**	*Professional*	*R*	• *Additional RMM (human health* • *Efficacy against viruses and bacteria proven for 1.4 mg/L active chlorine (lower concentrations withdrawn by the applicant)* • *Legionella withdrawn by the applicant, therefore spas and hot tubs not authorised*
2	*Disinfection of swimming pool water, sp's and hot tubs by shock dosing in case of contamination*			*Closed system / Disinfection large-scale swimming pools, spas and hot tubs by shock dosing in case of high microbial loads. Chlorine containers are connected to an automated dosing system by professionals. Products are dosed via a*	*<u>shock dosing in case of contaminatio:</u>* • *10 mg/L active chlorine, 10 minutes contact time (bacteria & viruses)* • *50 mg/L active chlorine, 3x 2h*		*R*	• *Additional RMM (human health)* • *Efficacy against bacteria and viruses proven for 6.7 mg/L active chlorine in 10 min* • *Efficacy not proven against Legionella, therefore efficacy*

				reservoir or buffer tank using an automatic pumping system, or directly in the water stream. Shock dosing is usually done overnight, when pools are not being used. In all cases a mechanical filter is present to clean the water.	*contact time (Legionella)"*			*for spas and hot tubs not proven*
3	*Disinfection of swimming pool water, spas and hot tubs by continuous dosing – pools compliant with high hygienic requirements*			*Closed system / Disinfection large-scale swimming pools, spas and hot tubs by continuous dosing. Chlorine containers are connected to an automated dosing system by professionals. PH and disinfectant levels are continuously monitored. Products are dosed via a reservoir or buffer tank using an automatic pumping system, or directly in the water stream. In all cases a mechanical filter is present to clean the water.*	*<u>Continuous dosing:</u> 0.3-1,4 mg/L active chlorine (bacteria incl. Legionella, viruses)*		*R*	• *Additional RMM (human health)* • *Efficacy against viruses and bacteria proven for 0.6 mg/L active chlorine and against Legionella for 1.2 mg/L active chlorine for pools with high hygienic standards according to national regulations or recommendations (e.g. DIN19643 for Germany)*

Codes for indicating the acceptability for each use

A	Acceptable
R	Acceptable with further restriction or risk mitigation measures (RMM)
N	Not acceptable

*The target organism Legionella and concentrations below 1.4 mg/L active chlorine were withdrawn by the applicant for use 1.

2.3 Identity and composition

NA-APP

The identity and composition of the biocidal product are

identical ☒

not identical ☐

to the identity and composition of the product(s) evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No 528/2012.

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Main constituent(s)	
Common name	*Active chlorine released from chlorine*
Chemical name	*Active chlorine released from chlorine*
Remarks	*As per the CAR:* *In water, chlorine (Cl_2) disproportionates into hypochlorous acid (HClO) and hydrochloric acid (HCl). Further, hypochlorous acid is a weak acid and it partially dissociates into hypochlorite anion (ClO–).* *The ratio of Cl2/HClO/ClO– is pH (hypochlorous acid is predominant in the pH range 4 to 5.5, whereas the hypochlorite anion predominates at pH >10. Chlorine can be present at pH < 4 only.) and temperature dependent.*
EC number	*231-959-5 (Releaser chlorine)*
CAS number	*7782-50-5 (Releaser chlorine)*
Index number in Annex VI of CLP	017-001-00-7
Minimum purity / content	*≥99.5%*
Structural formula	Cl-Cl

2.5 Information on the source(s) of the active substance(s)

NA-APP

Is the source "Donau Chemie AG" of active chlorine released from chlorine the same as the one(s) evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

☒ Yes

☐ No

2.6 Candidate(s) for substitution

No candidate for substitution has been identified.

2.7 Assessment of the endocrine-disrupting properties of the biocidal product

Active Substance

The biocidal product contains the active substance active chlorine released from chlorine.

According to the BPC opinion for active chlorine released from chlorine (2020, eCA: IT), there are no indications for endocrine disrupting properties of this active substance. However, a comprehensive ED-assessment for the active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.

Thus, the active substance contained in the biocidal product does not have endocrine-disrupting properties.

Non-active substance

As the biocidal product consists of chlorine gas only and there are no non-active substances included, an assessment of endocrine disrupting properties of co-formulants is not necessary.

2.8 Classification and labelling

Besides the active substance active chlorine released from chlorine, there are no other components that affect the classification of the biocidal product.

The current harmonised classification of the active substance hydrochloric acid is based on Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):
Skin Irrit. 2, H315
Eye Irrit. H319
Acute Tox. 3, H331
STOT SE 3, H335
Aquatic acute Cat 1 (H400)
Ox. Gas 1
Press. Gas Liq.

Table 2.4 Classification and labelling of the biocidal product

	Classification		**Labelling**	
Hazard Class and Category code	Skin Irrit. Cat 2 Eye Irrit. Cat 2 Acute Tox. Cat 3 STOT SE Cat 3 Aquatic acute Cat 1 Ox. Gas 1 Press. Gas Liq.		Skin Irrit. Cat 2 Eye Irrit. Cat 2 Acute Tox. Cat 3 STOT SE Cat 3 Aquatic acute Cat 1 Ox. Gas 1 Press. Gas Liq.	
Hazard Pictograms	 GHS06	 GHS03	 GHS06	 GHS03
	 GHS09	 GHS04	 GHS09	 GHS04
Signal word(s)	Danger, Warning		Danger, Warning	
Hazard statements	H270 - May cause or intensify fire; oxidiser. H280 - Contains gas under pressure; may explode if heated. H315 - Causes skin irritation H319 - Causes serious eye irritation H331 – Toxic if inhaled H335 - May cause respiratory irritation H400 – Very toxic to aquatic life.		H270 - May cause or intensify fire; oxidiser. H280 - Contains gas under pressure; may explode if heated. H315 - Causes skin irritation H319 - Causes serious eye irritation H331 – Toxic if inhaled H335 - May cause respiratory irritation H400 – Very toxic to aquatic life.	

Precautionary statements	P220: Keep/Store away from clothing and other combustible materials. P244: Keep reduction valves free from grease and oil. P261 Avoid breathing P264 Wash hands thoroughly after handling P271 Use only outdoors or in a well-ventilated area P273 – Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection. P302 + P352 IF ON SKIN: Wash with plenty of water/... P304 + P340 + P311: IF INHALED: Remove person to fresh air and keep comfortable for breathing.Call a doctor. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a doctor if you feel unwell. P332 + P313 If skin irritation occurs: Get medical advice/attention. P337 + P313 If eye irritation persists: Get medical advice/attention P362 + P364 Take off contaminated clothing and wash it before reuse P370 + P376: In case of fire: Stop leak if safe to do so. P391 – Collect spillage. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P410 + P403: Protect from sunlight. Store in a well-ventilated place. P501: Dispose of contents/container in accordance with local regulation.	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.
Supplemental hazard statements		
Notes		

All P-statements listed under the first column have also been listed in the SPC.

2.9 Letter of access

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[2]) of the active substance Active chlorine released from chlorine for use in Disinfectants and algaecides not intended for direct application to humans or animals (product-type 2). Please, refer to the corresponding Assessment Report for a reference list.

2.10 Data submitted in relation to product authorisation

Not relevant (no new data was submitted).

2.11 Similar conditions of use across the Union

Not relevant (national authorisation).

2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

3 Assessment of the biocidal product

3.1 Packaging

Table 3.1 Packaging

Type of packaging[1]	Size/volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Cylinder	4.8 – 140 L (6-175 kg Cl2)	Carbon/ stainless steel	Carbon steel/brass/PVDF/ nickel pressure resisting valve	Professional	Yes
Drum	400 – 1,000 L (500-1,250 kg Cl2)	Carbon/ stainless steel	Carbon steel/brass/PVDF/ nickel pressure resisting valve	Professional	Yes

3.2 Physical, chemical, and technical properties

The product in this dossier is liquefied chlorine under pressure (≥ 99.5 % w/w, in compliance with EN 937:2009), and is identical to the reference product described in the Assessment Report (AR) of Chlorine (Italy, 2017). Therefore, reference is made to the AR for chlorine for most physical-chemical properties. Furthermore, chlorine is a well-characterised, basic chemical of which the physical-chemical properties are already extensively investigated and published.
According to the AR of chlorine, physical-chemical data on e.g. density and acidity should be provided during product authorization, as well as a storage stability study (including reactivity towards container material) and a study on the effect of light, temperature and humidity on the product. However, as the product in this dossier is identical to the reference product, a rationale is given to waive these tests, or reference is made to available literature. This is in accordance with the conclusions of the APCP WG IV 2018.

Table 3.2 Physical, chemical, and technical properties

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>3.1.</td><td>Appearance at 20 °C and 101.3 kPa</td><td></td><td></td><td></td><td></td></tr>
<tr><td>3.1.1.</td><td>Physical state at 20 °C and 101.3 kPa</td><td rowspan="3">Refer to AR Chlorine</td><td rowspan="3">≥99.5%</td><td rowspan="3">Greenish-yellow gas with characteristic stringent odour</td><td rowspan="3">AR Chlorine (Italy, 2017)</td></tr>
<tr><td>3.1.2.</td><td>Colour at 20 °C and 101.3 kPa</td></tr>
<tr><td>3.1.3.</td><td>Odour at 20 °C and 101.3 kPa</td></tr>
<tr><td rowspan="2">3.2.</td><td rowspan="2">Acidity, alkalinity and pH value</td><td>Waived</td><td colspan="3">Acidity/alkalinity is only required for aqueous solutions of gases. By consequence, for the chlorine gas placed on the market as the biocidal product, this requirement can be waived.

WG agreed that the monitoring values of the pH-value under real-use conditions must be provided for uses where chlorine is diluted in water. The applicant has provided monitoring data for the uses: "pool- and drinking water from tap water, swimming pool water from potable water. The data provided by the applicant cover all the intended uses, as submitted in the dossier. The details are given below.</td></tr>
<tr><td>Monitoring of pH value:
20ml of a KJ solution (200g/l KJ) are added to 0,5ml of the chlorinated water. Then the sample was acidified with 10ml H2SO4 10%. The sample was diluted</td><td>Source of chlorine gas:
Donau Chemie AG, plant Brückl, Klagenfurterstrasse 17, 9371 Brückl, Austria (Reference source for the active substance)

Source of water: tap water

USE: pool- and drinking water</td><td>The pH-value after chlorine dosage depends on the acid capacity and by that on the hardness of the water.

For common tap water the change of the pH-value can be neglected for usual dosage rates in pool- and drinking water applications (< 5mg/l)
<table>
<tr><td>Active Cl2 mg/L</td><td>pH H2O demi</td><td>pH</td><td>pH KS4.3 = 2.05 mmol/L</td></tr>
</table></td><td>Analysis report: Dependency of pH-value from chlorine content in water, December 2019, by Donau Chemie AG</td></tr>
</table>

<table>
<tr><th>Numbering according to Annex III of BPR</th><th>Property</th><th>Guideline and Method</th><th>Tested product/batch (AS% w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>with 100ml H2O demineralized and was titrated with 0,1N Na-thiosulfate and KJ starch solution from blue to colorless.</td><td>from tap water</td><td>
<table>
<tr><td></td><td></td><td>KS4.3 [3] = 4.1 mmol/L</td><td></td></tr>
<tr><td>0</td><td>6.5</td><td>7.7</td><td>7.6</td></tr>
<tr><td>3</td><td>4.5</td><td>7.6</td><td>7.5</td></tr>
<tr><td>7</td><td>4.2</td><td>7.5</td><td>7.4</td></tr>
<tr><td>33</td><td>3.5</td><td>7.1</td><td>6.8</td></tr>
<tr><td>54</td><td>3.3</td><td>6.9</td><td>6.6</td></tr>
<tr><td>81</td><td>3.1</td><td>6.7</td><td>6.2</td></tr>
<tr><td>160</td><td>2.8</td><td>6.1</td><td>3.7</td></tr>
<tr><td>313</td><td>2.6</td><td>3.2</td><td>2.8</td></tr>
</table>
</td><td></td></tr>
<tr><td></td><td></td><td>Monitoring of pH value:
In order to demonstrate the efficacy of hypochlorite in swimming pools against pathogenic indicators under actual use conditions, long-term monitoring data (duration of two years) was collected for two</td><td>Source of chlorine: “Witty Pool Cl-flussig” (NaOCl solution with 150 g/L active chlorine)

Source of water: outdoor and indoor swimming pool (pool itself and 2 filtrates), situated in Germany, Niedersachsen

USE: pool- water from drinking water</td><td>Indoor pool:
Pool: pH variation from 6.72 to 7.70 (average 6.99)
Filtrate1: pH variation from 6.76 to 7.37 (average 7.01)
Filtrate2: pH variation from 6.76 to 7.37 (average 7.01)

Outdoor pool:
Pool: pH variation from 6.77 to 7.80 (average 7.13)
Filtrate1: pH variation from 6.85 to 7.86 (average 7.22)
Filtrate2: pH variation from 6.86 to 7.87 (average 7.22)

Concentration of free chlorine is 0.5 – 1 ppm, corresponding to 0.5 – 1 mg/L</td><td>Disinfection of swimming pools – monitoring data, June 2020, by Arche consortia</td></tr>
</table>

[3] The acid capacity of the water indicates how much acid is consumed by a defined amount of water to adjust the pH value to 4.3 It is determined according to DIN 38409-7 by adding hydrochloric acid until the pH value of the water sample is adjusted to 4.3 (KS 4.3). The acid capacity (KS 4.3) of the water forms the basis value for calculating the carbonate hardness.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
		swimming pools, one indoor and one outdoor and each time for 3 locations: water from the pool itself and two filtrates. For each pool, a monthly report was compiled by AGROLAB Agrar und Umwelt GmbH			
3.3.	Relative density / bulk density	Refer to AR Chlorine	The density of compressed liquid chlorine (purity: ≥99.5%) is reported in the AR to be 1.411 kg/dm3 (20°C, 10 kg/cm2 pressure). The density of chlorine varies with temperature and pressure, and is no constant value. Chlorine is stored in steel cylinders and tanks. Once connected to the chlorination installation, chlorine will start to flow from the receptacle. The flow rate will depend on the temperature and the amount of chlorine in the receptacle. As the volume of chlorine in the receptacle will decrease, also the pressure decreases and hence the density will decrease.		AR Chlorine (Italy, 2017) Euro Chlor document GEST 91/168.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.1.1.	Storage stability test – **accelerated storage**	- Chlorine is stored under pressure in steel cylinders (6-175 kg), drums (500-1250 kg) or road and railway tanks (18750 – 53750 kg). Chlorine packages for use within the EU should be constructed according to the Transportable Pressure Equipment Directive (TPED) and ADR. Compliance with TPED is indicated on packages and accessories (such as valves) by the ⊓ mark. According to ADR regulation, chlorine recipients should be tested every 5 years to verify they still comply and no damage is present. This evaluation includes visual inspection, weighing (max 5 % deviation from original weight acceptable), painting and installation and testing of the valve (15 bar for 30 sec). Bottles are filled with chlorine by the producers, transported to consumers for use, and recuperated by the producers to be refilled. This cycle is repeated for 5 years until the next check of the bottles. Although the gas is usually consumed within several months, due to the properties of the gas, the cylinders will in this time frame never be completely emptied, as the gas will stop flowing once the pressure in the bottle drops below a certain level (±1 bar). Then new gas is added, with a maximum filling rate of 1.25 kg Cl2 per L volume. - Chlorine is a naturally occurring element and is composed of the stable isotopes Chlor-35 and Chlor-37. Elemental chlorine itself thus does not decompose. Chlorine has no half-life and is stable for an indefinite time – an instability of the product is not known. Further, the product in this dossier is compliant to EN937, which specifies that chlorine is stable over a long term under the storage conditions specified in the document. Following these considerations, the WG IV 2018 has agreed that no degradation of chlorine gas is expected during the storage, and therefore this requirement could be waived			Guidance on the design and construction of chlorine packages is given in the GEST documents 88/138 and 79/76 .
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**				

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Waived	Storage should be done at temperatures >15°C to guarantee a good flow of chlorine from the gas bottle. Considering that this requirement is stricter than the default RMM "protect from frost", an adapted RMM "Store at a temperature >15°C" will be added to the label.		
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Refer to AR chlorine	Not applicable: - container under pressure: exposure to elevated temperatures (max. 50°C) or direct sunlight during storage not allowed (according to EN 937:216).		
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**				
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Dry chlorine at ambient temperature does not attack steel, copper or nickel, but reactivity of these metals is observed at higher temperatures (>200°C)	ADR, Chapter4.1, P200 safe handling of chlorine drums and cylinders HSE GEST 88 138 Edition 6 -Small Chlorine Packages Construction, Filling and Handling
3.5.1.	Wettability [indicate the concentration tested]	Waived	Not applicable since biocidal product is not a solid preparations to be dispersed in water.		
3.5.2.	Suspensibility, spontaneity, and dispersion stability [indicate the concentration tested]	Waived	Not applicable since biocidal product does not need to be diluted.		
3.5.3.	Wet sieve analysis and dry sieve test [indicate the concentration tested]	Waived	Not applicable since biocidal product is a gas.		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability [indicate the concentration tested]	Waived	Not applicable since biocidal product does not need to be emulsified.		
3.5.5.	Disintegration time	Waived	Not applicable since biocidal product is not a tablet and is not used in a water soluble bag.		
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability [the particle size distribution of droplets (MMAD) should be reported for RTU products if sprayed.]	Waived	Not applicable since biocidal product is not a granule or tablet.		
3.5.7.	Persistent foaming [indicate the concentration tested]	Waived	Not applicable since biocidal product is a gas.		
3.5.8.	Flowability/pourability/dustability	Waived	Not applicable since biocidal product is not granular/a suspension.		
3.5.9.	Burning rate — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.		
3.5.10.	Burning completeness — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.		
3.5.11.	Composition of smoke — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.		
3.5.12.	Spraying pattern — aerosols / spray	Waived	Not applicable since the biocidal product is not an aerosol.		
3.6.1.	Physical compatibility	Waived – see AR of Chlorine	Avoid heat or temperatures above 50°C. Do not expose to direct sunlight.		
3.6.2.	Chemical compatibility	Waived – see AR of Chlorine	The product is not intended to be used in combination with other products		
3.7.	Degree of dissolution and dilution stability (indicate the concentration tested)	Waived	Not applicable since biocidal product is a gas.		
3.8.	Surface tension [indicate the	Refer to AR	≥99.5%	18.2 mN/m (20 °C)	AR Chlorine (Italy,

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference
	conditions of the test and the concentration tested]	Chlorine			2017)
3.9.	Viscosity [indicate the shear rate and the temperature tested]	Refer to AR Chlorine	≥99.5%	12.4x10-3 Pa.s (0°C)	AR Chlorine (Italy, 2017)

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
ARCHE Chlorine POOL is identical to the active substance releaser chlorine described in the Assessment Report (Italy, 2017). It 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 no 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 assured. Exposure to elevated temperatures (max. 50°C) or direct sunlight during storage is not allowed. Dry chlorine at ambient temperature does not attack steel, copper or nickel, but reactivity of these metals is observed at higher temperatures (>200°C). Flammable and oxidizing materials, materials such as ammonia, sulfur dioxide, hydrocarbons, segregate from other compressed or liquefied gases are not compatible with the product. The surface tension is 18.2mN/m and the viscosity at 20°C is 13.3x10-3Pa.s. **Implications for labelling:** Keep containers with chlorine tightly closed and store in a cool, dry and well-ventilated place. Tightly screw on the valve outlet protection seal and the valve protection cap when storing. Prevent cylinders from falling over. Protect from heat and direct sunlight, the temperature of the container should never be below 15°C and > 50°C.

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
4.1.	Explosives	Waiver	- There are no chemical groups associated with explosive properties present in the molecule of chlorine - According to the AR of Chlorine: not applicable to gases		
4.2.	Flammable gases	Refer to AR Chlorine	≥99.5%	Flash-point: not applicable to gases Chlorine is known to be a non-flammable gas	AR Chlorine (Italy, 2017)
4.3.	Flammable aerosols	Waiver	Not relevant for the formulation type		
4.4.	Oxidising gases	The applicant refers to the AR of Chlorine. According to the CAR of the active substance, chlorine is confirmed to be an oxidizing gas by the calculation method under sec. 5.3 of ISO 10156:2017. Moreover, the harmonised classification of chlorine indicates **Ox. Gas 1 H270: may cause or intensify fire; oxidiser**. We propose therefore to classify the biocidal product as oxidising gas category 1.			
4.5.	Gases under pressure	According to the harmonised classification and the AR Chlorine, chlorine is classified as Press. Gas. Further, according to Note U, "When put on the market gases have to be classified as 'Gases under pressure', in one of the groups compressed gas, liquefied gas, refrigerated liquefied gas or dissolved gas. The group depends on the physical state in which the gas is packaged and therefore has to be assigned case by case." According to the applicant and the packaging type, the gas is to be classified as Liquefied Gas: **H280: Contains gas under pressure; may explode if heated**.			
4.6.	Flammable liquids	Waiver	Not relevant for the formulation type		
4.7.	Flammable solids	Waiver	Not relevant for the formulation type		
4.8.	Self-reactive substances and mixtures	Waiver	Not relevant for the formulation type		
4.9.	Pyrophoric liquids	Waiver	Not relevant for the formulation type		

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Reference
4.10.	Pyrophoric solids	Waiver	Not relevant for the formulation type		
4.11.	Self-heating substances and mixtures	Waiver	Not relevant for the formulation type		
4.12.	Substances and mixtures which in contact with water emit flammable gases	Waiver	Chlorine is a gas at room temperature and normal pressure, and upon contact with water forms hypochlorous acid, which is in equilibrium with the hypochlorite ion (ClO^-). This means that chlorine (Cl_2) itself is no longer available		
4.13.	Oxidising liquids	Waiver	Not relevant for the formulation type		
4.14.	Oxidising solids	Waiver	Not relevant for the formulation type		
4.15.	Organic peroxides	Waiver	No bivalent O – O - structure		
4.16.	Corrosive to metals	Waiver	According to the Guidance to Regulation (EC) No1272/2008 on CLP of substances and mixture), neither the corrosivity of gases nor the formation of corrosive gases is currently covered by CLP classes and are therefore not applicable here.		
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Waiver	According to the AR of Chlorine, the testing is not required for gases having no flammable range.		
4.17.2.	Relative self-ignition temperature for solids	Waiver	Not relevant for the formulation type		
4.17.3.	Dust explosion hazard	Waiver	Not relevant for the formulation type		

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The product Arche Chlorine POOL is classified as Ox Gas 1 (H270) and Liquefied gas under pressure (H280).

3.4 Methods for detection and identification

The product in this dossier is identical to the reference product described in the Assessment Report (AR) of Chlorine (Italy, 2017). Therefore, reference is made to the available methods in the AR for chlorine for the analytical methods for the analysis of the product as such including the active substance: ISO 2120, 1972, Liquid chlorine for industrial use - Determination of the content of chlorine by volume in the vaporized product

This International Standard specifies a method for the determination of chlorine content by volume in liquid chlorine for industrial use, after vaporization of the product. A known volume of chlorine is sampled (about 100 ml) obtained by gasification of liquid chorine. The chlorine is absorpted by 2 % zinc amalgam in the presence of 1 ml saturated sodium chloride solution. The residual gases (hydrogen, oxygen, nitrogen, carbon dioxide) as non-condensable gases are also measured with this method.

3.4.1 Analytical methods for air

The product in this dossier is identical to the reference product described in the Assessment Report (AR) of Chlorine (Italy, 2017). Two analytical methods (OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; Smith & Cochran Spectrophotometric determination of Free Chlorine in Air using Sulphamic acid/Tri-iodide procedure - Anal Chem 1986 Vol 58 pp 1591-1592 and OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; NIOSH free chlorine in air 01.01.75; ISO 7392/2 Water quality – Determination of free and total chlorine Part 2 Colorimetric method using DPD for routine control purposes 15.10.85) are available, which allow the determination of chlorine in workplace air in the range 0.3-7.0 mg Cl_2/m^3. In principle, the range can be expanded. Though not validated, the two available methods are published methods, so they can still be concluded to be acceptable for the purpose (determination of chlorine in workplace air).

Table 3.6 Conclusion on methods for detection and identification

Conclusion on methods for detection and identification
The applicant refers to the letters of access of the active substances. No new methods are presented. Methods for the detection of residues of active chlorine in air, and drinking water were provided and deemed acceptable at EU level. No other data is required. The product is not intended to be used on surfaces in contact with food/feed of plant and animal origin; therefore, analytical method for the determination of active substance in food/feed of plant and animal origin is not required. Analytical methods for the determination of residues of substances of concern are not necessary.

3.5 Assessment of efficacy against target organisms

3.5.1 Function (organisms to be controlled) and field of use (products or objects to be protected)

The biocidal product Arche Chlorine POOL, containing only chlorine releasing active chlorine, is intended to be used by professional users for the disinfection of water in swimming pools, spas and hot tubs (indoor and outdoor) (PT 2). The chlorine is directly injected into the water by a closed automated dosing system.

The biocidal product is intended to be used to treat the water against bacteria (including Legionella) and viruses.

Organisms to be protected are humans.

INFORMATION PROVIDED BY THE APPLICANT regarding the way of application of the product:

Disinfection large-scale swimming pools, spas and hot tubs by continuous or shock dosing.
Chlorine containers are connected to an automated dosing system by professionals.
In case of continuous dosing, pH and disinfectant levels are continuously monitored and products are dosed via a reservoir or buffer tank using an automatic pumping system.
In case of high microbial loads shock dosing (chlorination) can be performed with higher chlorine concentrations. This is usually done overnight, when pools are not being used.
In all cases a mechanical filter is present to clean the water.

A detailed description of chlorination installations can be found in the conf. annex to the PAR, chapter 10.2.

3.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Chlorine has a lethal effect on the target organisms or prevents their growth.

According to the Assessment Report of the active substance, the hypochlorite ion is in equilibrium with hypochlorous acid and chlorine depending on the pH value: chlorine is available only below pH 4, in the neutral pH range hypochlorous acid is the predominant species, and at pH values higher than 10 the only species present is the hypochlorite ion.

The disinfecting efficiency of hypochlorite aqueous solution is dependent on the active chlorine concentration and decreases with an increase in pH. The chlorination and the oxidation reaction of active chlorine are unspecific. Active chlorine reacts by chlorination of nitrogen with compounds like amino acids. This results in:
- a destructive permeability change in bacterial walls and leakage of cell contents,
- inactivation of enzymes essential to cell metabolism,
- destruction of virus capsids.

At low concentrations in water, active chlorine is still able to maintain the concentration of pathogens below a critical level. In such conditions the proteins of the membrane are partly destroyed and the bacteria are not able to multiply.

3.5.3 Efficacy data

The efficacy evaluation is based on the evaluation already performed within the Union authorisation discussed at BPC-39.
The provided efficacy tests have been performed with active chlorine released from NaOCl. The read-across proposed by the applicant has been accepted as it is in line with the conclusion in the CAR for active chlorine released from chlorine. Herein, it is stated that it is irrelevant whether active chlorine is generated from chlorine gas, calcium hypochlorite or sodium hypochlorite and all studies investigating hypochlorite aqueous solutions can be used for the evaluation and assessment of active chlorine released from any of the three releasers. However, it has to be ensured that pH and temperature conditions in the efficacy tests are representative of the claimed use and that the concentration of active chlorine generated is the same as claimed regardless of the releaser used in the efficacy studies.

Due to different naming of chlorine species in ISO 7393-2, the confidential efficacy data package and the BPR, the following overview is added for clarification:

chlorine species	**naming in**		
	confidential efficacy data package	**EN ISO 7393-2**	**BPR (CAR)**
HOCl + OCl- (+ Cl2)	active chlorine	free chlorine	active chlorine or available chlorine
HOCl (+ Cl2)	active available chlorine	active free chlorine	-

At EFF WGIII2020 and EFF WGI2022, it has been decided that the following data are required to demonstrate efficacy for the disinfection of water in swimming pools, spas and hot tubs: For bacteria, adapted phase 2, step 1 tests and simulated-use tests are required (both demonstrating > 4 lg reduction). In case of maintenance treatment / continuous dosing, simulated-use tests can be substituted by complete detailed monitoring data (already provided and accepted within the previous UA dossier discussed at BPC-39). For viruses, the tiered approach is not required and either adapted phase 2, step 1 tests or simulated-use tests (both demonstrating > 3 lg reduction) are sufficient. Adaptions of test conditions agreed at the EFF WG include modifications regarding soiling, temperature and implementation of product/soiling/inoculum.
According to the efficacy guidance Volume II part B/C, bacteria and virus are regarded as mandatory target organisms to support efficacy for the disinfection of water in swimming pools, spas and hot tubs (PT 2). This has been confirmed at EFF WGIII2020.

Only efficacy studies that were taken into account for the evaluation are listed in the following table. New studies, which were not included in the previous UA dossier discussed at BPC-39, are marked in blue. As some relevant efficacy data are confidential, details of these studies are included in the conf. annex to the PAR_MS ONLY, chapter 11.1. The applicant also provided phase 2, step 1 tests according to non-adapted standard protocols. As these were conducted with concentrations far above the claimed in-use concentrations, these studies have not been taken into account for the evaluation and have not been included in the table.

Table 3.7 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
PT and use number	**Test product**	**Function / Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference/Number in IUCLID section 6.7**
PT 2 Use 1+3 (continuous dosing)	12.5% NaOCl solution	**Bactericidal**	**Adapted EN 1276 (phase 2, step 1)** Contact time: 30 sec For details please refer to conf. Annex (MS only).	Results showed a >4 lg reduction for bacteria with 1.4 mg/L active chlorine. Acceptance criteria for test results are fulfilled.	Doc. "31_Study Summary Report - Efficacy testing for swimming pool.pdf"
PT 2 Use 1+3 (continuous dosing)	12.5% NaOCl solution	**Bactericidal**	**Adapted EN 1276 (phase 2, step 1)** Contact time: 30 sec, 1 min, 5 min For details please refer to conf. Annex (MS only).	Results showed a >4 lg reduction for bacteria with 0.6 mg/L active chlorine in 5 min. Acceptance criteria for test results are fulfilled.	Doc. "33_Summary P2S1-bacteria (including Legionella) and virus 20221014.pdf"
PT 2 Use 1+3 (continuous dosing)	150 000 mg/L Active chlorine	**Bactericidal /** *Escherichia coli* *Pseudomonas aeruginosa* *Legionella spp.*	**[already evaluated in the UA dossier discussed at BPC-39]Monitoring data with continuous dosing (phase 3) – Long term (2-year monitoring data)** Results collected from 2 swimming pools in Germany with 3 sampling locations (water from the pool and 2 filtrates) - <u>One exercise pool indoor:</u> Dimension: 50 m² - 80 m³ Average bather load: 29 pH: 6.72-7.70 (mean: 7.00) Temperature: 26.1-31.0°C (mean: 29.4°C)	Results showed that maintaining mean free chlorine concentrations in the range of 0.5-0.6 mg/L sufficiently controls monitored bacteria (including	Doc. "30_Monitoring data swimming pools_Chlorine consortium_V2.pdf" ARCHE Consortia (2020) *RI = 2*

coliform bacteria

total aerobic colony count

Product concentrations:

Location	Mean free chlorine	Min free chlorine	Max free chlorine
Pool water	0.57 mg/L	0.20 mg/L	1.56 mg/L
Filtrate 1	0.44 mg/L	0.10 mg/L	1.09 mg/L
Filtrate 2	0.41 mg/L	0.08 mg/L	0.98 mg/L

Microbiological examinations (average values):

Location	total aerobic colony count [CFU/mL] (acceptable up to 100 CFU/mL)	count of E. coli, P. aeruginosa and coliform bacteria [CFU/100 mL]	count of Legionella spp. [CFU/100 mL]
Pool	0.36	0.00	0.00
Filtrate 1	1.96	0.00	1.50
Filtrate 2	10.64	0.00	0.04

- <u>One outdoor pool:</u>
Dimension: 60 m² - 120 m³
Average bather load: 60
pH: 6.77-7.87 (mean: 7.19)
Temperature: 18.7-25.9°C (mean: 21.7°C)

Product concentrations:

Location	Mean free chlorine	Min free chlorine	Max free chlorine
Pool water	0.53 mg/L	0.09 mg/L	0.85 mg/L
Filtrate 1	0.45 mg/L	0.11 mg/L	1.10 mg/L
Filtrate 2	0.44 mg/L	0.02 mg/L	1.10 mg/L

Microbiological examinations (average values):

Location	total	count of E.	count of

Legionella).

			aerobic colony count [CFU/mL] (acceptable up to 100 CFU/mL)	**coli, P. aeruginosa and coliform bacteria [CFU/100 mL]**	**Legionella spp. [CFU/100 mL]**
			Pool	0.37	0.00	0.00
			Filtrate 1	3.59	0.00	0.00
			Filtrate 2	0.30	0.00	0.00
PT 2 Use 1+2+3 (continuous + shock dosing)	12.5% NaOCl solution	**Virucidal**	**Adapted EN 14476 (phase 2, step 1)** Contact time: 2 min and 10 min For details please refer to conf. Annex (MS only).		Results showed a >3 lg reduction for viruses with 1.12 mg/L active chlorine in 10 min Acceptance criteria for test results are fulfilled.	Doc. "31_Study Summary Report - Efficacy testing for swimming pool.pdf"
PT 2 Use 1+2+3 (continuous + shock dosing)	Sodium Hypo Solutions	**Virucidal**	**Adapted EN 14476 (phase 2, step 1)** Contact time: 10 min For details please refer to conf. Annex (MS only).		Results showed a >3 lg reduction for viruses with 1.2 mg/L active chlorine in 10 min Acceptance criteria for test results are fulfilled.	Doc. "33_Summary P2S1-bacteria (including Legionella) and virus 20221014.pdf"
PT 2 Use 3 (continuous dosing)	NaOCl solution (2-3 g/L active chlorine)	**Virucidal/** Bacteriophage MS2 ATCC 15597-B (F+-specific RNA phage, DSM	**Simulated-use test in UBA flow-through test rig (phase 2, step 2)** Test concentration: 0.3 mg/L active chlorine Contact times: 0.32-0.38 min (tap 1), 0.58-0.62 min (tap 2), 1.41-1.45 min (tap 3), 3.18-3.33 min (tap 4)		Results showed a >3 lg reduction for PRD1 with 0.3 mg/L active chlorine in about 0.38 min at 28°C.	F. El-Athman et al. Pool water disinfection by ozone-bromine treatment: Assessing the disinfectant efficacy and the occurrence and in vitro toxicity of brominated disinfection by-

		13767) Bacteriophage PRD1 (somatic DNA phage, DSM 19107)	Temperature: 28°C pH: 7.0-7.2 Interfering substance: 2 mg/L DOC Initial load of bacteriophages: 10^4-10^6 PFU/mL	Results showed >5 lg reduction for MS2 with 0.3 mg/L active chlorine in about 3.27 min at 28°C. Interpolation indicates a >3 lg reduction for MS2 at 2 min.	products. *Water Research* **204** (2021) 117648 *RI = 2*
PT 2 Use 1+3 (continuous dosing)	Free chlorine solutions	**Virucidal**	**[already evaluated in the UA dossier discussed at BPC-39]** **Literature review** 6 papers resulting from a literature survey are described and discussed. <u>Most relevant paper for applied uses:</u> Yamashita et al. Virucidal effect of chlorinated water containing cyanuric acid. *Epidem. Inf.* (1988), **101**, 631-639. Test organisms: Poliovirus 1 Test matrix: pool water Temperature: 25°C pH: 6.8 Test concentration: 0.5 mg/L free chlorine Test setup: 199 mL test suspension + 1 mL virus stock (10^6-10^8/mL)	The different papers demonstrated 3 lg reductions with 0.3-1 mg/L free chlorine, depending on contact time and setup. However, most studies were performed in buffered water without additional soiling, which is not representative for the applied uses. Most relevant for this dossier, the study by Yamashita et al. (1988) performed studies in pool	Doc "32_Virucidal activity of active chlorine in swimming pools.pdf" ARCHE Consulting (2020) Yamashita et al.: *RI = 2* other literature studies: *RI = 3 (due to inadequate test matrix, non-representative or missing test viruses and/or non-quantitative assessment)*

				water and demonstrated a 3 lg reduction for Poliovirus 1 with 0.5 mg/L free chlorine in 1.9 min at 25°C.	
PT 2 Use 1+2+3 (continuous + shock dosing)	NaOCl solution	*Legionella pneumophila*	**EN 1276:2019 (phase 2, step 1)** Contact time: 10 min For details please refer to conf. Annex (MS only).	Results showed a >4 lg reduction for Legionella with 1.2 mg/L active chlorine in 10 min Acceptance criteria for test results are fulfilled.	Doc. "33_Summary P2S1-bacteria (including Legionella) and virus 20221014.pdf"
PT 2 Use 1+3 (continuous dosing)	NaOCl solutions	*Legionella pneumophila*	**Adapted EN 1276:2019 (phase 2, step 1)** Contact time: 1 min For details please refer to conf. Annex (MS only).	Results showed **no** sufficient lg reduction for Legionella with 0.6 and 1.0 mg/L active chlorine in 1 min. Acceptance criteria for test results are fulfilled.	Doc. "33_Summary P2S1-bacteria (including Legionella) and virus 20221014.pdf" *supportive data*
PT 2 Use 2 (shock dosing)	12.5% NaOCl solution	**Bactericidal**	**Adapted EN 1276 (phase 2, step 1)** Contact time: 5 min and 15 min For details please refer to conf. Annex (MS only).	Results showed a >4 lg reduction for bacteria with 3.43 mg/L active chlorine in 5 min. Acceptance criteria for test	Doc. "31_Study Summary Report - Efficacy testing for swimming pool.pdf"

				results are fulfilled.	
PT 2 Use 2 (shock dosing)	12.5% NaOCl solution	**Bactericidal**	**Simulated-use test (phase 2, step 2)** Contact time: 0, 2, 60, 120, 300 and 1440 min For details please refer to conf. Annex (MS only).	Results showed a >5 lg reduction for bacteria with 6.7 mg/L active chlorine in 2 min. Acceptance criteria for test results are fulfilled.	Doc. "31_Study Summary Report - Efficacy testing for swimming pool.pdf"
PT 2 Use 2 (shock dosing)	15.2 % NaOCl solution	*Legionella pneumophila*	**[already evaluated in the UA dossier discussed at BPC-39]** **CSTB simulated-use test (phase 2, step 2)** Evaluation using Alpheo II equipment to treat *Legionella* in hot water networks. Initial concentration of Legionella > 10^4 CFU/L Temperature: +37°C Shock treatment at 50 ppm (3x 2h) as applied in the system followed by a continuous treatment at 1 ppm as residual concentration for 10 days. pH = 7.5 Interfering substance: natural soiling (~1-2 mg/L TOC)	Results showed only a >4 lg reduction with a shock treatment at 50 mg/L active chlorine (3x 2h) followed by a continuous treatment at 1 mg/L active chlorine for 10 days at 37°C. The achieved lg reduction directly after shock treatment was only ~3 lg.	Doc "25_Sim use - CSTB_37°C_Natural soiling_clean_P2S2_Legionella.pdf" CSTB (2019) EN-CAPE 19.083 C – V2 *RI = 3 (non-representative test conditions: drinking water without additional soiling as test matrix, inadequate test temperature)*

3.5.4 Efficacy assessment

Uses 1 and 3 (continuous dosing / maintenance treatment)

Efficacy against bacteria and viruses

For demonstrating efficacy against bacteria, amongst others the following tests have been provided:

1) adapted phase 2, step 1 test demonstrating bactericidal efficacy at 1.4 mg/L active chlorine in 30 sec,
2) adapted phase 2, step 1 test demonstrating bactericidal efficacy at 0.6 mg/L active chlorine in 5 min,
3) monitoring data showing sufficient bactericidal efficacy at 0.5-0.6 mg/L active chlorine.

Efficacy for pools operated with high hygienic requirements according to national regulations or recommendations (e.g. DIN 19643 for Germany, for further information regarding hygienic requirements see below) (use 3) is primarily demonstrated by the provided monitoring data in German swimming pools compliant with DIN 19643. This is further supported by phase 2, step 1 test with 0.6 mg/L active chlorine and a contact time of 5 min (higher compared to maximum contact time of 2 min for bacteria in OECD No. 170). This is considered to be acceptable as in such pools other treatment processes are used in combination with chemicals to disinfect the pools.

For other pools (use 1), the concentrations below 1.4 mg/L active chlorine were withdrawn by the applicant and therefore not further assessed.

Therefore, efficacy against bacteria is demonstrated at 1.4 mg/L for use 1 (continuous dosing) and at 0.6 mg/L active chlorine for use 3 (continuous dosing in pools compliant with high hygienic requirements).

For demonstrating efficacy against viruses, the following data have been taken into account:

1) adapted phase 2, step 1 tests with 1.2 mg/L, 1.12 mg/L and 0.6 mg/L active chlorine,
2) UBA simulated-use test (from UBA publication) demonstrating efficacy against viruses (bacteriophages) at 0.3 mg/L active chlorine in 2 min,
3) adapted phase 2, step 1 test (literature data) demonstrating efficacy against Poliovirus 1 at 0.5 mg/L active chlorine in 1.9 min.

The adapted phase 2, step 1 test showed sufficient virucidal activity at 1.12 mg/L in 10 min. However, at 0.6 mg/L active chlorine no sufficient virucidal activity was shown in 10 min. For further discussion of this result, please refer to the conf. annex to the PAR (MS only), chapter 11.2.

The UBA simulated-use test demonstrated efficacy against viruses (bacteriophages) at 0.3 mg/L active chlorine in 2 min. The test was performed with 2 mg/L DOC as interfering substance, which was considered acceptable to reflect continuous dosing in pools where chlorine concentration is constantly readjusted and the soiling is kept low by e.g. filtration and flocculation.
Furthermore, the UBA simulated-use test was conducted with the bacteriophages MS2 and PRD1 (standard test organisms in simulated-use tests for PT5) instead of Adenovirus and Rota-/Norovirus (recommended by OECD 170 and EFF Guidance/EFF WG). MS2 is a male-specific (F+) coliphage with ssRNA genome that belongs to the family *Leviviridae*. PRD1 is a somatic coliphage with a dsDNA genome that belongs to the family *Tectiviridae*. Both phages are non-enveloped viruses. PRD1 has an inner lipid-protein membrane (Caldentey

et al., 1990[4]) and shows properties similar to human adenoviruses (Bamford *et al*., 1991[5]; Poranen *et al*., 2015[6]). The bacteriophages MS2 and PRD1 have already been accepted as surrogate viruses in the UBA simulated-use test for PT5 applications. The suitability of using these bacteriophages as surrogates for viruses is also supported by several literature studies. Somatic and F+-specific coliphages have been suggested as valuable surrogates for enteric viruses, as they share many fundamental features, including structure, composition and morphology, and these coliphages are generally at least as resistant to unfavourable conditions including disinfection processes as enteric viruses (reviewed by Grabow, 2001[7]). Based on the data from the UBA study by El-Athman *et al*.(2021), MS2 seems to be less susceptible to chlorine treatment than PRD1 (CT_{99} value of 0.243 compared to 0.059). Tree *et al*. (2003) showed poor inactivation of MS2 phage with 0.2-1.0 lg reduction upon treatment with 8-30 mg/L chlorine in primary sewage effluent, while Poliovirus 1 was significantly more susceptible (2.8 lg reduction).[8] Durán *et al*. (2003) showed no significant differences in lg reductions for MS2 phage and Poliovirus 1, when spiked in secondary effluent after chlorination with 20 mg/L chlorine.[9] Based on a lot of efficacy data, it is very likely that Poliovirus 1 is generally less susceptible to chlorine treatment than Adenovirus and murine Norovirus. Besides, another study by Kanna (2015)[10] showed higher susceptibitily of canine Adenovirus 1 and murine Norovirus 1 (initial lg reductions of 3.94 and 3.48 with CT_{90} values of 0.58 and 0.28 min*mg/L, respectively) compared to MS2 phage (initial lg reduction of 0.34 with CT_{90} value of 12.6 min*mg/L) upon chlorination in different samples from water treatment plants.

In combination with the literature data by Yamashita *et al*. (1988) provided by the applicant, which showed sufficient inactivation of Poliovirus 1 with 0.5 mg/L free chlorine, it can therefore be expected that chlorine concentrations in this range are also efficacious against Adeno- and Rota-/Norovirus for disinfection in pools by continuous dosing, when chlorine concentration is constantly readjusted and the soiling is kept low, e.g. by filtration and flocculation.

Therefore, as long as no other appropriate simulated-use tests are available, the DE CA is of the opinion that the UBA simulated-use tests performed with bacteriophages in combination with the literature data is acceptable to demonstrate virucidal efficacy for maintenance treatment at 0.5 mg/L active chlorine in swimming pools, spas and hot tubs that are operated with high hygienic requirements in order to provide a constantly low level of target organisms and soiling.

Such hygienic requirements (e.g. which are mentioned in standard DIN 19643 for Germany) should include:

- treatment of the water with suitable combined treatments with filtration, flocculation, oxidation and/or adsorption in combination with chlorination (e.g. flocculation + multilayer filtration + chlorination, OR flocculation + adsorption to powdered activated carbon + ultrafiltration + chlorination) according to national regulations or recommendations (e.g., DIN 19643 for Germany),

[4] Caldentey, J., Bamford, J.K.H., Bamford, D.H., 1990. Structure and assembly of bacteriophage PRD1, an Escherichia coli virus with a membrane. J. Struct. Biol. 104, 44–51. https://doi.org/10.1016/1047-8477(90)90056-I

[5] Bamford, J.K.H., H¨anninen, A.L., Pakula, T.M., Ojala, P.M., Kalkkinen, N., Frilander, M., Bamford, D.H., 1991. Genome organization of membrane-containing bacteriophage PRD1. Virology 183, 658–676. https://doi.org/10.1016/0042-6822(91)90995-N

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- appropriate basin hydraulics for optimal distribution of the disinfectant in the well-flowed basin and for discharge of contaminants,
- compliance with specified limits for additional water parameters including pH, redox potential, turbidity, colouring (e.g. pH between 6.5 and 7.5, redox potential against Ag/AgCl 3.5 m KCl with at least 750 mV for 6.5≤pH≤7.3 and at least 770 mV for 7.3<pH≤7.5, turbidity up to 0.5 FNU (Formazine Nephelometric Units)),
- automatic and continuous measurement and readjustment of active chlorine concentration and pH value,
- sufficient exchange of pool water with fresh filling water of drinking water quality (at least 30L/bather as e.g. daily average) to keep the concentration of those substances low that cannot be removed by treatment of the water,
- regular cleaning of bottom and sides of basins and rinsing of filters,
- regular controls of water quality and technical installations.

With these requirements, levels of microorganisms and soiling are constanly kept low, so that lower in-use concentrations of active chlorine are expected to be sufficient to ensure appropriate disinfection of newly introduced microorganisms.

For other swimming pools, spas and hot tubs that do not fulfil the hygienic requirements mentioned above, the UBA publication could not be accepted, but instead the adapted phase 2, step 1 test showing virucidal efficacy at 1.12 mg/L active chlorine has to be taken into account.

Therefore, efficacy against bacteria and viruses is demonstrated at 1.4 mg/L active chlorine for use 1 (continuous dosing / maintenance treatment) and at 0.6 mg/L active chlorine for use 3 (continuous dosing / maintenance treatment in swimming pools, spas and hot tubs operated with high hygienic requirements according to national regulations or recommendations (e.g. DIN 19643 for Germany).

Efficacy against Legionella

For demonstrating efficacy against Legionella, a new (non-adapted) EN 1276:2019 study (phase 2, step 1) has been provided showing efficacy against Legionella at 1.2 mg/L active chlorine in 10 min.

Efficacy for pools operated with high hygienic requirements according to national regulations or recommendations (e.g. DIN 19643 for Germany) (use 3) is primarily demonstrated by the provided monitoring data in German swimming pools compliant with DIN 19643. This is further supported by the phase 2, step 1 test with 1.2 mg/L active chlorine and a contact time of 10 min (higher compared to 30 sec for Legionella in OECD No. 170). This is considered to be acceptable as in such pools other treatment processes are used in combination with chemicals to disinfect the pools.
Therefore, when considering the phase 2, step 1 test and the already provided monitoring data showing sufficient efficacy against Legionella at 0.5-0.6 mg/L active chlorine, efficacy against Legionella for use 3 (continuous dosing in swimming pools, spas and hot tubs compliant with high hygienic requirements) is demonstrated at 1.2 mg/L active chlorine.

For other pools (use 1), the target organism Legionella was withdrawn by the applicant. Therefore, spas and hot tubs cannot be authorised for use 1.

use 2 (shock dosing)

Efficacy against bacteria and viruses

For demonstrating efficacy against bacteria and viruses, the submitted data package has

already been evaluated and discussed within several previous product authorisations. This data package includes the following studies:

1) adapted phase 2, step 1 test demonstrating bactericidal efficacy at 3.43 mg/L active chlorine in 5 min,
2) simulated-use test demonstrating bactericidal efficacy at 6.7 mg/L active chlorine in 2 min,
3) adapted phase 2, step 1 test demonstrating virucidal efficacy at 1.12 mg/L active chlorine in 10 min.

According to the provided data, efficacy for the target organisms bacteria and viruses for use 2 (shock dosing) is demonstrated at 6.7 mg/L active chlorine in 10 min.

Efficacy against Legionella

For demonstrating efficacy against Legionella, a new (non-adapted) EN 1276:2019 study (phase 2, step 1) has been provided showing efficacy against Legionella at 1.2 mg/L active chlorine in 10 min. However, the simulated-use test already provided in the previous UA dossier discussed at BPC-39 has been conducted with non-representative test conditions, i.e. drinking water without additional soiling and an inadequate test temperature of 37°C. In addition, an insufficient reduction of only ~3 lg was achieved directly after the shock treatment. Therefore, this study could not be accepted as proof of efficacy for use 2 (shock dosing). Since no new simulated-use test conducted under relevant test conditions has been submitted by the applicant, efficacy against Legionella is not sufficiently demonstrated for use 2 (shock dosing). Therefore, efficacy for spas and hot tubs is not proven for use 2.

3.5.5 Conclusion on efficacy

The product demonstrated efficacy for the following uses:

use 1 (continuous dosing in swimming pools)
bacteria & viruses – 1.4 mg/L active chlorine
use 2 (shock dosing in swimming pools)

- bacteria & viruses – 6.7 mg/L active chlorine, contact time 10 min

use 3 (continuous dosing in swimming pools, spas and hot tubs compliant with high hygienic requirements)

- bacteria & viruses: 0.6 mg/L active chlorine
- Legionella: 1.2 mg/L active chlorine
- only for swimming pools, spas and hot tubs operated with high hygienic requirements according to national regulations or recommendations, e.g. DIN 19643 for Germany (including suitable combinations of water treatment processes such as filtration and flocculation in addition to disinfection processes, appropriate basin hydraulics, automatic and continuous measurement and readjustment of active chlorine concentration and pH value, sufficient addition of fresh filling water, regular cleaning and controls)

The minimum in-use concentration of 0.3 mg/L active chlorine as claimed by the applicant for use 3 has not been sufficiently demonstrated. Efficacy against Legionella for use 2 has not been sufficiently demonstrated.

3.5.6 Occurrence of resistance and resistance management

As stated in the assessment reports for Active chlorine released from chlorine, Active chlorine released from sodium hypochlorite and Active chlorine released from calcium hypochlorite, 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. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003 and Submission to SCENIHR, February 2008)] as one of the biocides where acquired resistance is least likely to develop. For the same reasons cross-resistance is not to be expected, nor has it been observed. Despite its use for almost a century in purifying drinking water, where very low (sub ppm) concentrations are continuously maintained, the development of acquired resistance has not been observed. Adaptation of organisms to hypochlorite can be determined by comparison of the Minimum Inhibitory Concentration (MIC) but this is not relevant in practice as the actual use concentrations are much higher and thus a sufficient margin of safety is provided.

No management strategies are necessary as acquired resistance to active chlorine has not developed nor will develop due to its reactive nature and unspecific mode of action. Some temporary adaptation giving modestly reduced susceptibility is sometimes observed in organisms exposed continuously at low concentrations (e.g. in water pipes through formation of biofilms), but this is readily managed e.g. by control/removal of the biofilm.

3.5.7 Known limitations

The efficacy of a specific active chlorine concentration is reduced by the presence of organic load and in general by the presence of particles. Furthermore, the activity decreases with increasing pH due to lower concentration of un-dissociated hypochlorous acid.

3.5.8 Relevant information if the product is intended to be authorised for use with other biocidal products

The biocidal product is not intended to be used in combination with other biocidal products.

3.6 Risk assessment for human health

3.6.1 Assessment of effects on human health

3.6.1.1 Skin corrosion and irritation

Table 3.8 Conclusion used in Risk Assessment – Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Causes skin irritation
Justification for the value/conclusion	The product does not contain other components then the active substance active chlorine released from chlorine (CAS-No. 7782-50-5). Therefore, the classification from Annex VI of Regulation (EC) No 1272/2008 and from the assessment report is adopted (AR, January 2017, Ref MS: IT)
Classification of the product according to CLP	Classification with Skin Irrit 2, H315 is required.

Table 3.9 Data waiving

Data waiving	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and section 3.1.1 "Skin corrosion or skin irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (Version 1.2, May 2018), "*testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.*" The composition of the biocidal product is known. Sufficient information on skin corrosive or skin irritating properties of the components of the biocidal product is available. There is no information or indication on synergistic effects. According to the Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing of the components and/or of the biocidal product is considered not necessary.

3.6.1.2 Eye irritation

Table 3.10 Conclusion used in Risk Assessment – Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye irritation
Justification for the value/conclusion	The product does not contain other components then the active substance active chlorine released from chlorine (CAS-No. 7782-50-5). Therefore, the classification from Annex VI of Regulation (EC) No 1272/2008 and from the assessment report is adopted (AR, January 2017, Ref MS: IT)
Classification of the product according to	Classification with Eye Irrit 2, H319 is required.

CLP	

Table 3.11 Data waiving

Data waiving	
Information requirement	8.2. Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and section 3.1.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (Version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Sufficient information on eye irritating properties of the components of the biocidal product is available. Information or indications on synergistic effects are not available. According to the Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing of the components and/or of the biocidal product is considered not necessary.

3.6.1.3 Respiratory tract irritation

Table 3.12 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Irritating to the respiratory tract.
Justification for the conclusion	The product does not contain other components then the active substance active chlorine released from chlorine (CAS-No. 7782-50-5). Therefore, the classification from Annex VI of Regulation (EC) No 1272/2008 and from the assessment report is adopted (AR, January 2017, Ref MS: IT).
Classification of the product according to CLP	Classification with STOT SE 3, H335, for respiratory tract irritation is required.

Table 3.13 Data waiving

Data waiving	
Information requirement	8.10. Other test(s) related to the exposure to humans
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory tract irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008.

3.6.1.4 Skin sensitization

Table 3.14 Conclusion used in Risk Assessment – Skin sensitisation

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin.
Justification for the value/conclusion	The biocidal product does not contain components classified for skin sensitisation. Hence, classification according to Regulation (EC) No

	1272/2008 is not required.
Classification of the product according to CLP	Classification for skin sensation is not necessary.

Table 3.15 Data waiving

Data waiving	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product family are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and section 3.1.3 "Skin sensitisation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (Version 1.2, May 2018), "*testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.*" The composition of the biocidal product is known. Sufficient information on skin sensitising properties of the components of the biocidal product is available. There is no information or indication on synergistic effects. According to the Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing of the components and/or of the biocidal product is considered not necessary.

3.6.1.5 Respiratory sensitization

Table 3.16 Conclusion used in Risk Assessment – Respiratory sensitisation

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Respiratory sensitisation is not expected from available data.
Justification for the value/conclusion	Data on respiratory sensitisation for the biocidal product or the components are not available.
Classification of the product according to CLP	Classification for respiratory sensitisation is not required.

Table 3.17 Data waiving

Data waiving	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or the components are not available.

3.6.1.6 Acute oral toxicity

Table 3.18 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not classified for acute oral toxicity.
Justification for the selected value	LD50 (oral) > 2000 mg/kg bw The product does not contain substances classified for oral toxicity in relevant concentrations.

Classification of the product according to CLP	No classification required.

Table 3.19 Data waiving

Data waiving	
Information requirement	8.5.1. By oral route
Justification	Studies on potential acute oral toxicity properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (Version 1.2, May 2018), "*testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.*" The composition of the biocidal product is known. Sufficient information on acute oral toxicity properties of the components of the biocidal product is available. There is no information or indication on synergistic effects. According to the Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing of the components and/or of the biocidal product is considered not necessary.

3.6.1.7 Acute inhalation toxicity

Table 3.20 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC50 (inhalation): < 5 mg/L (Toxic if inhaled)
Justification for the selected value	The product does not contain other components then the active substance active chlorine released from chlorine (CAS-No. 7782-50-5). Therefore, the classification from Annex VI of Regulation (EC) No 1272/2008 and is adopted. According to the assessment report for the active substance (AR, January 2017, Ref MS: IT), chlorine should be classified with Acute Tox. 2, H330. Since Annex VI of Regulation (EC) No 1272/2008 has not been adapted accordingly yet, this classification is considered not relevant for this biocidal product.
Classification of the product according to CLP	Classification of Acute Tox. 3, H331 is required.

Table 3.21 Data waiving

Data waiving	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute inhalation toxicity properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (Version 1.2, May 2018), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive

	1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. Sufficient information on acute inhalation toxicity properties of the components of the biocidal product is available. There is no information or indication on synergistic effects. According to the Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing of the components and/or of the biocidal product is considered not necessary.

3.6.1.8 Acute dermal toxicity

Table 3.22 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acute toxic by dermal route
Justification for the selected value	LD50 (dermal) > 2000 mg/kg bw The product does not contain other components then the active substance active chlorine released from chlorine (CAS-No. 7782-50-5). Therefore, the classification from the assessment report is adopted (AR, January 2017, Ref MS: IT)
Classification of the product according to CLP	Classification not required.

Table 3.23 Data waiving

Data waiving	
Information requirement	8.5.3. By dermal route
Justification	Studies on potential acute dermal toxicity properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and section 3.1.5 "Acute toxicity" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (Version 1.2, May 2018), *"testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."* The composition of the biocidal product is known. Sufficient information on acute dermal toxicity properties of the components of the biocidal product is available. There is no information or indication on synergistic effects. According to the Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing of the components and/or of the biocidal product is considered not necessary.

3.6.2 Information on dermal absorption

Table 3.24 Value(s) used in the Risk Assessment – Dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Chlorine released from chlorine (CAS-No. 7782-50-5)
Value(s)	Not relevant.

Justification for the selected value(s)	The product does not contain other components then the active substance active chlorine released from chlorine (CAS-No. 7782-50-5). Therefore, the conclusion on dermal absorption from the assessment report is adopted (AR, January 2017, Ref MS: IT) Chlorine causes only local effects (BPC TOX-WGIII-2016). Dermal absorption is considered not relevant. A value has not been derived.

3.6.3 Available toxicological data relating to substance(s) of concern

No substance of concern regarding human health was identified. Consequently, only the active substance was addressed in the human health risk assessment.

3.6.4 Other

Not relevant.

3.6.4.1 Food and feeding stuffs studies

Not relevant.

3.6.4.2 Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

Not relevant.

3.6.4.3 Other test(s) related to the exposure to humans

Not relevant.

3.6.5 Available toxicological data relating to endocrine disruption

The biocidal product does not contain any substances having endocrine-disrupting properties.

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Arche Chlorine POOL:

- According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Active chlorine released from chlorine is not part of the list[11] of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

- According to the CAR and BPC opinion on sodium hypochlorite: "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)."

[11] Please refer to CA-September18.Doc.7.5.a-final .

- However, please note that sodium chlorate, which can be formed during storage and is therefore considered as a relevant impurity, shows indications of ED properties. Indeed the BPC opinion on active chlorine generated from sodium chloride by electrolysis[12], published in 2020, refers to the EFSA Scientific Opinion on "Risks for public health related to the presence of chlorate in food"[13], which suggests that chlorate may disrupt the thyroid hormone homeostasis. However, no assessment of the endocrine-disrupting properties of chlorate was performed and no clear conclusion can be drawn based on the available data. The same conclusion is available in the REACH registration dossier of Potassium chlorate, which is partially based on the same data[14].

- No CoRAP procedure has been launched for sodium chlorate, unlike Perchlorate which has a similar mode of action[15] and for which a conclusion is available[16]. According to the evaluation report of sodium perchlorate (CAS N° 7601-89-0), the substance shows clear thyroid disrupting effects on non-target organisms, as well as ED effects on metamorphosis, development, reproduction, sex ratio and stress tolerance, leading to potential long-term and population relevant impacts. Perchlorates will thus be part of an upcoming SVHC identification process.

Therefore, DE eCA would consider that no clear conclusion on ED properties of sodium chlorate can be drawn up to the renewal of the approval of the active substance sodium hypochlorite or up to the outcome of SVHC identification process.

1. Assessment of the ED properties of non-active substances (co-formulants) in Arche Chlorine:
   - Since Arche Chlorine Pool only contain the active substance active chlorine released from chlorine, without others co-formulants, no further assessment of the ED properties has been performed for the formulated product Arche Chlorine Pool.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

Relevant guidance documents consulted for human health risk assessment

Please, consider chapter 4.4.2.

Relevant exposure models or exposure studies used for human health risk assessment

Exposure studies have not been submitted by the applicant. Exposure of non-professional users is not relevant as intended uses are for professional use only. For professional users,

[12] Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance: Active chlorine generated from sodium chloride by electrolysis - Product type: 3, ECHA/BPC/252/2020
[13] EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015;13(6):4135, 103 pp.
[14] https://echa.europa.eu/registration-dossier/-/registered-dossier/10580/7/1
[15] Beate Kettlitz, Gabriella Kemendi, Nigel Thorgrimsson, Nele Cattoor (2016). Why chlorate occurs in potable water and processed foods: a critical assessment and challenges faced by the food industry. Food Additives & Contaminants: Part A
[16] https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ea4f2

the relevevant exposure models ConsExpo Disinfectant Products FactSheet, 2006, Appendix "Exposure in public swimming pools) and exposure studies (Euro Chlor, 2001 (data taken from AR "Active chlorine released from chlorine", evaluating Competent Authority Italy, January 2017) were used for human health risk assessment.

Exposure of the general public with the product is expected by contact with water in swimming pools, spa and hot tubs. A risk assessment for secondary exposure of the general public was performed according to BPC opinion for the active substance active chlorine released from chlorine – PT2 (2016) and in the assessment report (Italy, 2017.) The dermal and inhalation exposure and oral uptake for swimming pool and spa users (secondary exposure of the general public: adults, children and infants) is calculated in the exposure assessment.

Strategy for human health risk assessment

Professional user:
According to the Assessment Report "Active chlorine released from chlorine" (Italy, 2017) 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 the product Chlorine for all relevant routes of exposure for the professional user (inhalation).
Exposure assessment is performed for chlorine as available chlorine (avCl) according to the assessment report of the active substance "Active chlorine released from chlorine".
The product is foreseen for disinfection of large-scale swimming pools, spas and hot tubs by continuous dosing.

- Inhalation exposure: For the inhalation route of exposure, a quantitative assessment has been performed. Exposure towards chlorine gas (Cl2 as avCL) and vapour (HClO as avCl) is conceivable.

At pH values of about 4-6, hypochlorous acid (HClO) is the predominant species and exposure to vapours of HClO (as avail. chlorine) are considered relevant.

Local quantitative risk assessment for the active substance active chlorine released from chlorine via the inhalation route was performed with the AEC of 0.5 mg/m^3.
A qualitative local risk assessment was also performed.

Secondary exposure of the general public:
Due to the local mode of action of clorine gas, potential systemic effects are secondary to its direct irritating reactivity. Consequently, only a local semi-quantitative 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.

Considerations on volatility of the active substance(s) and substance(s) of concern

No substance of concern was identified.

The active substance is volatile under specific conditions.

The product is marketed in gas cylinders or drums which contain the the a.s. chlorine (CAS No. 7782-50-5, up to 100% a.s.) in compressed liquid form. The free active substance is a gas under atmospheric conditions and readily soluble in water. As mentioned before, the

aqueous solution of chlorine undergoes pH dependent equilibrium reactions. Of relevance for this assessment is the fact that volatile hypochlorous acid (HClO) is the predominant species at pH values of about 4-6, while at higher pH values the non-volatile anionic form OCl^- becomes more dominant. Due to its volatility, exposure to vapours of HClO (as avail. chlorine) are considered relevant in the pH range foreseen for use of this product.

Therefore, exposure to vapour is considered in the risk assessment.

Strategy for livestock exposure and/or dietary risk assessment
Not relevant.

Strategy for the assessment of substance(s) of concern
Not applicable because the product does not contain substances of concern.

Strategy for disinfectant by-products assessment
Please refer to the confidential annex.

3.6.6.2 Identification of the main paths of human exposure towards active substance(s) and substance(s) of concern from use in the biocidal product

Table 3.25 Summary table: main paths of human exposure

Summary table: main paths of human exposure					
Exposure path	**Primary (direct) exposure**		**Secondary (indirect) exposure**		
	Professional users (including industrial users and trained professional users)	**Non-professional users**	**Professional users** (including industrial users and trained professional users)	**Non-professional bystanders/ General public**	**Via food**
Oral	No	n/a	n/a	Yes	n/a
Dermal	No	n/a	n/a	Yes	n/a
Inhalation	Yes	n/a	n/a	Yes	n/a

3.6.6.3 List of exposure scenarios

Table 3.26 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Primary exposure		
SCENARIO 1	Connecting and disconnecting of gas cyclinder containing the product to the automatic dosing system. The application takes place automatically in the water system	Professional
SCENARIO 2	Maintenance/repair the dosing system or the feed line	Professional
SCENARIO 3	Professional swim instructor only stands near the pool for giving instructions, are exposed to evaporating substance from the swimming pool.	Professional
Secondary exposure		
Scenario 4	Exposure in public hot tubes and spa	Non-professional bystander / General public
Scenario 5	Exposure in public swimming pools to swimmer	Non-professional bystander / General public

3.6.6.4 Reference values to be used in risk characterisation

Table 3.27 Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for absorption	Value
$NOAEC_{oral}$		0.1 % avCl	1		0.1 % avCl
$NOAEC_{dermal}$		1 % avCl	1		1 % avCl
$AEC_{inhalation\ (Chlorine/HClO)}$		0.5 mg avCl/m^3	1		0.5 mg avCl/m^3

3.6.6.5 Specific reference value for groundwater

No specific reference values for ground water were derived.

3.6.6.6 Professional users (including industrial users and trained professional users)

Scenario 5 1: Connecting chlorine gas cylinders to the automated dosing system

Description and input parameters

Table 3.28 Description and input parameters

Description of Scenario 1

The operation of chlorine gas systems in vacuum technology is the state of the art. Chlorine from chlorine gas containers is dissolved in a partial flow of the pool water filtrate in a closed system and then introduced into the main flow of the water recirculation. An injector creates a negative pressure in the gas line, which effectively prevents chlorine gas from escaping into the room air even if there is a leak in the gas line.
Nevertheless, for caution the presence of workers in chlorine gas container rooms must be limited to the extent necessary. They are not designed for a permanent stay.

When changing the chlorine gas containers, no moisture may penetrate the chlorinators or pipes, as chlorine attacks metals in the presence of moisture. In Germany, the Technical Rules for Operational Safety and Hazardous Substances for Transportable Pressure Gas Containers - Filling, Holding, Internal Transport, Emptying - requires to prevent corrosion damage that transportable pressure gas cyclinders do not contain any liquid in such quantity that it can cause dangerous corrosion. The so-called residual pressure safety device is mentioned as one of the possible measures to fulfill this requirement.

When changing the chlorine container/cylinder, a distinction can be made between 3 types:

1. The change of bottles that have been completely emptied into the vacuum. Due to the full vacuum technology, escape of chlorine gas from the cyclinder is unlikely.
2. The change of partially emptied bottles. There is an overpressure in the cylinder in this case. However, a vacuum is created in the connection between the cylinder valve and the vacuum control valve by closing the cylinder valve before the vacuum control valve closes with a time delay (evacuation), thus no escape of chlorine gas is expected in this case.
3. Changing partially emptied cylinders on systems with residual pressure safety device. The residual pressure safety device is located between the cylinder valve and the vacuum control valve or integrated in the vacuum control valve. The chlorine gas withdrawal is interrupted when the pressure inside the cylinder decreases to a level slightly above atmospheric pressure. Thus, there is always an overpressure in the only partially emptied containers as well as in the small connecting piece (few mL volume). Exposure to minor amounts of chlorine gas released from the small connecting piece is expected to occur when opening the connection between the pipe system and the connecting piece.

Regarding the exposure assessment, no models are available to estimate the exposure during mixing and loading of a gaseous substance. The quantitative exposure assessment is therefore based on a study of workers exposure to chlorine in the atmosphere during chlorine production (Euro Chlor, 2001). The exposure during filling operations described in this study is assessed as a reasonable worst-case covering connecting and disconnecting of gas cyclinders/drums in either of the three cases described above. For filling operators, measured values of chlorine and chlorinated species in the atmosphere ranged from 0-5 ppm (0-15 mg/m³) with an average of 0.077 ppm (0.231 mg/m³) and a median of 0.057 ppm (0.171 mg/m³). The 90th percentile of measured values of chlorine and chlorinated species was 0.166 ppm (0.498 mg/m³).

Although the quantitative exposure and risk assessment did not demonstrate exceedance of the AEC for avCl in the regular case, precautionary measures are deemed necessary for the case of gas leakage.

- An alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m³) must be in place which initiates safety procedures like wearing respiratory protective equipment (RPE). The electrochemical sensors used for measurements must be able to detect various chlorinated species in addition to chlorine itself. The sensors must measure exposure also when the operators are using RPE.
- At least a full face mask with appropriate gas filter, according to CEN standard EN 14387:2021: Respiratory protective devices – Gas filter(s) and combined filter(s) – Requirement, testing, marking (or equivalent), or a powered air purifying respirator with helmet/hood/mask (TH2/TM2)must be at hand when changing the gas cylinders/drums.
- Application of local exhaust ventilation (LEV) (according to the national regulation) and vacuum technology are in place to avoid chlorine

The RPE must be stored outside the chlorine gas rooms.

Input parameters for Scenario 1			
Inhalation			
	Parameters	Value	Reference and justification[3]
Tier 1 (no PPE)	Measured values of chlorine and chlorinated species in the atmosphere for filling operators	0.498 mg/m³ (0.166 ppm, 90th percentile)	Euro Chlor, 2001 (AR Chlorine, Italy, 2017, Doc. IIIA, Section A2, table A.2.10-4)

Scenario 2: Maintenance/repair

Description and input parameters

Table 3.29 Description and input parameters

Description of Scenario 2
During maintenance/repair tasks on the automatic dosing system the professional worker needs to disconnect the pipes and ventilate the dosing system. Thereby the worker may come into contact with chlorine in gaseous form. The only relevant exposure route is inhalation. Regarding the exposure assessment, no models are available to estimate the exposure during maintenance. However, measured exposure data of chlorine concentrations in different workplaces of chlor-alkali plants are available (Euro Chlor, 2001). For maintenance operations, measured values of chlorines and chlorinated species in the atmosphere ranged from 0-1 ppm (0-3 mg/m³) with an average of 0.082 ppm (0.246 mg/m³) and a median of 0.050 ppm (0.150 mg/m³). The 90th percentile for maintenance was 0.160 ppm (0.480 mg/m³). Contact with water containing chlorine is not likely, as the dosing system is shut down during the work. When changing the chlorine cylinders and during maintenance work, contact with water is also not likely. The chlorine system is located in a separate room so that the formation of chlorine, even in the form of an aerosol, is not possible during normal use.

Input parameters for Scenario 2			
Inhalation			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Measured values of chlorine and chlorinated species in the atmosphere for maintenace operators	0.48 mg/m³ (0.16 ppm, 90th percentile)	Euro Chlor, 2001 (AR Chlorine, Italy 2017, Doc. IIIA, Section A2, table A.2.10-4)

Scenario 3: Professional swim instructor

Description and input parameters

Table 3.30 Description and input parameters

Description of Scenario 3
A professional swim instructor is exposed via inhalation to evaporating substances from the treated indoor swimming pool (8 h/day). Since the swim instructor only stands near the pool for giving instructions, no dermal exposure is considered. According to the German norm for swimming pools, DIN 19463 (part 1), the pH of a swimming pool should be 6.5. At these pH values, the active chlorine present in swimming pool water will be mainly available as hypochlorous acid (HClO) and only exposure to vapours of HClO (as avCl) is considered relevant. Inhalation exposure is estimated with ConsExpo - Evaporation model (constant surface), using the "Disinfectant Products Fact Sheet" (Appendix: Exposure in public swimming pools p. 87). The assessment is based on a worst-case approach of the in-use concentration of 0.00014 % (w/w) avCl (1.4 mg/L av Cl, efficacy proven maximum application rate). In case of high microbial loads, shock dosing treatment is performed with higher chlorine concentrations (up to 50 mg/L avCl). This is done outside of opening hours and/or overnight. Consequently, the pool is not used by swimmers (no swimming allowed) and presence of other staff in the swimming hall is not expected. Responsible for shock dosing treatment is normally trained and comprehensively instructed. Chlorine levels in pool water are monitored (normally by automated measuring devices) and re-entry into the pool is allowed only after decrease of available chlorine to normal in-use concentrations.

Input parameters for Scenario 3			
Inhalation			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Weight fraction (%) Concentration active substance (as avCl)	0.00014% (or 1.4 mg/L)	maximum application rate
	Molecular weight (HClO)	52.5 g/mol	AR Chlorine, Italy, 2017
	Vapour pressure (HClO)	337 Pascal (28°C)	AR Chlorine, Italy, 2017
	Exposure duration	480 min	worst case assumption
	Amount of solution used	5.6 * 10^8 g	ConsExpo FactSheet Disinfectant, 2006
	Room volume	1150 m^3	Expert judgment
	Ventilation rate	2/hr	ConsExpo FactSheet Disinfectant, 2006
	Release area	375 m^2	surface swimming pool (25 m x 15 m)
	Application temperature	28 °C	ConsExpo FactSheet Disinfectant, 2006
	Mass transfer coefficient	10 m/h	ConsExpo Web
	Molecular weight matrix	18 g/mol	ConsExpo FactSheet Disinfectant, 2006
	Emission duration	480 min	worst case assumption

Outcome of systemic exposure and risk characterisation

Not applicable as only local effects are relevant.

Combined scenarios

Combined exposure is not relevant based on the absence of systemic effects after exposure towards chlorine (hypochlorous acid and hypochlorite). The primary mode of action of chlorine (hypochlorous acid and hypochlorite) is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by chlorine are rather concentration than time-dependent. For this reason, only the highest exposure level (concentration as 0.00014 % avCl or 1.4 mg avCl/L) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

Outcome of quantitative local exposure and risk characterisation

Table 3.31 Summary table: estimated local exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users						
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³]**	**Estimated exposure / AEC (%)** AECdermal = n.a. AECinhalation = 0.5 mg/m³	**Acceptable (yes/no)**
Scenario 1	1/no PPE	n.a.	0.498	0.498	99.6	Yes
	2/*no PPE*	n.a.	0.498	0.498	99.6	Yes
Scenario 2	1/no PPE	n.a.	0.480	0.480	96.0	Yes
	2/*no PPE*	n.a.	0.480	0.480	96.0	Yes
Scenario 3	1/no PPE	n.a.	0.002	0.002	0.41	Yes
	2/*no PPE*	n.a.	0.002	0.002	0.41	yes

n.a.: not applicable

Outcome of qualitative local risk assessment

Table 3.32 Outcome of qualitative local risk assessment

Hazard			Exposure information						Risk	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMMs & PPE**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
low	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3	-	2	Sc.1 – connecting cylinder	inhalation	few minutes per day	RESPIRATORY SYSTEM: Incidental contact to respiratory system possible	Technical Measure: Chlorine gas systems in full vacuum technology. Alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m³) initiates safety procedures like wearing RPE. Measuring device (electrochemical sensor), sensible not only to chlorine, also to other chlorinated substances. The sensors are also measuring exposure when the operators are using RPE. Well ventilated area, local exhaust ventilation (according to the national legislation) Organisation: Training for staff.	Acceptable + Used for short duration + Professionals using appropriate PPE	-

								Good standard of occupational hygiene. PPE: As a precaution for the case of gas leakage, at least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter (filter type (code letter, colour) according to CEN standard EN 14387:2021 (or equivalent) to be specified by the authorisation holder within the product information) must be at hand when changing the gas cylinders/drums.		
low	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3	-	2	Sc. 2 - Maintenance	inhalation	more than few minutes but equal to or less than few hours per day	RESPIRATORY SYSTEM: Incidental contact to respiratory system possible	Technical Measure: Chlorine gas systems in full vacuum technology. An alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m³) initiates safety procedures like wearing RPE. Measuring device (electrochemical sensor), sensible not only to chlorine, also to other chlorinated substances. The sensors are also	Acceptable + professionals using appropriate PPE	-

								measuring exposure when operators are using RPE. Well ventilated area, local exhaust ventilation (according to the national legislation) Organisation: Training for staff. Good standard of occupational hygiene is assumed. PPE: As a precaution for the case of gas leakage, at least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter (filter type (code letter, colour) according to CEN standard EN 14387:2021 (or equivalent),to be specified by the authorisation holder within the product information) must be at hand when changing the gas cylinders/drums.		

Conclusion

Based on the local risk assessment of the active substance active chlorine released from chlorine via the inhalation route, a risk for professional users resulting from all scenarios of the the biocidal product Arche Chlorine POOL is unlikely after TIER 1 consideration. Regarding occupational safety, there are no objections against the use(s) taking into account the provisions described in chapter 3.6.10 of this PAR.

3.6.6.7 Non-professional users

Exposure of non-professional users is not relevant as intended uses are for professional use only.

3.6.6.8 Secondary exposure to professional bystanders and non-professional bystanders/general public

Not applicable for professional users.

Scenario 4: Exposure in public hot tubes and spa

Table 3.33 Description and input parameters

Description of Scenario 4
Adults, children and infants are exposed to disinfected water while bathing in public hot tubes and spa. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water. Indoor use is the worst case. It is expected that adults and children are exposed 5 times a week, while infants are exposed once a week. According to the applicant company information, the pH of swimming pool water is around 6.8-7.7. According to the German norm for swimming pools, DIN 19463 (part 1), the pH of a swimming pool should be 6.5. At these pH values, the active chlorine present in the swimming pool water will be mainly available as hypochlorous acid (HClO). This chlorine species evaporates easily, and therefore, inhalation exposure to vapour of HClO is relevant. Exposure to vapour is calculated with the ConsExpo evaporation model, following the appendix of the Disinfectants Products FactSheet (2006, p. 87), 'Exposure in public swimming pools'. It is assumed that a person stays 2 hours in the bath. The temperature of the spa water is 40°C. Aerosol exposure is also possible (whirlpool bath or hot tub). In line with the exposure and risk assessment in the CAR for active chlorine from chlorine (PT 5, showering) the assessment has been performed according to the consumer product spraying and dusting model 2 – Handheld trigger spray (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 220), for more explanation see appendix 4.1.1. The exposure estimations of the applicant are based on a use concentration of 5 mg avCl/L. This is the maximal concentration of free chlorine (in hot tubs) allowed according to WHO recommendations[1] and is above the application rate proposed by the applicant for continuous dosing (1.4 mg/L) and even above the dose propsed by the applicant for re-entry of bathers after shock dosing (3 mg/L). It is also above the norms set by national authorities for the concentrations of free chlorine in swimming pool water, and can therefore be considered as worst case. The maximum in-use concentration for the exposure estimation is relatively high compared to the efficacious dose derived for this biocidal product. At the current state, this high dose has no impact on the outcome of the human health risk assessment.

[1] Guidelines for safe recreational water environments. Volume 2: swimming pools and similar environments. WHO, 2006.

Input parameters for Scenario 4			
Dermal, inhalation			
	Parameters[1]	Value	Reference and justification[3]
Tier 1 (no PPE)	Molecular weight HClO	52.5 g/mol	CAR DocIIB
	Weight fraction substance	0.0005 %	Applicant, WHO recommendation
	Vapour pressure HClO	725 Pa at 40°C	CAR, IT 2017 DocIIB
	Body weight Adult Child Infant	 60 kg 15.8 kg 8 kg	HEAdhoc recommendation No. 14 (ECHA)
	Frequency	5 / week	CAR, IT 2017 DocIIB
	Exposure model	Exposure to vapour - Evaporation	CAR, IT 2017 DocIIB
	Exposure duration	120 min	CAR, IT 2017 DocIIB
	Product is substance in pure form	No	-
	Molecular weight matrix	18.01 g / mol (water)	CAR, IT 2017 DocIIB
	The product is used in dilution	No	-
	Amount of solution used	$5.6*10^8$ g	Applicant
	Room volume	188 m^3	CAR, IT 2017 DocIIB
	Ventilation rate	2 / h	CAR, IT 2017 DocIIB
	Application temperature	40 °C	CAR, IT 2017 DocIIB
	Mass transfer coefficient	320000 m / h	CAR, IT 2017 DocIIB
	Release area mode	Constant	CAR, IT 2017 DocIIB
	Release area Adult, children Infant	 375 m^2 100 m^2	CAR, IT 2017 DocIIB
	Emission duration	120 min	CAR, IT 2017 DocIIB
	Indicative value from the consumer product spraying and dusting model 2	10.5 mg / m^3	Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 220, CAR PT 5, IT, 2017 Doc IIB

Calculations for Scenario 4

Detailed calulations are included in section 4.1.1

Summary table: estimated local exposure of adults, children and infants in SPA					
Scenario	**Tier**	**Local inhalation exposure** [mg avCl/m^3]		**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
		Vapor	**Aerosol**		
Scenario 4-1 (adult)	1	0.025	0.00005	0.0005	0.0005
Scenario 4-2 (child)	1	0.025	0.00005	0.0005	0.0005
Scenario 4-3 (infant)	1	0.025	0.00005	0.0005	0.0005

Scenrio Scenario 5: Exposure in public swimming pools to swimmer

Table 3.34 Description and input parameters

Description of Scenario 5

Adults, children and infants are exposed to disinfected water while swimming in public pools. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water. Indoor use is the worst case. It is expected that adults and children are exposed 5 times a week, while infants are exposed once a week.

According to applicant company information, the pH of swimming pool water is around 6.76-7.70. According to the German norm for swimming pools, DIN 19463 (part 1), the pH of a swimming pool should be 6.5. At these pH values, the active chlorine present in the swimming pool water will be mainly available as hypochlorous acid (HClO). This chlorine species evaporates easily, and therefore, inhalation exposure to vapour of HClO is relevant.
Exposure to vapour is calculated with the ConsExpo evaporation model, following the appendix of the Disinfectants Products FactSheet (2006, p. 87), 'Exposure in public swimming pools'.It is assumed that a person swims 2 hours in a pool, while an infant swims only 30 min. The temperature of the swimming pool water is assumed to be 28°C for adult and children and 32°C for infants.

The exposure estimations are based on a use concentration of 5 mg avCl/L.This is the maximal concentration of free chlorine (in hot tubs) allowed according to WHO recommendations[1] and is above the application rate proposed by the applicant for continuous dosing (1.4 mg/L) and even above the dose propsed by the applicant for re-entry of bathers after shock dosing (3 mg/L). It is also above the norms set by national authorities for the concentrations of free chlorine in swimming pool water, and can therefore be considered as worst case.

The maximum in-use concentration for the exposure estimation is relatively high compared to the efficacious dose derived for this biocidal product. At the current state, this high dose has no impact on the outcome of the human health risk assessment.

[1] Guidelines for safe recreational water environments. Volume 2: swimming pools and similar environments. WHO, 2006.

Input parameters for Scenario 5			
Oral, dermal, inhalation			
	Parameters	Value	Reference and justification
Tier 1 (no PPE)	Molecular weight HClO	52.5 g/mol	CAR DocIIB
	Weight fraction substance	0.0005 %	Applicant, WHO recommendation
	Vapour pressure HClO Adult, child Infant	 337 Pa at 28°C 438 Pa at 32°C	CAR, IT 2017 DocIIB
	Body weight Adult Child Infant	 60 kg 15.8 kg 8 kg	Ad hoc recommendation No. 14 (ECHA)
	Frequency	5/week	CAR, IT 2017 DocIIB
	Exposure model	Exposure to vapour - Evaporation	CAR, IT 2017 DocIIB
	Exposure duration Adult, chid Infant	 120 min 30 min	CAR, IT 2017 DocIIB
	Product is substance in pure form	No	-
	Molecular weight matrix	18.01 g/mol (water)	CAR, IT 2017 DocIIB
	The product is used in dilution	No	-
	Amount of solution used	$5.6*10^8$ g	Applicant
	Room volume Adult, children Infant	 188 m^3 50m^3	CAR, IT 2017 DocIIB
	Ventilation rate	2 / h	CAR, IT 2017 DocIIB
	Application temperature Adult, children Infant	 28°C 32°C	CAR, IT 2017 DocIIB
	Mass transfer coefficient	314000 m / h	CAR, IT 2017 DocIIB
	Release area mode	Constant	CAR, IT 2017 DocIIB
	Release area Adult, children Infant	 375 m^2 100 m^2	CAR, IT 2017 DocIIB
	Emission duration	120 min	CAR, IT 2017 DocIIB
	Absorption model	Fixed fraction	-
	Absorption fraction	1	-

Calculations for Scenario 5

Detailed calulations are included in section 4.1.1.

Summary table: estimated local exposure of adults, children and infants in swimming pools				
Scenario	**Tier**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
		Vapor		
Scenario 5-1 (adult)	1	0.012	0.0005	0.0005
Scenario 5-2 (child)	1	0.012	0.0005	0.0005
Scenario 5-3 (infant)	1	0.015	0.0005	0.0005

Outcome of (semi-)quantitative local exposure and risk characterisation

Oral Exposure

Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public				
Exposure scenario	**Tier/PPE**	**Estimated oral exposure [%]**	**Estimated exposure / AEC (%)** NOAECoral = 0.1 %	**Acceptable (yes/no)**
Scenario 4-1 (Adult)	1/no PPE	0.0005	0.5	Yes
Scenario 4-2 (Child)	1/no PPE	0.0005	0.5	Yes
Scenario 4-3 (Infant)	1/no PPE	0.0005	0.5	Yes
Scenario 5-1 (Adult)	1/no PPE	0.0005	0.5	Yes
Scenario 5-2 (Child)	1/no PPE	0.0005	0.5	Yes
Scenario 5-3 (Infant)	1/no PPE	0.0005	0.5	Yes

Dermal Exposure

Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public				
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated exposure / AEC (%)** NOAECdermal = 1 %	**Acceptable (yes/no)**
Scenario 4-1 (Adult)	1/no PPE	0.0005	0.05	Yes
Scenario 4-2 (Child)	1/no PPE	0.0005	0.05	Yes
Scenario 4-3 (Infant)	1/no PPE	0.0005	0.05	Yes
Scenario 5-1 (Adult)	1/no PPE	0.0005	0.05	Yes
Scenario 5-2 (Child)	1/no PPE	0.0005	0.05	Yes
Scenario 5-3 (Infant)	1/no PPE	0.0005	0.05	Yes

Inhalative Exposure

Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure [mg avCl/m³]**	**Estimated total exposure [mg avCl/m³]**	**Estimated exposure / AEC (%)** AECinhalation = 0.5 mg/m³	**Acceptable (yes/no)**
Scenario 4-1 (Adult)	1/no PPE	Vapour: 0.025 Aerosol: 0.00005	0.025	5	Yes
Scenario 4-2 (Child)	1/no PPE	Vapour: 0.025 Aerosol: 0.00005	0.025	5	Yes
Scenario 4-3 (Infant)	1/no PPE	Vapour: 0.025 Aerosol: 0.00005	0.025	5	Yes
Scenario 5-1 (Adult)	1/no PPE	Vapour: 0.012	0.012	2.4	Yes
Scenario 5-2 (Child)	1/no PPE	Vapour: 0.012	0.012	2.4	Yes
Scenario 5-3 (Infant)	1/no PPE	Vapour: 0.015	0.015	3.0	Yes

Conclusion

Regarding exposure to the concentrated product (gas form), the biocidal product is only intended to be used by the (trained) professional user in the dedicate installations specifically designed for a specific site, according to local requirements and regulations so that no exposure to the general public should be expected. However, it cannot excluded that systems with chlorine are also used in areas, which are principally accessible for the general public (e.g. larger houses with many tenants, which have a common swimming pool, spa or hot tub), that's why eCA considers relevant the following RMM:

- "Installations for disinfection has to be inaccessible to the general public (and pets.)"
- "Containers must be stored locked up."

Regarding exposure during bathing and swimming activity, the concentration of chlorine in the in-use solution is below the classification trigger of 10 % for local irritant effects (skin, eyes), and moreover below the $NOAEC_{dermal}$ of 1 % avCl or $NOAEC_{oral}$ of 0.1 % avCl so that no unacceptable risk is expected by dermal or oral route.

For inhalation exposure, according to the quantitative risk assessment no unacceptable exposure has been identified.

The assessment is based on the assumption of the applicant that the shock treatment is made in absence of bathers and that entrance to the pool is not allowed until the concentration decreases back to 3 mg/L of available chlorine or to national chlorine limit. Therefore, the following instructions has to be included.

- "Treatment must be made in absence of bathers for shock application."
- "Do not allow entrance to the pool until the concentration decreases back to 3 mg/L of available chlorine for swimming pools or to national chlorine limit."

3.6.6.9 Assessment of disinfection by products

Based on tier 1 approach, risks for human health due to DBPs cannot be ruled out. No refined risk assessment has been performed and no conclusion can be drawn with regard to the potential risks for human health due to DBP formation when using the biocidal product for swimming pools disinfections.

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.).

For more details see MS-only confidential annex, section "Assessment of disinfection by products".

3.6.7 Dietary risk assessment

The intended use description of the biocidal product "ARCHE chlorine POOL" for which authorisation is sought indicates that this use is not relevant in terms of residues in food and feed. The product is to be used for the disinfection of swimming pool water, spas and hot tubs (PT2) and no direct or indirect contact with food or feed is intended.
No chronic and acute risk for consumers via residues in food or feed from the intended use of "ARCHE chlorine POOL" is expected.

3.6.7.1 Maximum residue limits or equivalent

Table 3.35 Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value	Estimated food concentration (mg/kg)	MRL exceedance (Yes/No)
Drinking water limit – chlorate	Directive (EU) 2020/2184	Drinking water except for disinfection method Use of a disinfection method	0.25 mg/L 0.70 mg/L	Residues in drinking water are not expected from the intended use	No
MRLs – chlorates (incl. Mg, Na, K chlorates)	Reg. (EU) 2020/749	Food commodities of plant and animal origin	From 0.05 to 0.7 mg/kg	Residues in food and feed are not expected from the intended use	No

3.6.8 Aggregated exposure and risk characterisation

Not applicable for professional users and non-professional bystanders.

3.6.9 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not applicable for professional users and non-professional bystanders.

3.6.10 Overall conclusion on risk assessment for human health

Table 3.36 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1 / 2 / 3	Disinfection of swimming pool water, spas and hot	*Acceptable for professional users with the following risk mitigation*	Chlorine gas systems in full vacuum technology,

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
	tubs - connecting or disconnecting the product containers as well as for maintenance or repair of the gas pipe	*measures*	Alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m³) initiates safety procedures like wearing RPE. Measuring device (electrochemical sensors) sensible not only to chlorine, also to other chlorinated substances. The sensors are also measuring exposure when operators are using RPE. RPE: As a precaution for the case of gas leakage, at least a powered air purifying respirator with helmet/hood/mask (TH2/TM2), or a full face mask with gas filter (filter type (code letter, colour), according to CEN standard EN 14387:2021 (or equivalent), to be specified by the authorisation holder within the product information) must be at hand when changing the gas cylinders/drums.
1 /2 / 3	Disinfection of swimming pool water, spa and hot tubs	Acceptable for secondary exposure of the general public with the following risk mitigation measures	Installations for disinfection has to be inaccessible to the general public and pets. Containers must be stored locked up.

3.7 Risk assessment for animal health

3.7.1 Risk for companion animals

The human exposure and risk assessment covers also the exposure of pets. A specific assessment for pets is not required. Therefore, the same adapted rsik mitigation measures are also applicable.

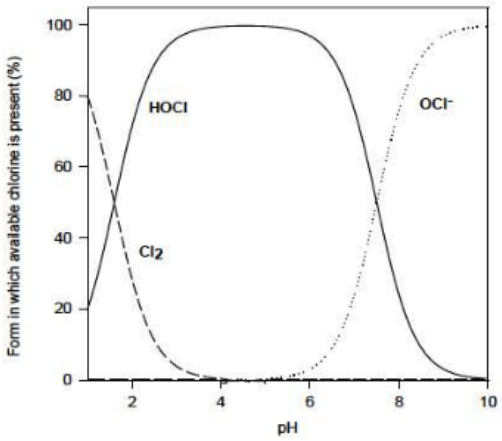
- "Installations for disinfection has to be inaccessible to (the general public) and pets."
- "Containers must be stored locked up."

3.7.2 Risk for livestock animals

Considering the use(s), exposure to livestock animals is not expected. Therefore, no risk assessment for animal health has been performed.

3.8 Risk assessment for the environment

The active substance released from sodium hypochlorite, calcium chlorite or chlorine in water, is active chlorine. Hypochlorous acid (HClO) is in equilibrium with the hypochlorite ion (ClO-) and chlorine (Cl_2). The equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is predominant, and at pH values higher than 10, the only species present is the hypochlorite ion, see figure below.



The sum of these species [hypochlorite ion + hypochlorous acid + chlorine] is defined as active chlorine or available chlorine. For the chemical reactivity in 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 can be used for evaluation and assessment of active chlorine released from any of the three substances.

During the ENV WG-I-2020 several conclusions were made regarding the harmonisation of the assessment of the products containing chlorine substances:

(1) On the assessment of the active substance:

"It was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively."

The uses of the product ARCHE Chlorine POOL do not lead to a direct release to the surface water compartment. Therefore, the environmental risk assessment for the active substance was qualitatively performed.

(2) On the assessment of the Disinfection by-products (DBPs):

As indicated in the Assessment Report of Active Chlorine released from Chlorine, an assessment of disinfection by-products (DBPs) should be done at product authorisation stage. The ENV-WG-I-2020 took the following conclusion: *"It was agreed that for the time being the information provided by the applicants in their dossiers on DBPs of all ongoing authorisation applications should be only summarized and no conclusion should be drawn referring to the current lack of guidance. In fact, all the participants agreed that the current*

'guidance' covering PT 2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment."

The applicant received a LoA to the Biocide DBP Consortium Data concerning the risk assessment of disinfection by-products. The DBP assessment can be found in the confidential annex. It is not specific to the biocidal product ARCHE Chlorine POOL but aims at providing an overall assessment of DBPs. Since the harmonization of the environmental risk assessment for DBPs is currently under investigation at EU level, any conclusion on the risk of DBPs for the environment cannot be drawn for the time being according to the ENV WG-I-2020 meeting agreements.

(3) On the assessment of Chlorate as relevant impurity formed during the storage :

"Chlorate is a by-product of the manufacturing process and can be formed during storage. It is also a disinfection by-product (DBP). Chlorate is considered as a relevant metabolite in drinking water. The discussion concerned only chlorate as an impurity (i.e., formed only during the storage) of products containing sodium/calcium hypochlorite. Generation of chlorate as a DBP was not considered under this discussion. The WG agreed that chlorate can be assessed qualitatively for all the environmental compartments […] [including] for groundwater.

Since the active substance is active chlorine released from chorine, chlorate as impurity cannot be formed during storage. Thus, a qualitative assessment of chlorate is not required.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance

No new endpoint studies have been submitted since the approval of the active substance. The risk assessment is entirely based on the list of endpoints as published in the assessment reports (AR for active chlorine released from chlorine PT 2, November 2020, AR for active chlorine released from sodium hypochlorite PT 2, November 2020 and AR for active chlorine released from calcium hypochlorite PT 2, November 2020 as well as active chlorine released from hypochlorous acid PT 2, July 2020) for which the first three IT and the last one SK were the rapporteur member states. The assessment reports are available on the ECHA website.

The fate and behaviour of active chlorine in the environment is described in detail in the CARs of sodium/calcium hypochlorite and active chlorine. Hypochlorite is a highly reactive compound, which reacts rapidly with organic matter in the sewer, STP, surface water and soil. Where organic and nitrogenous materials are present, hypochlorite acts as a highly reactive oxidizing agent. It reacts rapidly with organic matter in sewage or activated sludge and most (≈ 99%) of the available chlorine is converted to inorganic chloride. Oxidation is probably the predominant chemical reaction occurring in chlorine's disinfection processes. Furthermore, circumstances influencing the reactivity of hypochlorite are time, temperature, pH and the availability of amount and type of organic matter. The content of organic matter in soil is lower than in sewage or activated sludge but it is high enough to ensure complete decomposition in a relatively short time.
The kinetic model of Vandepitte and Schowanek (sodium hypochlorite CAR, doc IIIA) shows that hypochlorite is eliminated during transport in the sewer within the first minutes. The

$HClO/ClO^-$ (expressed as FAC = free available chlorine) concentration drops quickly in the sewer, parallel to a sharp increase of the chloramine concentration, which can be explained by the high availability of ammonia in the sewer. Chloramine further reacts as an oxidant during additional transport in the sewer, the STP and in the river. The extensive degradation of chloramine in the activated sludge can be explained by the presence of reduced organic material.
At environmental pH values (6.5-8.5) half of the active chlorine is present in the undissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion, assuming that the hypochlorous acid is the predominant species in Active Chlorine solution at pH 3-7.4. Only the hypochlorous acid fraction is volatile, but the amount of hypochlorous acid that could volatilise from water into air is expected to be very low.
Active chlorine does not bioaccumulate or bioconcentrate due to its high solubility in water and high reactivity.

The endpoints applied in the environmental risk assessment are summarised in the tables below.

Table 3.37 Endpoints and PNEC values for the active substance applied in the environmental risk assessment

Endpoints and PNEC values for the active substance applied in the environmental risk assessment				
	Value*		**Unit**	**Remarks**
	FAC			
	HClO [17]	**ClO^- [18]**		
Fate and behaviour in the environment				
Molecular weight	**52.46**	NaClO: 74.44; $Ca(ClO)_2$: 142.98	g/mol	
Melting point	-28.9[#]	NaClO: -28.9 $Ca(ClO)_2$: not applicable	°C	
Vapour pressure (at 20°C)	2.5E+03[#]	NaClO: 2.5E+03 $Ca(ClO)_2$: technically not feasible	Pa	
Water solubility	25 g HClO/ 100 g H_2O Temperature not stated in literature	26 g NaClO/100 g H_2O at 0°C; 243.6 g/l at 20°C (as $Ca(ClO)_2$)	g/L	

* values in bold are used for the calculation of the distribution in the STP by using SimpleTreat
[17] Data from LoEP of AR active chlorine released from hypochlorous acid PT 2, July 2020, SK
[18] Data from LoEPs of AR of active chlorine released from sodium hypochlorite PT 2, Nov. 2020, IT and AR for active chlorine released from calcium hypochlorite PT 2, Nov. 2020, IT
[#] Hypochlorous acid does not exist as a pure salt at room temperature. It is produced and handled in form of aqueous solutions. Data on hypochlorous acid is mainly based on data of recently performed studies on a 24% available chlorine solution (as this is the highest technically feasible concentration) and on literature data, which also addresses those physical-chemical parameters which are meaningful for hypochlorous acid. (LoEP of AR active chlorine released from hypochlorous acid PT 2, July 2020, SK)

pKa	**7.46**			In the ARs is given: K_a(HClO)= 3.5 x 10^{-8} mol/dm^3 (at 20°C) → pKa = -log(3.5 x 10^{-8})
Log Octanol/water partition coefficient (K_{ow})	**-0.87**		Log 10	Not required for inorganic substances; for hypochlorous acid a log P_{OW} is calculated
Organic carbon/water partition coefficient (K_{oc})	-		L/kg	Not relevant, active chlorine degrades to chloride
Henry's Law Constant (at 20°C)	**0.11**	not derived for NaClO (expected to be negligible, based on vapour pressure and solubility in water); not determined for $Ca(ClO)_2$	Pa×m^3/mol	For the purpose of risk assessment only, a HLC of 0.11 Pa×m^3/mol at 20 °C is considered for hypochlorous acid, which is the only volatile chlorine species present at the equilibrium at in-use pH values under PT2. (AR of active chlorine released from sodium hypochlorite and AR of active chlorine released from calcium hypochlorite; both 2020)
Characterisation of biodegradability	-			not applicable for inorganic substances
Rate constant for STP	124.77 (DT50=20 s) 46.22 (DT50=54 s [19]) **58.59** (DT50=42.6 s [20])		h^{-1} (at 25°C) h^{-1} (at 12°C) h^{-1} (at 15°C)	Derived from DT_{50} of 20 sec [20] in the sewer as given in the ESD for PT5 (kinetic model of Vandepitte and Schowanek (1997)) and in sodium and calcium hypochlorite CAR (doc IIB). This is a purely chemical process, no biodegradation occurs.
DT_{50} for biodegradation in surface water	-			Not applicable to inorganic substances
DT_{50} for hydrolysis in surface water	~ 300		s (model pH: 7)	Mathematic model; very rapid degradation of FAC (~ 300 s) in the presence of organic matter
Surface water/ Sediment	2.08 (DT50=20 min) 0.77 (DT50=54 min [20])		h^{-1} (at 25°C) h^{-1} (at 12°C)	Worst case assumption, based on the kinetic model of Vandepitte and Schowanek (1997) in sodium and calcium hypochlorite CAR (doc IIB), assuming slower degradation due to lower content of Corg in surface water and sediment when compared to raw sewer.
DT_{50} for degradation in soil	-			Not relevant, active chlorine degrades to chloride (very rapid)

[19] According to Technical Agreements for Biocides (TAB) – ENV, November 2021; ENV-182 the Arrhenius equation instead of eq. 28 from the Guidance BPR IV B+C (2017) is used for temperature correction and since only abiotic degradation processes are considered an activation energy of 54 kJ/mol is used.

[20] No temperature was indicated; a temperature of 25°C was assumed as worst case

Soil	124.77 (DT50=20 s) 44.22 (DT50=54 s [20])	h^{-1} (at 25°C) h^{-1} (at 12°C)	Worst case assumption, based on the kinetic model of Vandepitte and Schowanek (1997) in sodium and calcium hypochlorite CAR (doc IIB), assuming slower degradation due to lower content of Corg in soil when compared to raw sewer. The Vandepit and Schowanek kinetic model is also applicable to the soil. (TM-II-12)
DT_{50} for degradation in the sewer system	124.77 (DT50=20 s) 44.22 (DT50=54 s [20])	h^{-1} (at 25°C) h^{-1} (at 12°C)	Vandepitte and Schowanek (1997) [21], Doc. No. 989-003 Doc. IIIA, Section A7.1.2 (sodium and calcium hypochlorite CAR) Due to similar high content of organic substance, also transferable to the aeration tank of the STP
DT_{50} for degradation in air	2–4	hr (during day light)	Main reaction product is atomic chlorine which could react with saturated and unsaturated hydrocarbons and ozone; Tropospherical DT_{50} for hypochlorous acid is estimated to be 114.6 days (24-hr day), corresponding to 2750 hours
Distribution in the STP			
Air	0.01757	%	Calculated with SimpleTreat 4.0 (method 1); considering Technical Agreements for Biocides (TAB) – ENV, November 2021; ENV-9
Water	0.1741	%	
Sludge	0.05651	%	
Degradation in STP	99.75	%	
Predicted no effect concentrations (PNEC) for FAC			
Sewage treatment plant	4.11	mg/L	Based on a NOEC of 41.1 mg/L for respiration inhibition and an assessment factor of 10.
Surface water	0.042E-03	mg/L	An assessment factor of 50 was used based on two long-term NOECs from fresh- or saltwater species representing two trophic levels and one long-term NOEC from an additional marine taxonomic group (molluscs). Algae are most sensitive.
Sediment	0.045E-03	mg/kg wwt	No data is available. PNEC was calculated from the PNEC for surface water.
Soil	0.015E-03	mg/kg wwt	No data is available. PNEC was calculated from the PNEC for surface water.
Bird	-		No data available for birds and mammals as primary and secondary poisoning is not considered relevant.

[21] No temperature was indicated; a temperature of 25°C was assumed as worst case

Mammals	-		No data available for birds and mammals as primary and secondary poisoning is not considered relevant.

No PNECs are available for sediment and were therefore derived from the PNEC for surface water. Considering that both the predicted environmental concentration (PEC) in sediment and the PNEC for this compartment are calculated by equilibrium partitioning and because of the active substance's hydrophobicity no additional assessment factors are required, the risk ratios (PEC:PNEC) in sediment are always equal to those for water, except for substances with a log Kow ≥ 5, for which an additional safety factor of 10 is applied to the $PNEC_{sediment}$. The risk evaluation for sediments is therefore covered by the risk ratios for surface water. No PECs and PEC:PNEC ratios were consequently calculated for sediment.

No PNECs are available for soil and were therefore derived from the PNEC for surface water.

3.8.1.2 Endpoints for the product

There are no new additional data available for the product. The exposure assessment and classification and labelling are based on the agreed endpoints for the active substance.

3.8.1.3 Substance(s) of concern

As the product in this dossier is pure chlorine gas, no substances of concern should be taken into account.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

According to the BPC opinion for active chlorine released from chlorine (2020, eCA: IT), there are no indications for endocrine disrupting properties of this active substance on environmental non-target organisms. However, a comprehensive ED-assessment for the active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptors will need to be performed at the renewal stage.
As the biocidal product consists of chlorine gas only and there are no non-active substances included, an assessment of endocrine disrupting properties of co-formulants is not relevant.

3.8.2 Emission estimation

3.8.2.1 General information

During the ENV WG-I-2020 several conclusions were taken regarding the harmonisation of the assessment of products containing chlorine substances :
"It was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively."
The use of the product ARCHE Chlorine POOL, when used as described in the SPC and chapter 2.2 of this product assessment report, does not lead to a direct release to the surface water compartment. Therefore, a quantitative assessment with the calculation of Predicted Environmental Concentrations (PECs) for the active substance has not been performed.

Nevertheless, for the sake of completeness distribution in the STP has been calculated using SimpleTreat version 4.0 in which the concentration of suspended solids in the effluent has been increased to 30 mg/L in accordance with the TAB. Distribution in the STP and the environment is calculated based on the physical-chemical properties and experimental data

as listed in section 3.8.1 and is shown in Table 3.37.

The biocidal product ARCHE Chlorine POOL is a gaseous product containing active chlorine intended to be used for disinfection of swimming pool water, spas and hot tubs (PT 2) and releases after use is only to the STP. According to the ENV WG-I-2020, it was agreed that for releases via STP a qualitative assessment is sufficient. As the product in this dossier is pure chlorine gas, no substances of concern should be taken into account.
The table below summarises the receiving environmental compartments that have been identified as potentially exposed during the use of the product. Compartments highlighted in bold are directly exposed.

The risk assessment approach is summarised below and use numbers are in accordance with the list of all uses indicated under section 2.2 where further details are described.

Table 3.38 Environmental risk assessment

Environmental risk assessment					
Use number	**Scenario assessed**	**ESD applied**	**Maximum in-use concentration of the active substance active chlorine released from chlorine**	**Maximum in-use concentration of substance(s) of concern**	**Receiving compartments**
1 – Disinfection of swimming pool water, spas and hot tubs – by continuous dosing 3 – Disinfection of swimming pool water, spas and hot tubs by continuous dosing – compliant with high hygienic requirements	Scenario 1 – Public swimming pool	Technical Agreements for Biocides (TAB) – ENV, November 2021; ENV-51 ENV WG-I-2020 (item 7.7)	1,4 mg/L	---	Qualitative assessment, since only releases via **STP** are relevant
2 – Disinfection of swimming pool water, spas and hot tubs – by shock dosing in case of contamination			50 mg/L		

3.8.2.2 Emission estimation for the scenario

Scenario 1 - Public swimming pool

Qualitative assessment:

Use number 1, 2 and 3 *"Disinfection of swimming pool water, spas and hot tubs"* (releases via STP): As chlorine is always applied in specific, professional installations, it will only be used by professionals in larger (public) swimming pools that are connected to sewage system. Two types of release can occur, both via the sewage system: chronic release depending on the number of visitors, or acute release in case the swimming pool is completely emptied for maintenance.
The correct emission scenario for this use description is provided in the Technical Agreements for Biocides (TAB) – ENV, November 2021; ENV-51.
But as indicated in the above chapters and since the biocidal product is only released to the STP via the sewer system after use, the assessment is evaluated qualitatively for scenario 1, no quantitative calculation of the emission to the environment is necessary.

The use of the product ARCHE Chlorine POOL, when used as described in the SPC and chapter 2.2 of this product assessment report, does not lead to a direct release to the surface water compartment. Therefore, only a qualitative assessment is necessary and a quantitative assessment for the active substance has not been performed.

3.8.3 Exposure calculation and risk characterisation

As indicated above, a quantitative assessment and therefore a calculation of PEC values for the active substance is not required for use of the biocidal product.

Atmosphere

Qualitiative assessment: Hypochlorite might enter the atmosphere due to volatilisation from the STP. Exposure assessment in the AR showed emission to air via this pathway is not relevant. Given the adsorption of hypochlorite to aerosol particles, the volatilisation from water into air and the adsorption of hypochlorite onto soil are very low, thus hypochlorite will remain in the aqueous phase and degrade very rapidly. Exposure to air is thus not considered. There are no indications that active chlorine contributes to depletion of the ozone layer as it is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Therefore, the risks for the air compartment are considered acceptable.

Conclusion: No unacceptable risk for the atmosphere compartment is expected.

Sewage treatment plant (STP)

Qualitiative assessment: The measured DT50 of the active substance in the sewer is equal to 54 seconds i.e. a degradation rate of 44.22 h^{-1}. This rapid degradation is caused by the high reactivity of the active substance with organic matter and the high amount of organic matter in the sewer. The residence time of the product in the sewer before entering the sewage treatment plant is considered to be 1 hour (Sodium Hypochlorite CAR doc IIB). Taking these data into account, we can estimate that the concentration of active substance in the effluent to which microorganisms are exposed in the STP will be very low. The same approach has been used for a quantitative evaluation in the assessment report of Sodium Hypochlorite.
The concentration of hypochlorite in the environment is modelled by Vandepitte and

Schowanek and is estimated to drop down to "zero" within the first minutes after release in the sewer.

Conclusion: No unacceptable risk for the aquatic micro-organisms of the STP is expected.

Aquatic compartment

Qualitiative assessment: According to the reasoning followed for the STP, since the concentration entering the STP should already be close to zero, the concentration of active substance reaching the surface water compartment is expected to be even lower.

The risk assessment for surface water in the Assessment Report of Sodium Hypochlorite takes only into account the degradation in the sewer, shows very low concentration of active substance in surface water and does not highlight any risk for this compartment.
This reasoning is also valid for freshwater sediment organisms.

Conclusion: Based on the highest in-use concentrations and taking into account degradation of active chlorine in the sewer system, no unacceptable risk is expected for the following proposed uses: Uses 1, 2 & 3 "*Disinfection of swimming pool water, spas and hot tubs*" (PT2).

Terrestrial compartment

Qualitiative assessment: According to the reasoning followed for the STP, since the concentration entering the STP should already be close to zero, the concentration of active substance in sewage sludge applied to agricultural land is expected to be even lower.

Conclusion: As emission of this biocidal product is via STP only, it can be assumed that the level of risk to the terrestrial compartment can be considered acceptable.

Groundwater

Qualitiativ assessment: The hypochlorite concentration in the pore water of agricultural soil (after application of sewage sludge) is taken as an indication of potential groundwater levels. This is a worst-case assumption, because degradation in soil, transformation and dilution in deeper soil layers are not taken into account. Under real life conditions, it is very unlikely that any hypochlorite will reach the groundwater because hypochlorite rapidly degrades in sewage sludge and soil.

Conclusion: No unacceptable risk for the groundwater compartment is expected.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

The product is applied as a disinfectant for public swimming pool waters, spas and hot tubs. The gas is directly released to the water. Thus, primary poisoning is not expected for the intended uses.

3.8.4.2 Secondary poisoning

According to the AR (2020, eCA IT), active chlorine is an inorganic substance (K_{ow} is not required) and it degrades rapidly in the environment, hence no bioaccumulation is expected. Thus, no further assessment of secondary poisoning is deemed necessary.

3.8.5 Mixture toxicity

An assessment of mixture toxicity is non-relevant as the product contains only one active substance and no non-active substances.

3.8.6 Aggregated exposure (combined for relevant emission sources)

An agreed guidance document for aggregated exposure assessment is not available yet. Therefore, such an assessment was not conducted.

3.8.7 PBT assessment

According to the active substance AR (active chlorine released from chlorine, 2020, eCA: IT), active chlorine does not fulfil any of the PBT criteria, nor the POP criteria.

3.8.8 Overall conclusion on the risk assessment for the environment

Table 3.39 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1	Disinfection of swimming pool water, spas and hot tubs – by continuous dosing	acceptable	none
2	Disinfection of swimming pool water, spas and hot tubs – by shock dosing in case of contamination	acceptable	none
3	Disinfection of swimming pool water, spas and hot tubs by continuous dosing – compliant with high hygienic requirements	acceptable	none

3.9 Assessment of a combination of biocidal products

Not relevant (a use with other biocidal products is not intended).

3.10 Comparative assessment

Not relevant (no candidate for substitution was identified).

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Scenario 1: Exposure in public hot tubes - SPA

ASt: Scenario [4]

Local assessment		Adult 1-1	Child 1-2	Infant 1-3	Comment
Product details		WHO recommenda-tion	WHO recommenda-tion	WHO recommenda-tion	
Active substance concentration:	%	0.0005	0.0005	0.0005	
Molecular weight [acive substance]	g/mol	52.5000	52.5000	52.5000	
Molecular weight [release matrix]	g/mol	18.01	18.01	18.01	
Density diluted product	g/mL	1.00	1.00	1.00	
General default parameter					
Body weight	kg	60	15.8	8	
Ventilation rate	/hour	2	2	2	
Application parameters					
Application rate [product]	mg/L	5	5	5	
Volume desinfected	m3	562	562	562	
	L	562000	562000	562000	
Room volume	m^3	188	188	50	
Release area	m^2	375	375	100	
Amount [product]	g	562000000	562000000	562000000	
Application rate [active substance]	g	281000	281000	281000	
Task duration	min	120	120	120	
Fequency	/week	5	5	1	
Temperature	°C	40	40	40	
Vapour pressure	Pa	725	725	725	

Dermal exposure					

Local dermal exposure	%	0.0005	0.0005	0.0005	equivalent to the a.s. application concentration
NOAEC	%	1.00	1.00	1.00	
% NOAEC		0.05	0.05	0.05	
		Acceptable	**Acceptable**	**Acceptable**	

Oral exposure					
Local oral exposure	%	0.0005	0.0005	0.0005	equivalent to the a.s. application concentration
NOAEC	%	0.10	0.10	0.10	
% NOAEC		0.50	0.50	0.50	
		Acceptable	**Acceptable**	**Acceptable**	
Inhalation exposure	**Exposure to vapour - Evaporation**				
Mean event concentration ConsExpo [active substance]	mg/m³	0.025	0.025	0.025	
Actual inhalation exposure [active substance]	mg	0.025	0.025	0.025	
Number of applications/day	/day	5	5	1	
Total inhalation exposure/day [active substance]	mg/day	0.125	0.125	0.025	
Local inhalation exposure (vapour)	**mg/m³**	**0.025**	**0.025**	**0.025**	**according to Consexpo**
Inhalation exposure	**Exposure to aerosol**				
Indicative value	mg/m³	10.50	10.50	10.50	Biocides Human Health Exposure Methodology, p. 345
Local inhalation exposure (aerosol)	mg/m³	0.00005	0.00005	0.00005	Indicative value x active substance concentration / 100
Total local inhalation exposure	**mg/m³**	**0.02505**	**0.02505**	**0.02505**	
AEC	mg/m³	0.5	0.5	0.5	

% AEC-inhalation exposure	**%**	**5.0**	**5.0**	**5.0**	
		Acceptable	**Acceptable**	**Acceptable**	

Cons-Expo Reports:

Substance		
Name	HClO	
CASNumber		
Molecular weight	52.5	g/mol
KOW		
Product		
Name		
Weight fraction substance	0.0005	%
Population		
Name	EU framework Biocides adult	
Body weight	60	Kg
Scenario 4 (ASt 4)		
Frequency	5	per week
Description	**Adult swimmer in SPA**	
Inhalation		
Exposure model	Exposure to vapour - Evaporation	
Exposure duration	120	Minute
Product in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Product amount	5.6E+08	G
Weight fraction substance	0.0005	%
Room volume	188	m³
Ventilation rate	2	per hour
Inhalation rate		
Application temperature	40	°C
Vapour pressure	725	Pa
Molecular weight	52.5	g/mol
Mass transfer coefficient	3.2E+05	m/hr
Release area mode	Constant	
Release area	375	m²
Emission duration	120	Minute

Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario 4 (ASt 4)		
Inhalation		
Mean event concentration	0.0248	mg/m³
Peak concentration (TWA 15 min)	0.0235	mg/m³
Mean concentration on day of exposure	0.00207	mg/m³
Year average concentration	0.00148	mg/m³
External event dose		
External dose on day of exposure		

Substance		
Name	HClO	
CASNumber		
Molecular weight	52.5	g/mol
KOW		
Product		
Name		
Weight fraction substance	0.0005	%
Population		
Name	EU framework Biocides adult	
Body weight	44727	Kg
Scenario 4		
Frequency	5	per week
Description	**Child swimmer in SPA**	
Inhalation		
Exposure model	Exposure to vapour - Evaporation	
Exposure duration	120	Minute
Product in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Product amount	5.62E+08	G
Weight fraction substance	0.0005	%
Room volume	188	m³

Ventilation rate	2	per hour
Inhalation rate		
Application temperature	40	°C
Vapour pressure	725	Pa
Molecular weight	52.5	g/mol
Mass transfer coefficient	3.2E+05	m/hr
Release area mode	Constant	
Release area	375	m²
Emission duration	120	Minute
Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for scenario 4		
Inhalation		
Mean event concentration	0.0248	mg/m³
Peak concentration (TWA 15 min)	0.0235	mg/m³
Mean concentration on day of exposure	0.00207	mg/m³
Year average concentration	0.00148	mg/m³
External event dose		
External dose on day of exposure		

Substance		
Name	HClO	
CASNumber		
Molecular weight	52.5	g/mol
KOW		
Product		
Name		
Weight fraction substance	0.0005	%
Population		
Name	EU framework Biocides infant (6-12 months)	

Body weight	8	Kg
Scenario 4		
Frequency	1	per week
Description	**Infant in SPA**	
Inhalation		
Exposure model	Exposure to vapour - Evaporation	
Exposure duration	120	Minute
Product in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Product amount	5.62E+08	G
Weight fraction substance	0.0005	%
Room volume	50	m^3
Ventilation rate	2	per hour
Inhalation rate		
Application temperature	40	°C
Vapour pressure	725	Pa
Molecular weight	52.5	g/mol
Mass transfer coefficient	3.2E+05	m/hr
Release area mode	Constant	
Release area	100	m^2
Emission duration	120	Minute
Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for Scenario 4		
Inhalation		
Mean event concentration	0.0248	mg/m^3
Peak concentration (TWA 15 min)	0.0235	mg/m^3
Mean concentration on day of exposure	0.00207	mg/m^3
Year average concentration	0.000295	mg/m^3
External event dose		
External dose on day of exposure		

Scenario 5: Exposure in public swimming pools to swimmer

ASt: Scenario 5,6,7

Local assessment		**Adult**	**Child**	**Infant**	
Product details		shock dosing	shock dosing	shock dosing	
Active substance:	%	0.0005	0.0005	0.0005	
Molecular weight [acive substance]	g/mol	52.5000	52.5000	52.5000	
Molecular weight [release matrix]	g/mol	18.0100	18.0100	18.0100	
Density diluted product	g/mL	1.00	1.00	1.00	
General default parameter					
Body weight	kg	60	16	8	
Ventilation rate	/hour	2	2	2	
Application parameters					
Application rate [product]	mg/L	5	5	5	
Volume desinfected	m3	562	562	100	
	L	562000	562000	100000	
Room volume	m^3	188	188	50	
Release area	m^2	375	375	100	
Amount [product]	g	562000000	562000000	100000000	
Application rate [active substance]	g	281000	281000	50000	
Task duration	min	120	120	30	
Fequency	/week	5	5	1	
Temperature	°C	28	28	32	
Vapour presure	Pa	337	337	438	
Dermal exposure					
Local dermal exposure	%	0.0005	0.0005	0.0005	equivalent to the a.s. application concentration
NOAEC	%	1.00	1.00	1.00	
% NOAEC		0.05	0.05	0.05	
		Acceptable	**Acceptable**	**Acceptable**	
Oral exposure					
Local dermal exposure	%	0.0005	0.0005	0.0005	equivalent to the a.s. application concentration
NOAEC	%	0.10	0.10	0.10	
% NOAEC		0.50	0.50	0.50	

		Acceptable	**Acceptable**	**Acceptable**	
Inhalation exposure	**Exposure to vapour - Evaporation**				
Mean event concentration ConsExpo [active substance]	mg/m³	0.012	0.012	0.015	
Actual inhalation exposure [active substance]	mg	0.012	0.012	0.015	
Number of applications/day	/day	5	5	1	
Total inhalation exposure/day [active substance]	mg/day	0	0	0	
Local inhalation exposure (vapour)	mg/m³	0.012	0.012	0.015	according to Consexpo
Total local inhalation exposure	**mg/m³**	**0.012**	**0.012**	**0.015**	
AEC	mg/m³	0.5	0.5	0.5	
% AEC- inhalation exposure	%	**2.4**	**2.4**	**3.0**	
		Acceptable	**Acceptable**	**Acceptable**	

Cons-Expo Reports:

Substance		
Name	HClO	
CASNumber		
Molecular weight	52.5	g/mol
KOW		
Product		
Name		
Weight fraction substance	0.0005	%
Population		
Name	EU framework Biocides adult	
Body weight	60	kg
Scenario 5-1 (ASt: 5)		
Frequency	5	per week
Description	**Adult swimmer in Pool**	
Inhalation		
Exposure model	Exposure to vapour - Evaporation	
Exposure duration	120	minute
Product in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Product amount	100000000	g
Weight fraction substance	0.0005	%
Room volume	188	m³
Ventilation rate	2	per hour
Inhalation rate		

Application temperature	28	°C
Vapour pressure	337	Pa
Molecular weight	52.5	g/mol
Mass transfer coefficient	3.14E+05	m/hr
Release area mode	Constant	
Release area	375	m²
Emission duration	120	minute
Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for Scenario 5-1 (ASt: 5)		
Inhalation		
Mean event concentration	0.012	mg/m³
Peak concentration (TWA 15 min)	0.0114	mg/m³
Mean concentration on day of exposure	0.000999	mg/m³
Year average concentration	0.000714	mg/m³
External event dose		
External dose on day of exposure		

Substance		
Name	HClO	
CASNumber		
Molecular weight	52.5	g/mol
KOW		
Product		
Name		
Weight fraction substance	0.0005	%
Population		
Name	EU framework Biocides adult	
Body weight	44727	kg
Scenario 5-2 (ASt: 6)		
Frequency	5	per week
Description	**Child swimmer in Pool**	
Inhalation		

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	120	minute
Product in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Product amount	100000000	g
Weight fraction substance	0.0005	%
Room volume	188	m³
Ventilation rate	2	per hour
Inhalation rate		
Application temperature	28	°C
Vapour pressure	337	Pa
Molecular weight	52.5	g/mol
Mass transfer coefficient	3.14E+05	m/hr
Release area mode	Constant	
Release area	375	m²
Emission duration	120	minute
Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for Scenario 5-2 (ASt: 6)		
Inhalation		
Mean event concentration	0.012	mg/m³
Peak concentration (TWA 15 min)	0.0114	mg/m³
Mean concentration on day of exposure	0.000999	mg/m³
Year average concentration	0.000714	mg/m³
External event dose		
External dose on day of exposure		

Substance		
Name	HClO	
CASNumber		
Molecular weight	52.5	g/mol

KOW		
Product		
Name		
Weight fraction substance	0.0005	%
Population		
Name	EU framework Biocides infant (6-12 months)	
Body weight	8	kg
Scenario 5-3 (ASt: 7)		
Frequency	1	per week
Description	**Infant swimmer in Pool**	
Inhalation		
Exposure model	Exposure to vapour - Evaporation	
Exposure duration	30	minute
Product in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Product amount	5.62E+08	g
Weight fraction substance	0.0005	%
Room volume	50	m³
Ventilation rate	2	per hour
Inhalation rate		
Application temperature	32	°C
Vapour pressure	438	Pa
Molecular weight	52.5	g/mol
Mass transfer coefficient	3.14E+05	m/hr
Release area mode	Constant	
Release area	100	m²
Emission duration	30	minute
Absorption model	n.a.	
Dermal		
Exposure model	n.a.	
Absorption model	n.a.	
Oral		
Exposure model	n.a.	
Absorption model	n.a.	
Results for Scenario 5-3 (ASt: 7)		
Inhalation		
Mean event concentration	0.0154	mg/m³

Peak concentration (TWA 15 min)	0.0153	mg/m³
Mean concentration on day of exposure	0.00032	mg/m³
Year average concentration	4.58E-05	mg/m³
External event dose		
External dose on day of exposure		

Calculation sheets for exposure and risk assessment for professional users are available in the document "Output table professional.xlsm"(see attached).

4.1.2 Dietary assessment

Not relevant.

4.1.3 Environment

As only a qualitative assessment was deemed necessary, no calculations were performed.

4.2 New information on the active substance(s) and substance(s) of concern

Not relevant (no new information on the active substance is available).

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
Anonymous	2018	6.7 Efficacy data to support these claims	7_EN14476:2013+A1:2015_25°C_2min-30min_0.3 g/L bovine albumin_clean_P2S1	Evaluation of the effectiveness of SH-BPF-640 against human rotavirus strain Wa following EN 14476:2013+A1:2015 (clean conditions) Report No.: L18/0412R.1 Dr Brill + Partner GmbH Institut für Hygiene und Mikrobiologie	Study report	Anonymous	no	yes
Anonymous	2018	6.7 Efficacy data to support these claims	8_EN14476:2013+A1:2015_25°C_10min-30min_0.3 g/L bovine albumin_clean_P2S1	Evaluation of the effectiveness of SH-BPF-640 against adenovirus type 5 following EN 14476:2013+A1:2015 (clean conditions) Report No.: L18/0412A.1	Study report	Anonymous	no	yes

				Dr Brill + Partner GmbH Institut für Hygiene und Mikrobiologie				
Anonymous	2018	6.7 Efficacy data to support these claims	9a_EN14476:2013+A1:2015_20°C_5min-30min_0.3 g/L bovine albumin_clean_P2S1	Evaluation of the effectiveness of SH-BPF-640 against adenovirus type 5 following EN 14476:2013+A1:2015 (clean conditions) Report No.: L18/0557A.2 Dr Brill + Partner GmbH Institut für Hygiene und Mikrobiologie	Study report	Anonymous	no	yes
Anonymous	2018	6.7 Efficacy data to support these claims	9b_EN14476:2013+A1:2015_20°C_5min-30min_0.3 g/L bovine albumin_clean_P2S1	Evaluation of the effectiveness of SH-BPF-640 against poliovirus type 1 following EN 14476:2013+A1:2015 (clean conditions) Report No.: L18/0557Po.1 Dr Brill + Partner GmbH Institut für Hygiene und Mikrobiologie	Study report	Anonymous	no	yes

Anonymous	2018	6.7 Efficacy data to support these claims	9c_EN14476:2013+A1:2015_20°C_5min-30min_0.3 g/L bovine albumin_clean_P2S1	Evaluation of the effectiveness of SH-BPF-640 against murine norovirus (as surrogate of human norovirus) following EN 14476:2013+A1:2015 (clean conditions) Report No.: L18/0557M.2 Dr Brill + Partner GmbH Institut für Hygiene und Mikrobiologie	Study report	Anonymous	no	yes
Anonymous	2020	6.7 Efficacy data to support these claims	32_Virucidal activity of active chlorine in swimming pools	Virucidal activity of active chlorine in swimming pools *Report and Study No. not provided Source and/or Testing facility not provided*	Literature review	*Study sponsor not provided*	GLP information not provided	no
Anonymous	2022	6.7 Efficacy data to support these claims	33_Summary P2S1 - bacteria (including Legionella) and virus 20221014	Study summary report of the Efficacy testing for biocidal product in swimming pool *Report and Study No. not provided Source and/or Testing facility not*	Study report	Anonymous	GLP information not provided	yes

				provided				
Anonymous	2021	6.7 Efficacy data to support these claims	31_Study summary report - Efficacy testing for swimming pool	Study summary report of the efficacy testing for biocidal product in swimming pool *Report and Study No. not provided Source and/or Testing facility not provided*	Study report	Anonymous	GLP information not provided	yes
Anonymous	2018	6.7 Efficacy data to support these claims	1_EN1276: 2010_20°C _5min-30min_0.3 g/L bovine albumin_clean_P2S1	Quantitative suspension test for the evaluation of bactericidal activity of SH-BPF-640 in Food, Industrial, Domestic and Institutional Areas (DIN EN 1276 Ber 1:2010; Phase 2, Step 1*) Report No.: L18/0142.39 Dr Brill + Partner GmbH Institut für Hygiene und Mikrobiologie	Study report	Anonymous	no	yes

Anonymous	2018	6.7 Efficacy data to support these claims	2_EN1276: 2010 (OECD 170)_27.5° C_30sec-2min_0.3 g/L bovine albumin_clean_P2S1	Test report no L18/0142.48 Report No.: L18/0142.48 Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology	Study report	Anonymous	no	yes
Anonymous	2019	6.7 Efficacy data to support these claims	25_Sim use - CSTB-shock_37° C_6h_Natural soiling_clean_P2S2_Legionella	Efficacy evaluation of NaOCl against Legionella pneumophila Report No.: EN-CAPE 19.083 C - V2 CSTB	Study report	Anonymous	no	yes
Anonymous	2019	6.7 Efficacy data to support these claims	21_EN 13623 (OECD 170)_35°C_0,5 min_0,3 g/L bovine albumin_clean_P2S1_Legionella	Quantitative suspension test - bactericidal activity against Legionella pneumophila (phase 2, step 1) Study No.: SN 28582 HygCen	Study report	Anonymous	no	no
Anonymous	2019	6.7 Efficacy data to support these claims	22a_EN1276:2010_25 °C_30sec_ BFA soiling_P2S1_Bacteria	Quantitative suspension test - bactericidal activity (S. aureus, E. coli, P. aeruginosa) (phase 2, step 1) - BFA soiling	Study report	Anonymous	no	yes

				Report No.: 2019-1796 HygCen Germany				
Anonymous	2019	6.7 Efficacy data to support these claims	22b_EN1276:2010_25 °C_2min_BFA soiling_P2S1_Bacteria_Faecium	Quantitative suspension test - bactericidal activity (E. faecium) (phase 2, step 1) - BFA soiling Report No.: 2019-1797 HygCen Germany	Study report	Anonymous	no	yes
Anonymous	2019	6.7 Efficacy data to support these claims	23a_EN14476:2013+A2:2019_25 °C_2min_BFA soiling_clean_P2S1_Rota	Quantitative suspension test - virucidal activity (phase 2, step 1) test run with Human Rotavirus A BFA soiling Report No.: 2019-2369 HygCen Germany GmbH	Study report	Anonymous	no	yes
Anonymous	2019	6.7 Efficacy data to support these claims	23b_EN14476:2013+A2:2019_25 °C_2min_BFA soiling_clean_P2S1_Adeno	Quantitative suspension test - virucidal activity (phase 2, step 1) test run with Adenovirus Type 5 BFA soiling Report No.: 2019-	Study report	Anonymous	no	yes

				2370 HygCen Germany GmbH				
Anonymous	2019	6.7 Efficacy data to support these claims	26_EN 13623_25° C_0,5 min_BFA soiling_clean_P2S1_Legionella	Quantitative suspension test - bactericidal activity against Legionella pneumophila (phase 2, step 1) Report No.: 2019-2593 HygCen	Study report	Anonymous	no	no
Anonymous	2020	6.7 Efficacy data to support these claims	30_Monitoring data - disinfection of swimming pools	Disinfection of swimming pools - monitoring data *Report and Study No. not provided Source and/or Testing facility not provided*	Study report	*Study sponsor not provided*	no	yes

4.4 References

4.4.1 References other than list of studies for the BP

- El-Athman, F., Zehlike, L., Kämpfe, A., Junek, R., Selinka, H.C., Mahringer, D., Grunert, A. Pool water disinfection by ozone-bromine treatment: Assessing the disinfectant efficacy and the occurrence and in vitro toxicity of brominated disinfection by-products, *Water Research*, **204**, 2021
- Caldentey, J., Bamford, J.K.H., Bamford, D.H.. Structure and assembly of bacteriophage PRD1, an Escherichia coli virus with a membrane, *Journal of Structural Biology*, **104**, 1990
- Bamford, J.K.H., Hänninen, A.L., Pakula, T.M., Ojala, P.M., Kalkkinen, N., Frilander, M., Bamford, D.H.. Genome organization of membrane-containing bacteriophage PRD1. *Virology,* **183**, 1991
- Poranen, M.M., Bamford, D.H., Oksanen, H.M.. Membrane-containing bacteriophages, *eLS*, 2015. https://doi.org/10.1002/9780470015902.a0000779.pub3
- Grabow, W.O.K.. Bacteriophages: update on application as models for viruses in water, *WaterSA*, **27**, 2001
- Tree, J.A., Adams, M.R., Lees, D.N.. Chlorination of Indicator Bacteria and Viruses in Primary Sewage Effluent, *Appl Environ Microbiol*, **69**(4), 2003
- Durán, A.E., Muniesa, M., Mocé-Llivina, L., Campos, C., Jofre, J., Lucena, F.. Usefulness of different groups of bacteriophages as model micro-organisms for evaluating chlorination, *Journal of Applied Microbiology*, **95**, 2003
- Kanna, C.R.. Inactivation of Viruses in water by chlorination using bacteriophages as model organisms, 2015. https://stud.epsilon.slu.se/8757/1/kanna_c_r_160121.pdf

4.4.2 Guidance documents

Packaging
- ADR, Chapter 4.1, P200 (ADR 2023 - Agreement concerning the International Carriage of Dangerous Goods by Road | UNECE)
- TPED Richtlinie 2010/35/EU des Europäischen Parlaments und des Rates vom 16. Juni 2010 über ortsbewegliche Druckgeräte
- Guidance on the BPR Volume_I_Part_A,B,C Version 2.1, 2022

Physical, chemical, and technical properties
- Guidance on the BPR: Volume I Parts A+B+C - v 2.0, 2018
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020

Physical hazards and respective characteristics
- Guidance on the BPR: Volume I Parts A+B+C – v.2.0, 2018
- Guidance on the Application of the CLP Criteria – v. 5.0, 2017
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020
- UN Manual of Tests and Criteria – 7th revised edition, 2019

Methods for detection and identification
- Guidance on the BPR: Volume I Parts A+B+C - v 2.0, 2018
- Technical Agreements for Biocides (TAB) – APCP v.2.0, 2020
- Guidance on the Biocidal Products Regulation: Volume I: Identity of the active substance/physico-chemical properties/analytical methodology - Information Requirements, Evaluation and Assessment. Parts A+B+C:; Version 2.1, March 2022; 1.8.2 and 1.8.3
- Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830 rev. 1 of 2021-02-24)

Efficacy
- Guidance on the Biocidal Products Regulation, Volume II: Efficacy, Part A: Information Requirements, Version 2.0, May 2018, available under: https://echa.europa.eu/documents/10162/2672387/vol_ii_part_a_v2-0_superseded_en.pdf/325c3672-32dd-d619-90b5-d5b65d10a400?t=1648538979738
- Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C), Version 3.0, April 2018, available under: https://echa.europa.eu/documents/10162/2324906/bpr_guidance_assessment_evaluation_part_vol_ii_part_bc_v3-0_en.pdf/950efefa-f2bf-0b4a-a3fd-41c86daae468?t=1639123792963

Human health
- Guidance on the Biocidal Products RegulationVolume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, 2017. (https://echa.europa.eu/documents/10162/2324906/biocides_guidance_human_health_ra_iii_part_bc_en.pdf)
- EFSA guidance on dermal absoption, 2017
- Biocides Human Health Exposure Methodology
- Recommendations of the Ad hoc Working Group on Human Exposure
- BPC opinion: Active chlorine released from chlorine-PT2_2016

Animal health
No guidance agreed yet.

Environment
- Guidance on BPR Vol. IV Part B+C, 2017
- Minutes of ENV WG-I-2020 (item 7.7)
- Technical Agreements for Biocides (TAB) – ENV, November 2021

4.4.3 Legal texts

- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22.05.2012 year concerning the making available on the market and use of biocidal products
- Regulation (EC) No 1272/2008 (CLP)

4.5 Confidential information

Please refer to the separate document Confidential Annex of the PAR.