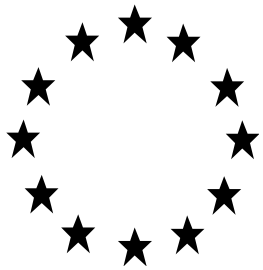
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the BELGIAN eCA)



Arche Chlorine

Product type(s): 2 and 5

Active chlorine released from chlorine

Case Number in R4BP: BC-UQ045679-98

Evaluating Competent Authority: Belgium

Date: [day/month/year]

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1 CONCLUSION

The outcome of the assessment for the biocidal product 'Arche Chlorine' is specified in the BPC opinion following discussions at the BPC-39 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Arche Chlorine	Union Authorisation (members states of the EEA and Switzerland)

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Arche Consortia
	Address	Liefkensstraat 35d 9032 Gent (Wondelgem) Belgium
Pre-submission phase started on	31 May 2018	
Pre-submission phase concluded on	04 July 2018	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	PCC Rokita SA
Address of manufacturer	Sienkiewicza 4, 56-120 Brzeg Dolny Poland
Location of manufacturing sites	Sienkiewicza 4, 56-120 Brzeg Dolny Poland

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Active chlorine released from chlorine
Name of manufacturer	PCC Rokita SA
Address of manufacturer	Sienkiewicza 4, 56-120 Brzeg Dolny Poland
Location of manufacturing sites	Sienkiewicza 4, 56-120 Brzeg Dolny Poland

2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

Yes ☒
No ☐

2.1.2.1 Identity of the active substance

Active substance	
ISO 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 Cl_2/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.*
Releaser	
ISO name	Chlorine
IUPAC or EC name	Chlorine
EC number	231-959-5
CAS number	7782-50-5
Index number in Annex VI of CLP	017-001-00-7
Minimum purity / content	≥99.5%
Structural formula	Cl-Cl

2.1.2.2 Candidate(s) for substitution

Chlorine should not be considered a candidate for substitution since none of the conditions of Article 10 of the BPR are met. The active substance is not a candidate for substitution.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Chlorine	Chlorine	Releaser	7782-50-5	231-959-5	100% (technical), ≥99.5% (pure), ≥99.5% (purity)
Active chlorine released from chlorine	-	Active substance released	-	-	100% (technical), ≥99.5% (pure), ≥99.5% (purity)

2.1.2.4 Information on technical equivalence

The source of the active substance releaser is the same as the one evaluated in connection with the approval for listing of the active substance (releaser) on the Union list of approved active substances under Regulation No. 528/2012. Therefore, an assessment of technical equivalence of the active substance releaser is not required.

2.1.2.5 Information on the substance(s) of concern

The product Arche Chlorine does not contain substances of concern. Please see the confidential annex for further details.

2.1.2.6 Type of formulation

GA (gas)

2.1.3 Hazard and precautionary statements

Classification and labelling of the products according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Oxidising Gas 1 Press. Gas (Liq. Gas) Acute Toxicity (inhal.) 3 Eye Irritation 2 STOT SE 3 Skin Irritation 2 Aquatic Acute 1

Hazard statement	H270 May cause or intensify fire; oxidizer H280 Contains gas under pressure; may explode if heated (liquefied gas) H331 Toxic if inhaled. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H315 Causes skin irritation. H400 Very toxic to aquatic life.
Labelling	
Signal words	Danger
GHS pictogram	GHS03; GHS06; GHS09
Hazard statements	H270 May cause or intensify fire; oxidizer H280 Contains gas under pressure; may explode if heated H331 Toxic if inhaled. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H315 Causes skin irritation. H400 Very toxic to aquatic life.
Precautionary statements	P220: Keep away from clothing or other combustible materials. P244: Keep valves and fittings free from oil and grease. P273: Avoid release to the environment. P260: Do not breath gas. P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P264 Wash ... thoroughly after handling P271 Use only outdoors or in a well-ventilated area P302 + P352 IF ON SKIN: Wash with plenty of water/... P311 Call a POISON CENTER/doctor/... P321 Specific treatment (see ... on this label) 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. P280: Wear protective gloves/protective clothing/eye protection/face protection. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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 POISON CENTRE/doctor/...if you feel unwell. 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.

Note	According to CLP guidance: *Pictogram GHS04 is not required for gases under pressure where pictogram GHS02 or pictogram GHS06 appears.* Based on AR Chlorine (January 2017) and Harmonised classification.

2.1.4 Authorised use(s)

The biocidal product in this dossier is used for disinfection of water in dedicated, closed installations, handled only by (trained) professionals. Chlorine gas is dosed automatically based on the concentration of active chlorine (AC) in the system (please refer to Confidential Annex for information on the dosing system). Therefore, the concentrations mentioned in the tables below refer to in-use concentration of active chlorine.

2.1.4.1 Use description

Error! Reference source not found. **– Disinfection of swimming pool water and hot tubs**

USE NOT GRANTED, since efficacy not proven enough.

Error! Reference source not found. **– Disinfection of waste water after the waste-water plant**

Product Type	PT 2: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria Viruses
Field of use	Indoor/outdoor : Disinfection of waste water after the waste-water plant, by shock dosing (in case of contamination)
Application method(s)	shock dosing (automated, closed dosing system).
Application rate(s) and frequency	Active against bacteria and viruses with 477 mg/L Active Chlorine in 30 min contact time
Category(ies) of users	Industrial, professional, trained professional
Pack sizes and packaging material	Please see section 2.1.7.

2.1.4.2 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automatic, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rates indicated in the table above.

2.1.4.3 Use-specific risk mitigation measures

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

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Reference is made to section 2.1.5.3.

2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

Reference is made to section 2.1.5.4.

2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Reference is made to section 2.1.5.5.

Error! Reference source not found. **– <u>Disinfection of raw water from rivers or wells for the preparation of industrial water.</u>**

USE NOT GRANTED (for more details, see the efficacy assessment).

Error! Reference source not found. **– <u>Disinfection of drinking water at drinking water suppliers</u>**

Product Type	PT 5 : Drinking water
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria Viruses
Field of use	Indoor/outdoor : Disinfection at the drinking water suppliers and their water distribution systems, by continuous dosing
Application method(s)	Automated dosing system
Application rate(s) and frequency	Active against bacteria and viruses with 0.5 mg/L Active Chlorine (as residual concentration in the system)

Category(ies) of users	professional, trained professional
Pack sizes and packaging material	Please see section 2.1.7.

2.1.4.7 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automatic, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rates indicated in the table above.

Please note that some member states after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as "Secondary disinfection: 0,1 to 0.5 mg/L available chlorine (residual)" has been considered as covered by the primary disinfection"

2.1.4.8 Use-specific risk mitigation measures

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

Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Directive 2020/2184.

2.1.4.9 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Reference is made to section 2.1.5.3.

2.1.4.10 Where specific to the use, the instructions for safe disposal of the product and its packaging

Reference is made to section 2.1.5.4.

2.1.4.11 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Reference is made to section 2.1.5.5.

Error! Reference source not found. **– <u>Disinfection of water in reservoirs</u>**

Product Type	PT 5: Drinking water
Where relevant, an exact description of the authorised use	/
Target organism	Bacteria

(including development stage)	Viruses
Field of use	Indoor/Outdoor : Disinfection of water (with water coming from tap water network), in reservoirs/tanks, by continuous dosing
Application method(s)	Automated dosing system (continuous) : The disinfection is carried out in the inlet of the reservoir, in order to assure proper distribution of the disinfectant in the water.
Application rate(s) and frequency	Active against bacteria and viruses with 0.5 mg/L Active Chlorine (as residual concentration in the system)
Category(ies) of users	professional, trained professional
Pack sizes and packaging material	Please see section 2.1.7.

2.1.4.12 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automatic, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rates indicated in the table above.

2.1.4.13 Use-specific risk mitigation measures

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

Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Directive 2020/2184.

2.1.4.14 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Reference is made to section 2.1.5.3.

2.1.4.15 Where specific to the use, the instructions for safe disposal of the product and its packaging

Reference is made to section 2.1.5.4.

2.1.4.16 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Reference is made to section 2.1.5.5.

Error! Reference source not found. **– <u>Disinfection of water in collective systems</u>**

Product Type	PT 5: Drinking water
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria (including *Legionella pneumophila*) Viruses
Field of use	Indoor/outdoor : in Public institutions, healthcare facilities Disinfection of drinking water in collective drinking water systems, by continuous dosing
Application method(s)	Automated, closed dosing system
Application rate(s) and frequency	Active against bacteria (including Legionella pneumophila) and viruses with 1 mg/L Active Chlorine (as residual concentration in the system)
Category(ies) of users	professional, trained professional
Pack sizes and packaging material	Please see section 2.1.7

2.1.4.17 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automatic, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration according to the table above.

2.1.4.18 Use-specific risk mitigation measures

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

Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Directive 2020/2184.

2.1.4.19 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Reference is made to section 2.1.5.3.

2.1.4.20 Where specific to the use, the instructions for safe disposal of the product and its packaging

Reference is made to section 2.1.5.4

2.1.4.21 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Reference is made to section 2.1.5.5.

Error! Reference source not found. **– <u>Disinfection of drinking water for animals</u>**

Product Type	PT 5: Drinking water
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria Viruses
Field of use	Indoor/outdoor : in Agricultural areas Disinfection of drinking water for animals (with water coming from tap water network), by continuous dosing
Application method(s)	Automated, closed dosing system (continuous)
Application rate(s) and frequency	Active against bacteria and viruses with 0.5 mg/L Active Chlorine (as residual concentration in the system)
Category(ies) of users	professional, trained professional
Pack sizes and packaging material	Please see section 2.1.7.

2.1.4.22 Use-specific instructions for use

Connect the chlorine cylinder or drum to the automatic, closed dosing system. Set up the parameters of the system to obtain an active chlorine concentration in the water according to the application rates indicated in the table above.

2.1.4.23 Use-specific risk mitigation measures

For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Regulation 2020/749.

2.1.4.24 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Reference is made to section 2.1.5.3.

2.1.4.25 Where specific to the use, the instructions for safe disposal of the product and its packaging

Reference is made to section 2.1.5.4.

2.1.4.26 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Reference is made to section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Please refer to use-specific instructions for use.

2.1.5.2 Risk mitigation measures

For connecting or disconnecting the product containers as well as for maintenance or repair of the gas pipe system, the following risk mitigation measures (RMMs) are mandatory: - an alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m³) is in place with initiates safety procedures like wearing RPE (EN141B); - application of LEV (according to the national legislation) and low-pressure/vacuum are in place to avoid chlorine emission; - the electrochemical sensors used for measurements detect various chlorinated species additional to chlorine itself; - sensors are measuring exposure also when the operators are using RPE (EN141B)

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Avoid breathing this toxic gas as much as possible. IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Immediately call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Immediately initiate life support measures, thereafter call a POISON CENTRE. IF SWALLOWED: Not applicable. IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice. IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Storage conditions:
Airtight pressure tanks: Due to its chemical and physical properties, chlorine gas is always stored in dedicated carbon/steel recipients with special, dedicated valves. Chlorine packages for use within the EU should be constructed and labelled according to the Transportable Pressure Equipment Directive (TPED) and ADR. Maximum filling 1.25 kg/l (80% of volume approx.).

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 <15°C and >50°C.

Chlorine should be kept away from reactive products (materials to avoid: reducing agents, combustible materials, metals in powder, acetylene, hydrogen, ammonia, hydrocarbons and organic materials).

2.1.6 Other information

professionals and/or trained professionals if required by national legislation.

2.1.7 Packaging of the biocidal product

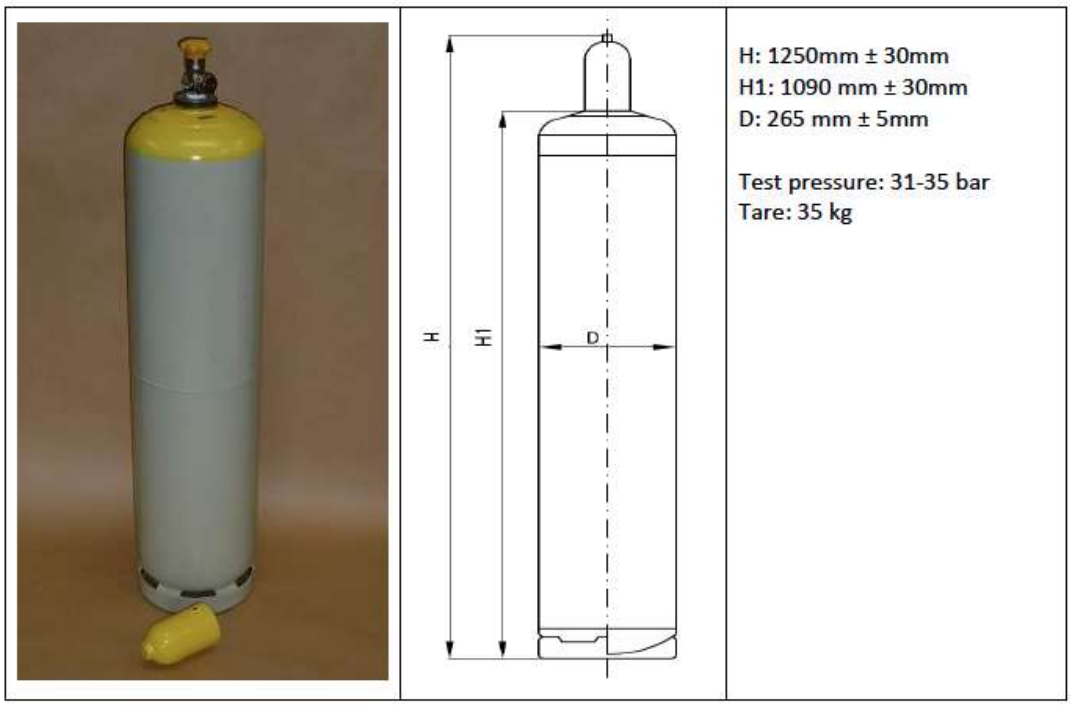
Due to its chemical and physical properties, chlorine gas is always stored in dedicated carbon/steel recipients with special, dedicated valves. Chlorine packages for use within the EU should be constructed and labelled according to the Transportable Pressure Equipment Directive (TPED) and ADR. Guidance on the design and construction of chlorine packages is also given in the GEST documents 88/138 and 79/76. The maximum filling rate is 1.25 kg Cl_2 per L volume.

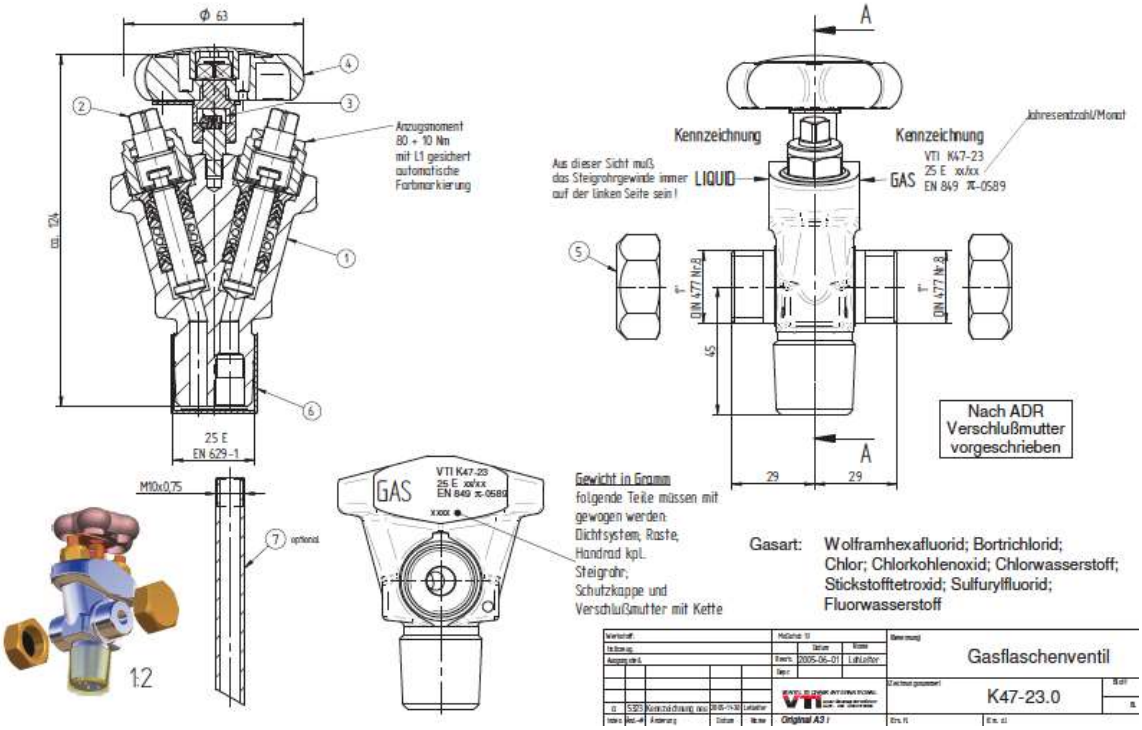
Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Cylinder	4.8 – 140 L (6-175 kg Cl_2)	Carbon/stainless steel	Carbon steel/brass/PVDF/nickel pressure resisting valve	(Trained) Professional, industrial	Yes
Drum	400 – 1,000 L (500-1,250 kg Cl_2)	Carbon/stainless steel	Carbon steel/brass/PVDF/nickel pressure resisting valve	(Trained) Professional, industrial	Yes

For information, the applicant has also added the following packaging used only for transportation.

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Road tanks	15,000 L (18,750 kg Cl_2)	Carbon/stainless steel	Carbon steel/brass/PVDF/nickel pressure resisting valve	(Trained) Professional, industrial	Yes
Railway tanks	43,000-44,000 L (53,750 - 55,000 kg Cl_2)	Carbon/stainless steel	Carbon steel/brass/PVDF/nickel pressure resisting valve	(Trained) Professional, industrial	Yes

An example of a 52 L gas cylinder and the technical drawing of a typical valve are given below.





During normal use, chlorine bottle/cylinders are connected to a closed circuit, and chlorine flows out of the recipient due to the pressure in the cylinders. During use, the pressure and chlorine flow will decrease gradually. When the pressure in the bottle/cylinder is too low to allow a sufficient flow of chlorine (±1 bar), it will be replaced. This implies that a bottle/cylinder is never completely empty when it is replaced, but the remaining chlorine (and hence pressure) is no longer sufficient to generate a chlorine flow. 'Empty' recipients are sent back to the producer to be refilled.
The cycle of filling and use of chlorine bottles and cylinders is repeated for about 5 years, after which they are subjected to an evaluation to guarantee they still fulfil the safety requirements. An example of the testing procedure is given below:

1) Water is filled into the bottle and the bottle is set under pressure for 1 minute.
2) The bottles are emptied under pressure
3) The bottles are dried at 120°C for at least 80 minutes (residual moisture would lead to corrosion)
4) The bottle is cleaned outside and optically checked inside with a LED lamp.
5) Removal of paint layer by sandblasting
6) Weighing of the bottle (indication of thickness of the walls, max. 5 % deviation from original weight is acceptable. If deviation is higher, the bottle will not be used any more)
7) Painting of the bottle
8) Screwing in of the valve, pressurizing at 15bar for 30 sec.
9) Adding the new barcode and date of the next check.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

For the APCP part, the applicant has submitted the data on pH monitoring, in agreement with the conclusions made in the APCP WG IV 2018.

MRL data were provided by the applicant (a list of national active chlorine limits for swimming pools and drinking water).

No other new data on the active substance has been generated since the active substance approval.

2.1.8.2 Access to documentation

The applicant received a LoA to the complete active substance dossier that was submitted by Eurochlor to the Rapporteur Member state in support of the approval active chlorine released from chlorine for product types 2 and 5.

The applicant received a LoA to the DBP Consortium Data concerning the disinfection by-products risk assessment and supporting data in accordance with Article 61 of Regulation 528/2012.

The applicant received a LoA to the required efficacy studies from the Sodium hypochlorite BPF Consortium. The studies related to these negotiations have been included.

2.1.8.3 Similar conditions of use

The biocidal product "Arche Chlorine" is deemed to be eligible for Union authorisation. Based on the information provided by the applicant, it appears that the application could meet the basic requirements of Article 42(1) of the Biocidal Products Regulation.
No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product "Arche Chlorine" falls outside of the scope of the BPR, or had been attributed the wrong product types, or that it would have non-similar conditions of use across the Union.

2.2 Assessment of the biocidal product

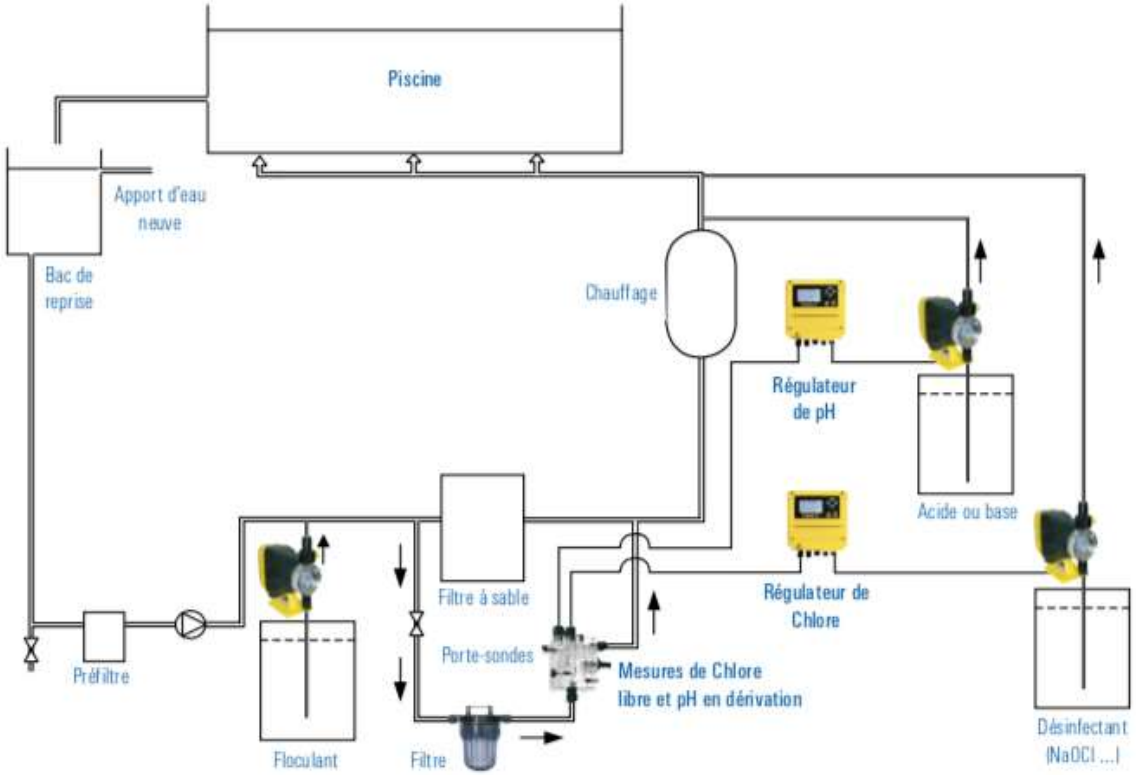
2.2.1 Intended use(s) as applied for by the applicant

The application of chlorine is done in automated, closed installations, dedicated for the use with chlorine gas and only performed by professionals. These installations are specifically designed for a specific site, according to local requirements and regulations. Also the storage and handling of chlorine cylinders is highly regulated. A general description and example of chlorination installations are given in the confidential annex.

Intended Error! Reference source not found. – Disinfection of swimming pool water and hot tubs

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.



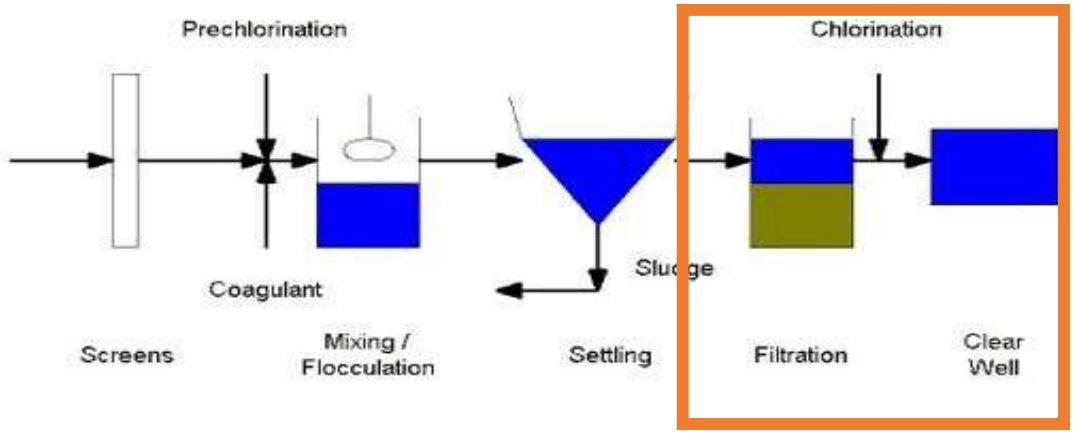
Intended Error! Reference source not found. – Disinfection of swimming pool water and hot tubs

Product Type(s)	PT 2
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria, viruses, yeast & fungal spores, algae, protozoa
Field of use	Indoor & outdoor large-scale swimming pools, spas and hot tubs
Application method(s)	Continuous or shock dosing (automated, closed dosing system)
Application rate(s) and frequency	0.5-1 mg/L AC (bacteria incl. *Legionella*) 1-5 mg/L AC (algae, viruses, protozoa, yeast & fungal spores) shock dosing: 15-50 mg/L AC (to be confirmed)
Category(ies) of user(s)	(trained) professional
Pack sizes and packaging material	Please see section 2.1.7

Intended Error! Reference source not found. – Disinfection of waste water after the waste-water plant

Disinfection of sewage waste/waste water in an industrial or municipal sewage treatment plant, in a post-chlorination step (see picture below) by automated dosing. The dose can either be fixed or vary with water flow rate.

Water is retained in a buffer or basin after treatment, before discharging to surface



Intended Error! Reference source not found. – Disinfection of waste water after the waste-water plant

Product Type(s)	PT 2
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Bacteria, viruses
Field of use	indoor/outdoor Disinfection of sewage waste/waste water after the waste water plant (post-chlorination).
Application method(s)	Continuous or shock dosing (automated, closed dosing system).
Application rate(s) and frequency	475 mg/L AC, 30 min contact time
Category(ies) of user(s)	Industrial, (trained) professional
Pack sizes and packaging material	Please see section 2.1.7.

Intended Error! Reference source not found.– Disinfection of raw water from rivers or wells for the preparation of industrial water.

Disinfection of raw water obtained from a well or river. After a chlorination step, the water can be further purified, for instance by coagulation, decantation and/or filtration. Industrial water is used by the textile industry as process water, and in several (heavy)

industries, such as petrochemical industry, refinery, thermoelectric central, production of resins, container terminals, ships,... as process water, for steam production, production of demineralized water, washing, fire networks,... Industrial water is not used in food production or processing plants.

Due to the type of processes for which the water is used (e.g. to avoid bleaching in textile industry, avoid damage to filters for production of demineralized water,...), the applied concentrations of chlorine are deliberately kept low.

In this application, chlorine is applied to prepare industrial water, after which it is distributed to (several) plants, not to preserve water during circulation within a plant.

Intended Error! Reference source not found. – Disinfection of raw water from rivers or wells for the preparation of industrial water.

Product Type(s)	PT 2
Where relevant, an exact description of the authorised use	Disinfection of raw water from wells or rivers for the preparation of industrial water. After disinfection, industrial waterer is to be used as process water, for steam production, production of demineralized water, washing, fire networks,... in textile industry, and heavy industry (petrochemical industry, refinery, thermoelectric central, production of resins, container terminals, ships,...). Industrial water is not to be used as a preservative of process water, or in food production or processing facilities
Target organism (including development stage)	Bacteria, algae
Field of use	indoor/outdoor Industrial settings
Application method(s)	Automated, closed dosing system
Application rate(s) and frequency	475 mg/L AC, 25 min
Category(ies) of user(s)	Industrial, (trained) professional
Pack sizes and packaging material	Please see section 2.1.7.

Intended Error! Reference source not found. - Disinfection of drinking water at drinking water suppliers

Disinfection of water during drinking water treatment in water plants of drinking water suppliers, during transport in between drinking water suppliers, and prior to distribution into (part of) the communal piping system (primary disinfection). Chlorine can also be added by drinking water suppliers to the previously-treated water already in the public distribution network to ensure that an adequate disinfectant residual is maintained throughout the system (secondary disinfection). An example of the different steps during drinking water disinfection is provided in the confidential annex.

Disinfectant is applied by automated dosing (shock or continuous dosing).

Intended Error! Reference source not found. – Disinfection of drinking water at drinking water suppliers

Product Type(s)	PT 5

Where relevant, an exact description of the authorised use	Disinfection at the drinking water suppliers and their water distribution systems.
Target organism (including development stage)	Bacteria, viruses
Field of use	indoor/outdoor Water treatment plants, drinking water distribution facilities
Application method(s)	Automated dosing system (continuous)
Application rate(s) and frequency	Pre-chlorination: 95 mg/L AC, 10 min (bacteria) 475 mg/L AC, 10 min (viruses) Secondary disinfection: 0.5-5 mg/L AC, 10 min
Category(ies) of user(s)	(trained) professional
Pack sizes and packaging material	Please see section 2.1.7.

Intended Error! Reference source not found.– Disinfection of stationary water in reservoirs

Disinfection of water stored in large tanks and reservoirs, such as water towers. Normally drinking water is used to fill the tanks, but also other water types can be used. Chlorine is applied by automated dosing, both by continuous and shock dosing.

Intended **Error! Reference source not found.** – Disinfection of stationary water in reservoirs

Product Type(s)	PT 5
Where relevant, an exact description of the authorised use	Disinfection of stationary water in reservoirs
Target organism (including development stage)	Bacteria, viruses
Field of use	indoor/outdoor Tanks and reservoirs
Application method(s)	Automated dosing system (continuous)
Application rate(s) and frequency	Pre-chlorination: 95 mg/L AC, 10 min (bacteria) 475 mg/L AC, 10 min (viruses) Secondary disinfection: 0.5-5 mg/L AC, 10 min
Category(ies) of user(s)	(trained) professional
Pack sizes and packaging material	Please see section 2.1.7.

Intended Error! Reference source not found. – Disinfection of water in collective systems

Disinfection of drinking water in collective drinking water systems like hospitals and other healthcare facilities, hotels, penitentiary institutions, etc. Sources include local drinking water suppliers, wells, natural springs, water courses. Disinfectant is applied by automated dosing, both continuous and shock dosing.

Intended Error! Reference source not found. – Disinfection of water in collective systems

Product Type(s)	PT 5
Where relevant, an exact description of the authorised use	Disinfection of drinking water in collective drinking water systems
Target organism (including development stage)	Bacteria, viruses, Legionella
Field of use	indoor/outdoor Public institutions, healthcare facilities
Application method(s)	Automated, closed dosing system
Application rate(s) and frequency	0.5 mg/L AC, 10 min – viruses & bacteria Legionella: 50 mg/L (shock dosing, 3x2h) 1-5 mg/L (continuous)
Category(ies) of user(s)	(trained) professional
Pack sizes and packaging material	Please see section 2.1.7.

Intended Error! Reference source not found. – Disinfection of drinking water for animals

Disinfection of water used in animal housing, including both drinking water and water for other uses. Origin of water can be from local drinking water suppliers or raw water. Pre-treatment by filtration might be required. Disinfectant is applied by automated dosing, both by continuous and shock dosing.

Intended Error! Reference source not found. – Disinfection of drinking water for animals

Product Type(s)	PT 5
Where relevant, an exact description of the authorised use	Disinfection of drinking water for animals
Target organism (including development stage)	Bacteria, viruses
Field of use	indoor/outdoor agricultural areas
Application method(s)	Automated, closed dosing system (continuous)
Application rate(s) and frequency	0.5-5 mg/L AC, 10 min
Category(ies) of user(s)	(trained) professional
Pack sizes and packaging	Please see section 2.1.7.

material	

2.2.2 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.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state, colour, odour at 20 °C and 101.3 kPa	Refer to AR Chlorine	≥99.5%	Greenish-yellow with characteristic stringent odour gas	AR Chlorine (Italy, 2017)
Acidity / alkalinity	Waived	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 following uses: "pool- and drinking water from tap water, drinking water from river water, swimming pool water from potable water, raw industrial water from river water, and waste water. The data provided by the applicant cover all the intended uses, as submitted in the dossier. The details are given below.		
	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	(See Confidential PAR) Source of water: tap water USE: pool- and drinking water from tap water	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	(See Confidential PAR)

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td>10ml H2SO4 10%. The sample was diluted with 100ml H2O demineralized and was titrated with 0,1N Na-thiosulfate and KJ starch solution from blue to colorless.</td><td></td><td>for usual dosage rates in pool- and drinking water applications (< 5mg/l)
<table>
<tr><th>Active Cl2 mg/L</th><th>pH H2O demi</th><th>pH KS4.3 = 4.1 mmol/L</th><th>pH K4.3 = 2.05 mmol/L</th></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>Monitoring of pH value:
The pH control is only carried out on surface water. This control is carried out through the automatic dosing of CO2 according to the flow of water to be treated and the pH value (set point) after dosing, which is measured in continuous analyzers. The goal in pH control is to control the coagulation step with aluminum sulfate in order to precipitate the aluminum avoiding its dissolution in water. The pH</td><td>(See Confidential PAR)

USE: drinking water from river water</td><td>pH value is around 7 before and after chlorination (from 6.9 to 7.3) for doses of 1.3 – 1.6 mg/L active chlorine</td><td>(See Confidential PAR)</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	is just one of the parameters that influence the dissolution of aluminum in water (alkalinity is another), so the target is to have a pH value close to 7.0 after the addition of aluminum sulfate.			
		(See Confidential PAR)	3 treatment plants have been monitored. For all of them pH varies from 7.52 to 7.64 when chlorine dose applied is 2.19, 2.56 or 2.06 mg/L per day. The values of the doses of added chlorine are defined by the temperature, CO2 concentration, various substances and minerals dissolved in the water of the rivers.	(See Confidential PAR) Remark : test unsigned , not dated, incomplete. For information only.
	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 swimming	(See Confidential PAR) Source of water: outdoor and indoor swimming pool (pool itself and 2 filtrates), situated in Germany, Niedersachsen USE: pool- water from drinking water	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	Disinfection of swimming pools – monitoring data, June 2020, by Arche consortia

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	pools, one indoor and one outdoor and each time for 3 locations: water from the pool itself and two filtrates. (See Confidential PAR)		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	
	Monitoring of pH value: Equipment for pH measurement: portable measuring equipment, CRISON, model MM40	(See Confidential PAR) USE: raw water from rivers or wells for the production of industrial water	pH value is around 8.1 in the entrance of WTP (before chlorination) and around 7.9 in the Rapid Mixing Chamber (after chlorination) pH ranges from 7.7 to 8.3 for both locations, with doses of 3 - 5 mg/L active chlorine	(See Confidential PAR)
	Monitoring of pH value: pH is measured using internal method (electrometry MI fq 13)	Chlorination is performed on waste water in the STP. The pH is measured at the entrance and exit of the STP USE: Disinfection of waste water after the waste-water plant	pH value is around 7.5 (pH range: 7.3 to 7.9) in the entrance of STP (before chlorination) and around 7.3 (pH range: 6.7 to 7.9) at the exit of the STP (after chlorination) Applied dose: 5 mg/L active chlorine	(See Confidential PAR)
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		AR Chlorine (Italy, 2017) Euro Chlor document GEST 91/168.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		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.		
Storage stability test – **accelerated storage** Storage stability test – **long term storage at ambient temperature**	- 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 .
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 temperatures >15°C" will be added to the label.		
Effects on content of	Refer to AR	Not applicable:		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
the active substance and technical characteristics of the biocidal product - **light** Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	chlorine	- container under pressure: exposure to elevated temperatures (max. 50°C) or direct sunlight during storage not allowed.[1] - dry chlorine at ambient temperature does not attack steel, copper or nickel, but reactivity of these metals is observed at higher temperatures (>200°C).[2]		
Wettability	Waived	Not applicable since biocidal product is not a solid preparations to be dispersed in water.		
Suspensibility, spontaneity and dispersion stability	Waived	Not applicable since biocidal product does not need to be diluted.		
Wet sieve analysis and dry sieve test	Waived	Not applicable since biocidal product is a gas.		
Emulsifiability, re-emulsifiability and emulsion stability	Waived	Not applicable since biocidal product does not need to be emulsified.		
Disintegration time	Waived	Not applicable since biocidal product is not a tablet and is not used in a water soluble bag.		
Particle size distribution, content of dust/fines, attrition, friability	Waived	Not applicable since biocidal product is not a granule or tablet.		
Persistent foaming	Waived	Not applicable since biocidal product is a gas.		
Flowability/Pourability/Dustability	Waived	Not applicable since biocidal product is not granular/a suspension.		
Burning rate — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.		
Burning completeness — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.		
Composition of smoke — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.		
Spraying pattern —	Waived	Not applicable since the biocidal product is not an		

[1] According to EN 937:216

[2] "Safe handling of chlorine from drums and cylinders" (2nd edition), HSE 1999

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
aerosols		aerosol.		
Physical compatibility	Waived – see AR of Chlorine	Avoid heat or temperatures above 50°C. Do not expose to direct sunlight.		
Chemical compatibility	Waived – see AR of Chlorine	The product is not intended to be used in combination with other products[3]		
Degree of dissolution and dilution stability	Waived	Not applicable since biocidal product is a gas.		
Surface tension	Refer to AR Chlorine	≥99.5%	18.2 mN/m (20 °C)	AR Chlorine (Italy, 2017)
Viscosity	Refer to AR Chlorine	≥99.5%	$12.4x10^{-3}$ Pa.s (0°C) $13.3x10^{-3}$ Pa.s (20°C)	AR Chlorine (Italy, 2017)

Conclusion on the physical, chemical and technical properties of the product
The product in this dossier is identical to the active substance releaser chlorine described in the Assessment Report (Italy, 2017). Arche Chlorine is a greenish-yellow gas with a characteristic stringent odour. The density of compressed liquid chlorine is reported in the AR to be 1.411 kg/dm3 (20°C, 10 kg/cm2 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.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Waiver	- There are no chemical groups associated with explosive properties present in the molecule of chlorine		

[3] Moreover, it is specified in the CAR of the a.s. that chlorine should be kept away from reactive products (materials to avoid: reducing agents, combustible materials, metals in powder, acetylene, hydrogen, ammonia, hydrocarbons and organic materials).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		- According to the AR of Chlorine: not applicable to gases		
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)
Flammable aerosols	Waiver	Not relevant for the formulation type		
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.			
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.**			
Flammable liquids	Waiver	Not relevant for the formulation type		
Flammable solids	Waiver	Not relevant for the formulation type		
Self-reactive substances and mixtures	Waiver	Not relevant for the formulation type		
Pyrophoric liquids	Waiver	Not relevant for the formulation type		
Pyrophoric solids	Waiver	Not relevant for the formulation type		
Self-heating substances and mixtures	Waiver	Not relevant for the formulation type		
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 (Cl2) itself is no longer available		
Oxidising liquids	Waiver	Not relevant for the formulation type		
Oxidising solids	Waiver	Not relevant for the formulation type		
Organic peroxides	Waiver	No bivalent O – O - structure		
Corrosive to metals	Waiver	According to the Guidance to Regulation (EC) No1272/2008 on CLP of substances and mixture),		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		neither the corrosivity of gases nor the formation of corrosive gases is currently covered by CLP classes and are therefore not applicable here.		
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.		
Relative self-ignition temperature for solids	Waiver	Not relevant for the formulation type		
Dust explosion hazard	Waiver	Not relevant for the formulation type		

Conclusion on the physical hazards and respective characteristics of the product
The most of properties are assessed in the CAR of the active substance. The product has the following hazard classification: Ox Gas 1 and Liquefied gas under pression.

2.2.4 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,
- analytical method for active substance residues in soil, air, animal and human body fluids and tissues, drinking water and food and feeding stuff.

Conclusion on the methods for detection and identification of the product
The product in this dossier is identical to the pure active substance 'chlorine'. Analytical methods for monitoring and detection for active substance and residues are available in the active substance dossier.

2.2.5 Efficacy against target organisms

2.2.5.1 Function (organisms to be controlled) and field of use (products/objects to be protected)

***MG 01* : Disinfectants**

- **PT2** : *Disinfectants and algaecides not intended for direct application to humans or animals*
- **PT5** : *Drinking water*

Chlorine is used for the disinfection of water. It is directly added to water in swimming pools, waste water after the sewage treatment plant, water for industrial purposes (PT2) or drinking water (PT5) as described below :

As originally claimed by the Applicant, by the time of the application submission :

Use # 1	Disinfection of swimming pool water and hot tubs
Use # 2	Disinfection of waste water after the waste-water plant
Use # 3	Disinfection of raw water from rivers or wells for the production of industrial water (not to be used in food production or processing).
Use # 4	Disinfection of drinking water at drinking water suppliers
Use # 5	Disinfection of stationary water in reservoirs
Use # 6	Disinfection of water in collective systems
Use # 7	Disinfection of drinking water for animals

Chlorine is used to treat water against bacteria (incl. Legionella) and viruses. In case of use in swimming pools, spas and hot tubs, also efficacy against fungal spores, algae and protozoa is claimed. Disinfection of raw water from rivers or wells for the preparation of industrial water is intended to reduce the bacterial and algal load.

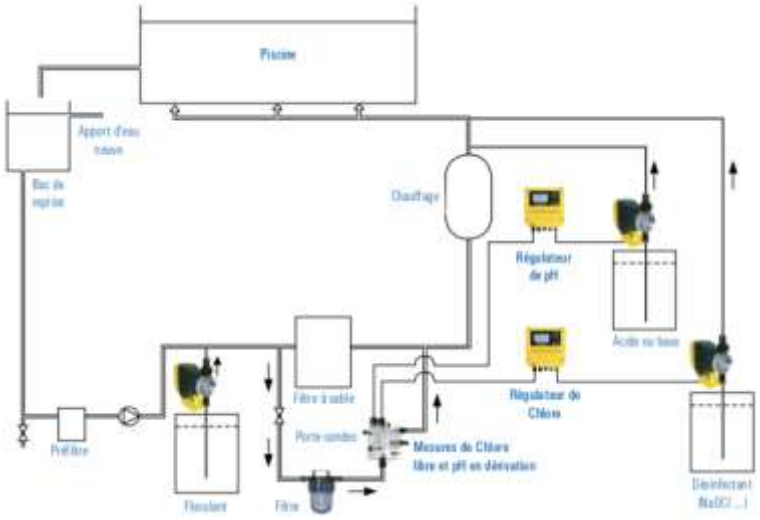
Chlorine is used for hygienic purposes to protect humans and animals, with the aim to control infectious diseases.

The products will be used by professional users.

INFORMATION PROVIDED BY THE APPLICANT
About way of application of the products

Use # 1 – Disinfection of swimming pool water and hot tubs

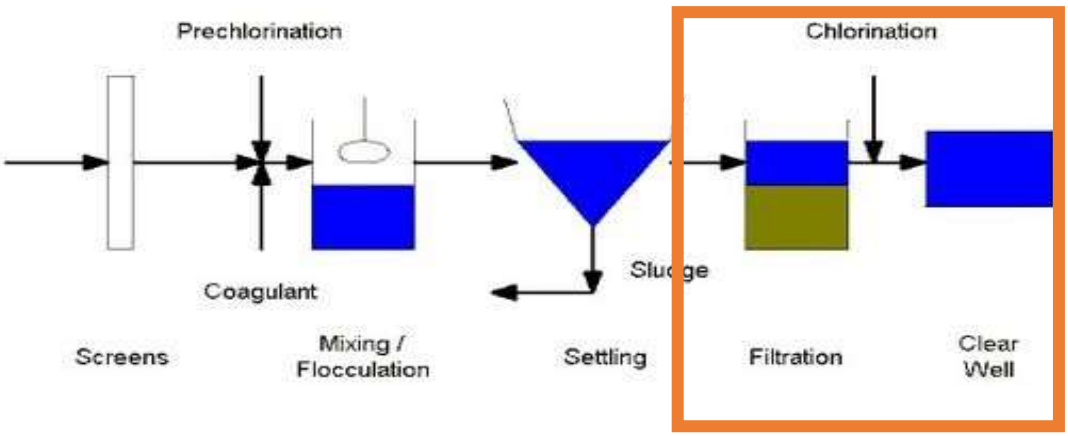
Disinfection large-scale swimming pools, spas and hot tubs by continuous or shock dosing. Chlorine containers are connected to an automated dosing system by professionals.
In case of continuous dosing, pH and disinfectant levels are continuously monitored and products are dosed via a reservoir or buffer 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.



Use # 2 – Disinfection of waste water after the waste-water plant

Disinfection of sewage waste/waste water in an industrial or municipal sewage treatment plant, in a post-chlorination step (see picture below) by automated dosing by professional users. The dose can either be fixed or vary with water flow rate.

Water is retained in a buffer or basin after treatment, before discharging to surface



Use # 3 – Disinfection of raw water from rivers or wells for the preparation of industrial water.

Disinfection of raw water obtained from a well or river. After a chlorination step, the water can be further purified, for instance by coagulation, decantation and/or filtration. Industrial water is used by the textile industry as process water, and in several (heavy) industries, such as petrochemical industry, refinery, thermoelectric central, production of resins, container terminals, ships,... as process water, for steam production, production of demineralized water, washing, fire networks,... Industrial water is not used in food production or processing plants.

Due to the type of processes for which the water is used (e.g. to avoid bleaching in textile industry, avoid damage to filters for production of demineralized water,...), the applied concentrations of chlorine are deliberately kept low.

In this application, chlorine is applied to prepare industrial water, after which it is distributed to (several) plants, not to preserve water during circulation within a plant.

Use # 4 - Disinfection of drinking water at drinking water suppliers

Disinfection of water during drinking water treatment in water plants of drinking water suppliers, during transport in between drinking water suppliers, and prior to distribution into (part of) the communal piping system (primary disinfection). Chlorine can also be added by drinking water suppliers to the previously-treated water already in the public distribution network to ensure that an adequate disinfectant residual is maintained throughout the system (secondary disinfection). An example of the different steps during drinking water disinfection is provided in the confidential annex.

Use # 5– Disinfection of stationary water in reservoirs

Disinfection of water stored in large tanks and reservoirs, such as water towers. Normally drinking water is used to fill the tanks, but also other water types can be used. Chlorine is applied by automated dosing, both by continuous and shock dosing.

Use # 6 – Disinfection of water in collective systems

Disinfection of drinking water in collective drinking water systems like hospitals and other healthcare facilities, hotels, penitentiary institutions, etc. Sources include local drinking water suppliers, wells, natural springs, water courses. Disinfectant is applied by automated dosing, both continuous and shock dosing.

Use # 7 – Disinfection of drinking water for animals

Disinfection of water used in animal housing, including both drinking water and water for other uses. Origin of water can be from local drinking water suppliers or raw water. Pre-treatment by filtration might be required. Disinfectant is applied by automated dosing, both by continuous and shock dosing.

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

Chlorine has a lethal effect on the target organisms or prevents growth. Chlorine aqueous solutions are an extremely efficient biocide for prions, viruses, bacteria, parasites and fungi.

The hypochlorite ion is in equilibrium with hypochlorous acid (HClO) and chlorine (sum: active chlorine or available 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.

Hypochlorite reacts actively by chlorination of nitrogen with compounds like amino acids. 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 hypochlorous acid are unspecific. Hypochlorous acid reacts by chlorination of nitrogen within 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 (0.1 to 1 mg/L) hypochlorite is able to inhibit bacterial growth. In this case the proteins of the membrane are partly destroyed, and the bacteria are not able to multiply.

The time delay or contact time needed for sufficient efficacy depends on the chlorine concentration, the organic matter content, pH and temperature of the disinfectant mixture and on the tolerance of the species to be controlled.

2.2.5.3 Efficacy data

INFORMATION PROVIDED BY THE APPLICANT

Following the BPR, authorization will only be granted if a biocidal product is sufficiently effective. Efficacy data need to be provided to support biocidal claims against target organisms. In general, the following efficacy tests need to be performed:

- Phase 2, step 1 tests or quantitative suspension tests to establish that a product has bactericidal, fungicidal, virucidal etc. activity, simulating practical conditions appropriate to its intended use.
- Phase 2, step 2 tests are quantitative laboratory tests, often using carriers or living tissues with dried-on micro-organisms, simulating practical conditions to establish that the product has bactericidal, fungicidal, virucidal etc. activity.
- For some claims Phase 3 tests are required: field tests under practical conditions.

The standard suspension and simulated-use tests start from the principle that the efficacy of a product is tested under specific test settings, i.e. temperature, soiling, contact time, etc. and a certain specified log reduction (LogR) has to be achieved. Required LogR are often very high (in the order of LogR 4 or 5) and therefore organisms have to be cultured in high numbers to achieve sufficient abundances at T0. After the product is applied, a limited contact time is tested (often 5 to 10 minutes) and reduction in target organisms is assessed. These methods are ideal to test efficacy for products that are applied once and fast action against organisms is required. Unfortunately, these methods are not realistic for continuous dosing disinfection methods where a constant level of the active substance is maintained and organism abundances are constantly being suppressed.

Upon dilution in water, chlorine will form active chlorine, which is an equilibrium between hypochlorous acid (HClO), hypochlorite ion (ClO^-) and chlorine (Cl_2). As it is irrelevant whether active chlorine is generated from chlorine gas, calcium hypochlorite or sodium

hypochlorite, all studies on hypochlorite aqueous solution can be used to assess the efficacy of active chlorine from any of these three releasers. Due to the physical state of the BP in this dossier and the risks related to the use of chlorine gas, liquid sodium hypochlorite was added as a test item in the suspension tests, as it also forms active chlorine as active substance. As NaOCl has a transformation rate of 95% (1 mg/L NaOCl in water results in 0.95 mg/L active chlorine), while chlorine gas has a transformation rate of 100%, efficacy testing on NaOCl solutions can be considered as worst case.

In practice, chlorine is dosed automatically in a closed system based on the active chlorine concentration in the water (please refer to the Confidential Annex for information on chlorination systems). However, in the standardized tests described above, the NaOCl is added to the suspension test, a big part of the active chlorine reacts with the soiling and only the remaining fraction will be left over to perform disinfection. At that point, however, it is unclear how much of the active substance remains available in the water for the disinfection and is dependent on the specific soiling that is used (use claim related). So, the real 'active' concentration is unknown. In real situations, chlorine gas is continuously added to water in small quantities and the residual chlorine in the water is continuously monitored and adjusted if necessary. This deviates substantially from how products are tested in laboratory suspension and simulated-use tests.

Since the P2S1 and P2S2 tests start from "unrealistic" high numbers of target organisms and there is only a short reaction time tested, higher minimum efficacious concentrations are obtained compared to when products are dosed continuously and active substance concentration is kept stable, buffering the impact of soiling on product efficacy and not allowing organisms to grow to such large numbers. These tests are still very useful to check if the active substance is efficacious or not against the organisms and allows standardized comparison with other active substances. However, since unrealistic high minimum efficacious concentrations are obtained under these lab test conditions, the BPR requirements could force too high in-use concentrations to be used. This could lead to over-dosing with unacceptable risks to the environment or human health. Therefore, disinfection of water is often regulated by the national or regional legislation, especially in case of drinking water and swimming pools. If, due to technical restrictions with the efficacy tests, a higher effective concentration would need to be accepted according to BPR, users will no longer be able to comply with these national or regional legislations. In annex 3.7.1, an overview is presented for several national/regional limits on chlorine concentrations used for disinfection of swimming pool water, waste water, industrial water and drinking water, uses directly relevant for this dossier.

Since chlorine has already been used for decades as a disinfectant, there is plenty of research available proving its efficacy at much lower in-use concentrations than found in the laboratory suspension and simulated-use tests, it would not be logical to set dosing instructions based solely on the P2S1 and P2S2 data. Therefore, monitoring data and research publications should be incorporated and taken into account.

Most efficacy tests described in the table below are performed with an aqueous dilution of NaOCl, without adding any co-formulants. The product SH-BPF-640 is a product containing only the technical active substance as manufactured (with 5% NaOCl). Efficacious concentrations will also be indicated in mg/L active chlorine (AC).
As NaOCl has a transformation rate of 95% (1 mg/L NaOCl in water results in 0.95 mg/L active chlorine), while chlorine gas has a transformation rate of 100%.

Active chlorine can indeed be present in a solution under the equilibrium of Cl2/HClO/ClO-. The ratio between these species in solution is pH and temperature dependent.
It is indicated at note (6) in CAR of NaOCl PT2 (Italy, 2017) that the content of active chlorine in a solution is usually determined by a titrimetric method and the results are typically expressed as available (active) chlorine using a conversion with the molecular weight of elemental chlorine in calculations, in compliance with the EN 901:2013. The content of NaOCl can be converted using a conversion factor (MWNaOCl/MWCl2 = 74.44/70.91).
In order to avoid the confusion between different types of active chlorine which might present in solutions, in this dossier the available (active) chlorine is always expressed and calculated as elemental chlorine, and this does not mean the elemental chlorine is the only active chlorine presenting in the solution.
All the proposals are therefore still valid and the applicant would like to kindly ask the eCA to consider using the value active chlorine as elemental chlorine in all the assessments.

Hypochlorous acid (HClO) and hypochlorite anion (ClO—) are in equilibrium at pH 7.5.

The results of all the EFF studies provided by the Applicant are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

CLAIMED by APPLICANT

Use #1 : PT2 - Disinfection of large-scale swimming pools, spas and hot tubs

- Continuous or shock dosing (automated, closed dosing system)
- Bacteria, viruses, fungal spores, algae, protozoa
- 3 mg/L CA (continuous ⇔ maintenance) or 50 mg/L CA (shock dosing ⇔ curative treatment)

Experimental data on the efficacy of the biocidal products against target organisms				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010)** Quantitative suspension test Temperature : 20°C ± 1°C Contact time : 5 min Concentrations tested : 2.857 – 428.57 mg/L AC (dilutions from a stock solution containing 2857 mg/L AC with pH = 8.2) I.S. : 300 mg/L BSA (clean conditions)	**Bactericidal activity** at +20°C in clean conditions in 5 min at **143 mg/L AC**	Doc. "1_EN 1276_20°C_5 min_0,3 g_L bovine albumin_clean_P2S1_Bacteria" *"SH-BPF-640 EN 1276 2010 L18-0142-39"* **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** Obligatory test organisms: *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus* *+ E. faecium*	**EN 1276 (2010)** Quantitative suspension test Temperature : +25°C ± 1°C Contact time : 30 sec. or 2 min Concentrations tested : 4.7619 => 238 mg/L AC I.S. : BFA at 6,432 mg/L pH not reported	Active against *E.coli , Pseudomonas aeruginosa and Staphylococcus aureus* in 30 sec. at **95.238 mg/L AC** Active against *E. faecium* in 2 min at **95.238 mg/L AC** at +25°C in BFA at 6,432 mg/L	Doc. 22a_EN 1276_25°C_5 min_BFA-soiling_clean_P2S1_Bacteria Doc. 22b_EN 1276_25°C_2 min_BFA-soiling_clean_P2S1_Bacteria_Faecium **R.I. 2** **(*E. hirae* not tested)** **R.I. 3 (N°22b) since E. faecium not relevant at +20°C**
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** Obligatory test organisms: *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**OECD 170 (2012)** Quantitative suspension test Temperature : +27,5°C ± 1°C Contact time : 30 sec. / 2 min (*for E. faecium*) Concentrations tested : 48.57 – 142.86 mg/L AC (dilutions from a	Active against *E.coli , Pseudomonas aeruginosa, Staphylococcus aureus and Legionella pneumophila* in 30 sec. at 0.0102% NaOCl (↓*Log* ≥ *5*) ⇔ **97 mg/L AC** at +27,5°C in clean conditions.	Doc. 2_EN 1276 (OECD 170)_27,5°C_0,5 min_0,3 g/L bovine albumin_clean_P2S1_Bacteria" **R.I. 1**

	+ *E. aecium* + *Legionella pneumophila*	stock solution containing 2857 mg/L AC with pH = 8.2) I.S. : 300 mg/L BSA (clean conditions)	Active against *E. faecium* in 2 min at **48.57 mg/L AC** at +27,5°C in clean conditions.	
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** *Legionella pneumophila*	**EN 13623 (2010)** Quantitative suspension test Temperature : +35°C ± 1°C Contact time : 30 sec. Concentrations tested : 71.43 => 952.38 mg/L AC I.S. : 300 mg/L BSA (clean conditions) pH not reported	Active against *Legionella pneumophila* in 30 sec. at **240 mg/L AC** at +35°C in clean conditions.	Doc. "21_EN 13623_35°C_0,5 min_0,3 g-L bovine albumin_clean_P2S1_Legionella" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** *Legionella pneumophila*	**EN 13623 (2010)** Quantitative suspension test Temperature : +25°C ± 1°C Contact time : 30 sec. Concentrations tested : 4.762 => 238 mg/L AC I.S. : BFA at 6,432 mg/L pH not reported	Active against *Legionella pneumophila* in 30 sec. at **95 mg/L AC** at +25°C in BFA at 6,432 mg/L	Doc. "26_EN 13623_25°C_0,5 min_BFA-soiling_clean_P2S1_Legionella" **R.I. 1**
150 000 mg/L AC	**Bactericidal activity** *E.coli* *Staphylococcus aureus* *Legionella pneumophila*	**P3 Monitoring data (with continuous dosing) – Long term (2-year monitoring data)** Results collected from 2 swimming-pools with 3 locations (water from the pool itself and 2 filtrates) - One exercise pool indoor Max free chlorine = 1.56 mg/L Mean bather load : 27 - One outdoor pool Max free chlorine = 1.10 mg/L Mean bather load : 57	Conclusion : pH should be kept btw 6.8 and 7.8 with Free Chlorine btw 0.5 and 1 mg/L CA For bacteria & *Legionella pneumophila* **ONLY**	***NEW*** *7/07/2020* Doc. "30_Monitoring data swimming pools_Chlorine consortium_V2"

SH-BPF-640 product 47 619 mg/L AC	**Fungicidal/yeasticidal activity** Obligatory test organisms: *Candida albicans* *Aspergillus brasiliensis*	**EN 1650 + A1 (2013)** Quantitative suspension test Temperature : + 27,55°C ± 1°C Contact time : 5 min Concentrations tested : 142.86 => 860 mg/L AC (dilutions from a stock solution containing 2857 mg/L AC with pH = 8.2) I.S. : 300 mg/L BSA (clean conditions)	**Fungicidal/yeasticidal activity** in 5 min at **860 mg/L AC** at + 27,55°C in clean conditions.	Doc.24_EN1650 (OECD170)-_27,55°C_5min_0,3 g_L bovine albumin_clean-P2S1 **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Virucidal activity** *Human Rotavirus*	**OECD 170 (2012)** Quantitative suspension test Temperature : +25°C ± 1°C Contact time : 2 min Concentrations tested : 66.67 => 666.7 mg/L AC I.S. : 300 mg/L BSA (clean conditions) pH = 8.33 at 0.07%	Active against *Human Rotavirus* in 2 min at **334 mg/L AC** at +25°C in clean conditions.	Doc. "7_EN 14476_25°C_2 min_0,3 g_L bovine albumin_clean_P2S1_Viruses" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Virucidal activity** Adenovirus	**OECD 170 (2012)** Quantitative suspension test Temperature : +25°C ± 1°C Contact time : 10 min Concentrations tested : 0.007 => 0.07% NaOCl I.S. : 300 mg/L BSA (clean conditions) pH = 8.33 at 0.07%	Active against Adenovirus Type *5* in 10 min at 0.035% NaOCl ⇔ **333 mg/L AC** at +25°C in clean conditions	Doc. "8_EN 14476_25°C_10 min_0,3 g_L bovine albumin_clean_P2S1_Viruses" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Virucidal activity** Adenovirus Murine norovirus Poliovirus	**EN 14476 (2013)** Quantitative suspension test Temperature : +20°C ± 1°C Contact time : 5 – 30 min Concentrations tested : 66.67 => 952.38 mg/L AC I.S. : 300 mg/L BSA (clean conditions) pH = 9.05 at 0.07%	Active against Adenovirus Type *5* & norovirus in 5 min at **333 mg/L AC** And **FULL virucidal activity** in 5 min at **477mg/L AC** at +20°C in clean conditions	Docs "9a_EN 14476_20°C_5 min_0,3 g_L bovine albumin_clean_P2S1_Viruses" "9b_EN 14476_20°C_5 min_0,3 g_L bovine albumin_clean_P2S1_Viruses" "9c_EN 14476_20°C_5 min_0,3 g_L bovine albumin_clean_P2S1_Viruses"

				R.I. 1
SH-BPF-640 product 47 619 mg/L AC	**Virucidal activity** *Human Rotavirus*	**EN 14476 (2013)** Quantitative suspension test Temperature : 25°C ± 1°C Contact time : 2 min Concentrations tested : 47.62 => 714.28 mg/L AC I.S. : BFA at 6,432 mg/L pH not reported	Active against *Human Rotavirus* in 2 min at **238 mg/L AC** at +25°C in BFA at 6,432 mg/L	Doc.23a_ "23a_EN 14476 (OECD 170)_25°C_2 min_BFA-soiling_clean_P2S1_Viruses_Rota" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Virucidal activity** Adenovirus Type *5*	**EN 14476 (2013)** Quantitative suspension test Temperature : 20°C ± 1°C Contact time : 10 min Concentrations tested : 47.62 => 714.28 mg/L AC I.S. : BFA at 6,432 mg/L pH not reported	Active against Adenovirus Type *5* in 10 min at **238 mg/L AC** at +20°C in BFA at 6,432 mg/L	Doc.23b_ "23b_EN 14476 (OECD 170)_25°C_10 min_BFA-soiling_clean_P2S1_Viruses_Adeno" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Algicidal activity** *Chlorella vulgaris* *Anabaena flos-aquae*	**OECD 201 (2012)** Quantitative suspension test Temperature : +20°C ± 1°C Contact time : 15 – 60 min Concentrations tested : 143 => 2286 mg/L AC I.S. : 3000 mg/L BSA (dirty conditions) pH not reported	at +20°C in dirty conditions. 2286 mg/L AC - 15 min => 99.76% (≈ Log3 reduction) 2286 mg/L AC - 60 min => 99.80% Active against algae in 15 min at 2286 mg/L AC	Doc. "16_OECD 201_20°C_15 min-60 min_3 g-L bovine albumin_dirty_P2S1_Algae" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Protozoal activity** *Giardia duodenalis* cysts	**EN 1276 (2010) Modified + OECD 170 N°4 guidelines** With Targeted performance characteristic for an effective free-chlorine concentration (according to the OECD 170 N°4 document): ≥ 3 $\log_{10}$ reduction of Giardia cysts. **Quantitative suspension test -** measure of cysts removal (DNA analyses) and viability loss (mRNA analyses)	↓Log ≥ 3.63 with 200 mg/L active chlorine in 45 min at +25°C. Active against protozoa cysts in 45 min at 200 mg/L AC at +25°C in clean conditions.	Doc. "3_EN 1276 (mod)_25°C_45 min_0,3 g_L bovine albumin_clean_P2S1_Protozoa" **R.I. 1**

		Temperature : 25°C ± 1°C Contact time : 45 min Concentrations tested : 4 – 10 – 50 – 200 – 500 mg/L AC I.S. : 300 mg/L BSA (clean conditions) pH = 7.3		

SUMMARY of RESULTS from VALIDATED STUDIES		
EN 1276	**1**	at +20°C in clean conditions - in 5 min at **143mg/L AC**
	2	in 30 sec. at **97 mg/L AC** at +27.5°C in clean conditions.
	22a	at +25°C in BFA at 6,432 mg/L - in 30 sec. at **95 mg/L AC**
EN 13623	**2**	in 2 min at **49 mg/L AC** at +27.5°C in clean conditions.
	21	in 30 sec. at **238 mg/L AC** at +35°C in clean conditions.
	26	in 30 sec. at **95 mg/L AC** at +25°C in BFA clean conditions.
P3 Monitoring data	**30**	Bacteria & *Legionella pneumophila* **(continuous dosing ONLY)** with Free Chlorine btw **0.5 - 1 mg/L AC**
EN 1650	**24**	**Y :** in 5 min at **143 mg/L AC** **F/Y :** in 5 min at **857 mg/L AC** at + 27,55°C in clean conditions.
EN 14476	**23a**	**Active against *Human Rotavirus*** in 2 min at **238 mg/L AC** at +25°C in BFA at 6,432 mg/L
EN 14476	**23b**	**Active against *Adenovirus*** in 10 min at **238 mg/L AC** at +25°C in BFA at 6,432 mg/L
OECD 170	**7**	**Active against *Human Rotavirus*** in 2 min at **333 mg/L AC** at +25°C in clean conditions.
	8 (+ 9)	**FULL virucidal activity** in 5 min at **477 mg/L AC** at +25°C in clean conditions
OECD 201 Algae	**16**	in 15 min at **2286 mg/L AC** at +20°C in dirty conditions.
EN 1276	**3**	in 45 min at **200 mg/L AC**

Protozoa		at +25°C in clean conditions.

For use #1 – DISCUSSION & CONCLUSION :
According to the ECHA EFF guidance (from April 2018), for swimming-pool water disinfection, quantitative suspension P2S1 tests, simulated-use tests and field tests (P3/monitoring data) should be provided against at least bacteria and viruses (as basic requirements) in order to show efficacy of the product according to the intended use.

Please note that an Early WG meeting on efficacy requirements for disinfectants of swimming pools and spas (PT 2) has occurred on the 8th of Sept. 2020 at the initiative of France in order to discuss about test protocols for bacteria, virus and algae. Our FR colleagues have presented two documents for discussion with summary of studies provided by an Applicant in the context of applications submitted to FR eCA (confidential data). After a quite long discussion, it seems that most of the decisions made should be confirmed.
Based on the decisions made at the EFF WG-IV 2018, the Applicant for ARCHE Chlorine has provided modified P2S1 tests performed with BFA (exact formulation as the one presented in the WG document) at a 30 sec. contact time at +25°C, in order to have representative conditions of swimming pools. According to the results of the EN 1276 test, a solution with 0.01 % NaOCl is active against *E.coli, Pseudomonas aeruginosa* and *Staphylococcus aureus* in 30 sec. However, the mandatory representative target organism *E. hirae* was not tested. Considering that *E. hirae* is not a relevant representative target organism for swimming-pools, the test is acceptable as supportive information.

For continuous (maintenance) dosing, a Monitoring data/P3 test with bacteria & *Legionella pneumophila* has been performed & provided with proven efficacy between 0.5 and 1 ppm AC final.

According to the WHO document from 2006 "*Guidelines for safe recreational water environments. Volume 2 - Swimming pools and similar environments*" on page 94, an adequate routine disinfection should be achieved with a free chlorine level of 1 ppm throughout the pool .
As the conclusion, the EFF expert made the decision to validate the **1 mg/L AC final** maximum dose reported for continuous maintenance dosing.

However, lower doses seem required in most other EU countries (under national legislations), according to the doc. "*30_Monitoring data swimming pools_Chlorine consortium_V2*" including an overview of regulatory requirements for swimming pool water quality in some EU countries provided on page 8 (table 2).

About shock dosing against bacteria (including *Legionella pneumophila*), the Applicant has proposed to use the in-use concentrations derived from the SIM test (#25) provided for use #6 i.e. 50 mg/L AC (3 times 2h) for shock dosing (in clean water), followed by 1 mg/L AC final for continuous dosing. However, this test was not performed under BFA conditions. But, according to the P2S1 tests provided by

the Applicant (even if not relevant for chlorine-based products) with bacteria & *Legionella pneumophila*, choosing interfering substances clean BSA or BFA doesn't seem to have a significant impact on efficacy.
According to the WHO document from 2006 "*Guidelines for safe recreational water environments. Volume 2 - Swimming pools and similar environments*", using a shock dose of chlorine as a preventive measure or to correct specific problems may be part of a strategy of proper pool management (p.88). … As a preventive measure, routine shock dosing (which is practised in some countries) typically involves raising free chlorine levels to at least 10 mg/l for between 1 and 4 h. Intervention shock dosing for a water quality problem (such as an accidental faecal release) may involve raising the free chlorine residual to 20 mg/l for an 8-h period while the pool is empty.
Then, due to the absence of specific tests, the EFF expert made the decision to use the proposed values i.e. **50 mg/L AC (3 times 2h) for shock dosing (in clean water)**, followed by **1 mg/L AC final for continuous dosing.**

About efficacy against viruses, according to the results of the EN 14476 tests performed under BFA conditions, a solution with 0.025 % NaOCl is active against *Human Rotavirus* and Adenovirus in 2 and 10 min respectively. The other target organism relevant for swimming-pools (i.e. norovirus) seems to have the same susceptibility as adenovirus, according to the results of the other EN 14476 test. But no SIM or P3 test is provided for viruses.
Considering that a discussion is ongoing at the EU level to decide if viruses are still relevant for swimming-pools and that viruses are mentioned neither in WHO documents for swimming-pools nor in national regulatory requirements for Belgium (and for many other EU countries), the BE EFF expert is wondering if the virucidal claim should be rejected only because no SIM or P3 tests not submitted.
The BE EFF expert is willing to consider the data provided for viruses as sufficient since the Applicant made some effort to provide efficacy tests against viruses using BFA soiling. As an additional effort, the applicant has summarized the available literature for the efficacy of viruses in swimming pools in the document presented below :

(See Confidential PAR)

Summary of the results from the document :

In order to demonstrate the efficacy of hypochlorite (NaOCl solution with 150 g/L active chlorine) in swimming pools against pathogenic indicators under actual use conditions, long-term monitoring data (duration of two years) was collected in Germany for two swimming pools :

- *one indoor/exercise pool (dimension = 50 m^2 & volume = 80 m^3)*
- *one outdoor pool (dimension = 60 m^2 & volume = 120 m^3)*

and each time for 3 locations : water from the pool itself and two filtrates.

Standard monitoring for bacteriological parameters includes culturable micro-organisms colony count (Colony Forming Units or CFU, revivable at 36-37°C), thermotolerant coliforms (for example Escherichia coli) and Staphylococcus or Pseudomonas aeruginosa. Legionella spp. can also cause issues in swimming pools (especially at higher temperatures) so can also be monitored. Other claimed target organisms like yeast, fungi, viruses, protozoa and algae are not as easily assessed as bacteria and obtaining monitoring data is therefore not possible.

- ⇨ From table n°3 (Summary of 2-year monitoring data for the exercise pool), taking into account the 3 locations, an average of 0.5 ppm free chlorine with an average pH of 7 is reported. Neither E. coli nor P. aeruginosa is detected. However, *legionella* (not relevant for swimming-pools in current T°C) is found in both filtrates.
- ⇨ From table n°4 (Summary of 2-year monitoring data for the outdoor pool), taking into account the 3 locations, an average of 0.5 ppm free chlorine with an average pH of 7.2 is reported. Neither E. coli nor P. aeruginosa is found, wo *Legionella*.

As the conclusion, the pH should be kept within the range of 6.8 – 7.8 (with % HClO > % $HOCl^-$) and maintaining a free chlorine concentration of 0.5 – 1 ppm sufficiently controls the monitored organisms (i.e. bacteria).
However, the presented monitoring data does not cover viruses.

Considering these results and the WHO document from 2006 "*Guidelines for safe recreational water environments. Volume 2 - Swimming pools and similar environments*", maintaining a "continious" residual free chlorine concentration of 1 mg/L in the system does sufficiently control the monitored organisms (i.e. bacteria). The conclusion of the EFF expert is confirmed and the use #1 "Disinfection of water from swimming-pools" via maintenance continious dosing (with residual free chlorine concentration of 1 mg/L in the system) could be granted.

According this document, all the observations/lines of evidence argue in favour of a sufficient antiviral activity of free chlorine between 0.5 and 1 mg/L free chlorine concentration in swimming pools.
The dosage validated above for bacteria could be then acceptable and applicable for viruses. Furthermore, the virucidal claim is acceptable for drinking water uses with application rates lower than the ones proposed for swimming-pools.

OTHER TARGET ORGANISMS CLAIMED i.e. algae, yeasts/fungi and protozoa
For all claimed target organisms (i.e. B + V + F /Y + Algae + Protozoa), P2S1 tests, simulated-use tests and Monitoring Data/P3 tests should also have been provided. Since neither simulated-use tests nor Monitoring Data/P3 field tests have been provided for additional target organisms, the use should not be granted from an EFF point of view for these additional target organisms.

As the overall conclusion, the BE EFF expert is of the opinion that the product could be granted for use in swimming-pools with the following application rates :

- Bacteria (including *Legionella pneumophila*) + Virus :1 mg/L AC_{FINAL} for continuous dosing
- Bacteria (including *Legionella pneumophila*) + Virus : 50 mg/L AC_{FINAL} (3x 2h) for shock dosing

FINAL conclusion after peer-review :

According to the ECHA EFF Guidance (from April 2018) and also to the decisions made during the WG-Eff-III2020 meeting, viruses are and remain mandatory target organisms for the disinfection of swimming pool water. Since the Applicant didn't provide in due time adapted phase 2, step 1 test, simulated use test, field test or monitoring data about viruses, the efficacy against viruses (neither via shock dosing nor via continuous dosing) should be considered as not proven enough.
Via shock-dosing, considering the comments received from several MS during the peer-review, the efficacy against bacteria is not demonstrated, despite the BE eCA proposal to derive the use concentration from SIM tests used for use #6 (Doc. N°25 performed at +37°C and only with *Legionella pneumophila*).
Altogether, the use #1 via shock-dosing has been rejected for authorisation at the end of the peer-review phase.
About the use #1 via continuous-dosing, since in addition lab test at the application rate claimed for continuous dosing haven't been provided, the use #1 via continuous dosing has been also rejected for authorisation at the end of the peer-review phase.

CLAIMED by APPLICANT

Use #2 : PT2 - Disinfection of waste water (post-STP)

- Continuous or shock dosing (automated, closed dosing system)
- Bacteria, viruses
- 7.5 mg/L (continuous) or 40 mg/L (shock dosing) AC

Test product	Function & Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results : effects	Reference & R.I.
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas*	**EN 1276 (2010)** Quantitative suspension test Temperature : 10°C ± 1°C Contact time : 5 min Concentrations tested : 35.71 => 571.43 mg/L AC I.S. : 20 mg/L DOC pH not reported	**Bactericidal activity** in 5 min at **72 mg/L AC** at +10°C in 20 mg/L DOC (dirty conditions)	Doc. 17 "17_EN 1276_10°C_5 min_20 mg-L DOC_dirty_P2S1_Bacteria" **R.I. 1**

<table>
<tr><td></td><td>aeruginosa
Staphylococcus aureus</td><td></td><td></td><td></td></tr>
<tr><td>SH-BPF-640 product

47 619 mg/L AC</td><td>Bactericidal activity

<u>Obligatory test organisms</u>:
Enterococcus hirae
E.coli
Pseudomonas aeruginosa
Staphylococcus aureus</td><td>EN 1276 (2010)
Quantitative suspension test

<u>Temperature</u> : +15°C ± 1°C
<u>Contact time</u> : 25 min
<u>Concentrations tested</u> :
10 – 250 – 500 – 750 – 1500 mg/L AC
<u>I.S.</u> : BSA 3000 mg/L (dirty conditions)</td><td>Bactericidal activity
At 477 mg/L AC in 25 min at +15°C in 3000 mg/L BSA (dirty conditions)

<table><tr><td></td><td></td></tr><tr><td>E. hirae</td><td>Log ↓ = 5.2 with mini 500 ppm</td></tr><tr><td>E. coli</td><td>Log ↓ = 5.49 with mini 250 ppm</td></tr><tr><td>P. aeruginosa</td><td>Log ↓ = 5.25 with mini 250 ppm</td></tr><tr><td>S. aureus</td><td>Log ↓ = 5.26 with mini 500 ppm</td></tr></table></td><td>NEW 8/06/2020
Doc. “28_EN 1276_15°C_25 min_3g_L BSA_dirty_P2S1_bacteria”

R.I. 1</td></tr>
<tr><td>SH-BPF-640 product

47 619 mg/L AC</td><td>Algaecidal activity
Chlorella vulgaris
Anabaena flos-aquae</td><td>EN 1276 (2010)
Quantitative suspension test

<u>Temperature</u> : +15°C ± 1°C
<u>Contact time</u> : 25 min
<u>Concentrations tested</u> :
10 – 250 – 500 – 750 – 1500 mg/L AC
<u>I.S.</u> : 20 mg/L DOC</td><td>Algaecidal activity (with a Log 3 reduction)
At 477 mg/L AC in 25 min at +15°C
in DOC dirty conditions</td><td>NEW 8/06/2020
Doc. “29_SEN1276_15°C_25 min_20 mg_L DOC_dirty_P2S1_algae”</td></tr>
<tr><td>47 619 mg/L AC</td><td>Bactericidal activity
Enterococcus faecium
E.coli
Staphylococcus aureus</td><td>ASTM E645 (2018) + EN 1276 (2019)
Simulated use test / modified protocol
With 3 samples from Styria state (southeast of Austria): 2 samples from municipal wastewater (with one sample with higher load) and 1 sample from industrial wastewater.

<u>Temperature</u> : +12-15°Csw
<u>Contact time</u> : 30 min
<u>Concentrations tested</u> : 476.19 mg/L AC</td><td>Bactericidal activity
in 30 min at 477 mg/L AC (↓Log ≥ 4.64)
at +12-15°C in natural (dirty) conditions.</td><td>Doc. 27a “27a_EN 1276_ASTM E645-18 waste water_12-15°C_natural soiling_P2S2_bacteria”

R.I. 1
(please note that according to early discussion for UA disinfection of municipal wastewater (WG VI 2018), P.</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>S.I. :
<table>
<tr><th>Parameter (3 measures)</th><th>Sample 1</th><th>Sample 2</th><th>Sample 3</th></tr>
<tr><td>Conductivity (☐S/cm)</td><td>1127</td><td>1480</td><td>3.29</td></tr>
<tr><td>Salinity</td><td>0.5</td><td>0.7</td><td>1.7</td></tr>
<tr><td>Total Dissolved Solids (mg/L)</td><td>1125</td><td>1482</td><td>> 2000</td></tr>
<tr><td>pH</td><td>7.57</td><td>7.77</td><td>7.77</td></tr>
<tr><td>Dissolved Oxygen (mg/L)</td><td>5.87</td><td>5.49</td><td>5.26</td></tr>
<tr><td>TOC (ppm)</td><td>4.130</td><td>5.591</td><td>8.057</td></tr>
<tr><td>DOC (mg/L)</td><td>4.23</td><td>5.457</td><td>8.394</td></tr>
</table></td>
<td></td>
<td>*aeruginosa* is NOT mandatory for the SU test)</td>
</tr>
<tr>
<td>!SH-BPF-640 product

47 619 mg/L AC</td>
<td>Virucidal activity
Adenovirus
Murine norovirus
Poliovirus</td>
<td>EN 14476 (2013)
Quantitative suspension test

Temperature : 10°C ± 1°C
Contact time : 5 min
Concentrations tested : 47.62 => 1190.47 mg/L AC
I.S. : 20 mg/L DOC
pH not reported</td>
<td>FULL virucidal activity
in 5 min at 238 mg/L AC

at +10°C in 20 mg/L DOC (dirty conditions)</td>
<td>Doc. “18_EN 14476_10°C_5 min_20 mg-L DOC_dirty_P2S1_Viruses_Adeno”

Doc. “19_EN 14476_10°C_5 min_20 mg-L DOC_dirty_P2S1_Viruses_Murine”

Doc. “20_EN 14476_10°C_5 min_20 mg-L DOC_dirty_P2S1_Viruses_Polio”

R.I. 1</td>
</tr>
<tr>
<td>47 619 mg/L AC</td>
<td>Virucidal activity
Adenovirus
Murine norovirus</td>
<td>ASTM E645 (2018) + EN 1276 (2019)
Simulated use test / modified protocol
With 3 samples from Styria state (southeast of Austria): 1 sample from municipal wastewater (sample 1 – WWTP1), 1 sample</td>
<td>Virucidal activity
in 30 min at 477 mg/L AC (↓Log ≥ 4.33)
at +12-15°C in natural (dirty) conditions.</td>
<td>Doc. 27b “27b_N 1276_ASTM E645-18 waste water_12-15°C_natural soiling_P2S2_viruses”</td>
</tr>
</table>

<table>
<tr>
<td></td>
<td>Poliovirus</td>
<td>from municipal wastewater with higher load (sample 2 – WWTP2) and 1 sample from industrial wastewater (sample 3 – WWTP3).

Temperature : +12-15°C
Contact time : 30 min
Concentrations tested : 476.19 mg/L AC
S.I. :

<table>
<tr><th>Parameter (3 measures)</th><th>Sample 1</th><th>Sample 2</th><th>Sample 3</th></tr>
<tr><td>Conductivity (☐S/cm)</td><td>1127</td><td>1480</td><td>3.29</td></tr>
<tr><td>Salinity</td><td>0.5</td><td>0.7</td><td>1.7</td></tr>
<tr><td>Total Dissolved Solids (mg/L)</td><td>1125</td><td>1482</td><td>> 2000</td></tr>
<tr><td>pH</td><td>7.57</td><td>7.77</td><td>7.77</td></tr>
<tr><td>Dissolved Oxygen (mg/L)</td><td>5.87</td><td>5.49</td><td>5.26</td></tr>
<tr><td>TOC (ppm)</td><td>4.130</td><td>5.591</td><td>8.057</td></tr>
<tr><td>DOC (mg/L)</td><td>4.23</td><td>5.457</td><td>8.394</td></tr>
</table>
</td>
<td></td>
<td>Doc. 27c "27c_N 1276_ASTM E645-18 waste water_12-15°C_natural soiling_P2S2_physchem"

R.I. 1</td>
</tr>
<tr>
<td>SH-BPF-640 product

47 619 mg/L AC</td>
<td>Bactericidal activity
Total coliforms, Fecal coliforms, E. coli</td>
<td>Pilot plant at conventional waste water treatment plant (Milan, Italy) – Municipal waste water with high industrial flow.</td>
<td>Bactericidal activity
in 18 min at 7.5 mg/L AC
at +10°C in DOC dirty conditions</td>
<td>Doc. 12 "12_Literature Study__30 min_20 mg/L DOC_dirty_P3 _Bacteria"

Supporting information</td>
</tr>
</table>

For use #2 – DISCUSSION & CONCLUSION :
Since the EFF requirements for this use are not clearly mentioned in the ECHA EFF guidance (in the Annex IV), the Applicant has provided P2S1 and SIM tests (for bacteria and viruses) on the advice of the BE eCA.

SUMMARY of RESULTS from VALIDATED STUDIES		
EN 1276	**17**	in 5 min at **72 mg/L AC** at +10°C in 20 mg/L DOC
SIM	**27a**	in 30 min at **477 mg/L AC** at +12-15°C in natural (dirty) conditions.
EN 14476	**18** **19** **20**	in 5 min at **238 mg/L AC** at +10°C in 20 mg/L DOC
SIM	**27b**	in 30 min at **477 mg/L AC** at +12-15°C in natural (dirty) conditions.

According to the SIM tests provided by the Applicant, **477 mg/L AC** final in 30 min at +12-15°C in dirty conditions is effective against bacteria and viruses.

For this use, the Applicant does claim use for both continuous and shock dosing. The application rate claimed by the Applicant for continuous dosing is only supported by literature study on bacteria. Since there is no information about the virucidal activity but duly claimed by the Applicant,
this use via continuous dosing should not be granted.
Nevertheless, considering the rather high use concentration, the BE EFF expert is of the opinion to grant the product only for shock dosing procedures with the following application rates :

- ⇨ **In case of contamination (effective against bacteria and viruses) – in 30 min contact time, with 477 mg/L AC at +12-15°C at pH 7.4 in dirty conditions.**

CLAIMED by APPLICANT
Use #3 : PT2 - Disinfection of raw water from rivers or wells for the production of industrial water - Continuous (automated, closed dosing system) - Bacteria and algae

- 5 mg/L (continuous)

Experimental data on the efficacy of the biocidal products against target organisms				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010)** Quantitative suspension test Temperature : +15°C ± 1°C Contact time : 25 min Concentrations tested : 10 => 1500 mg/L AC I.S. : BSA 3000 mg/L (dirty conditions)	**Bactericidal activity** **at 477 mg/L AC** in 25 min at +15°C in dirty conditions	***NEW*** 8/06/2020 Doc. "28_EN 1276_15°C_25 min_3g_L BSA_dirty_P2S1_bacteria" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Algaecidal activity** *Chlorella vulgaris* *Anabaena flos-aquae*	**EN 1276 (2010)** Quantitative suspension test Temperature : +15°C ± 1°C Contact time : 25 min Concentrations tested : 10 => 1500 mg/L AC I.S. : 20 mg/L DOC	**Algaecidal activity** (with a Log 3 reduction) **at 477 mg/L AC** in 25 min at +15°C in DOC dirty conditions	***NEW*** 8/06/2020 Doc. "29_SEN1276_15°C_25 min_20 mg_L DOC_dirty_P2S1_algae"

SUMMARY of RESULTS from VALIDATED STUDIES		
EN 1276	**28**	in 25 min at **477 mg/L AC** at +15°C – in BSA 3g/L
EN 1276 Algae	**29**	in 25 min at **477 mg/L AC** at +15°C in 20 mg/L DOC

For use #3 – DISCUSSION & CONCLUSION :
This use is considered as a PT2 use by the BE eCA.

According to the decisions made during the early WG-Eff discussion during the WG-V 2019 meeting, the EFF WG agreed with the proposal of the eCA in general i.e. phase 2, step 1 and simulated use tests should be provided by the Applicant. The CT should be the same for phase 2, step 1 test and simulated use test.
Since the exact raw water quality will depend on the source and the season, P2S1 tests should be performed at +15°C, in max 30 min, in dirty conditions :
- Using 3 g BSA/L for bacteria (EN 1276) & 5 log reduction should be achieved
- Using 15-20 mg DOC/L for algae & 3 log reduction should be achieved
It was clarified that in the simulated use test log reduction should be 2 with 10 min CT and 4 with 25 min CT (PT5 raw water).
Regarding the determination of algae, it was commented that 95% reduction of algal biomass might not be feasible, but rather live/dead staining and flow cytometry could be considered as a detection method.

Since no simulated-use test was provided in due time, ***the use #3 is not granted.***

CLAIMED by APPLICANT

Use #4 : PT5 - Disinfection of drinking water at drinking water suppliers
Use #5 : PT5 - Disinfection of stationary water in reservoirs (secondary disinfection - continuous dosing)
- Continuous (automated, closed dosing system)
- Bacteria, viruses
- 1.5 mg/L (primary) / 0.1-0.5 mg/L (secondary)

Use #6 : *PT5 - Disinfection in collective drinking water systems*
- Continuous (automated, closed dosing system)
- Bacteria, viruses
- 0.5 mg/L
- Legionella

- 1-5 mg/L
- Shock dosing
- Legionella
- 50 mg/L (3x2h)

Use #7 : PT5 - Disinfection of drinking water for animals (secondary disinfection - continuous dosing)

- Continuous (automated, closed dosing system)
- Bacteria, viruses
- 0.5 mg/L

Experimental data on the efficacy of the biocidal products against target organisms				
Test product	**Function & Test organism(s)**	**Test method / Test system / concentrations applied / exposure time**	**Test results : effects**	**Reference & R.I.**
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas aeruginosa* *Staphylococcus aureus*	**EN 1276 (2010)** Quantitative suspension test Temperature : +15°C ± 1°C Contact time : 25 min Concentrations tested : 2.857 => 95 mg/L AC I.S. : 2 mg DOC/L adjusted with bovine albumin (clean conditions) 15 mg DOC/L adjusted with bovine albumin (dirty conditions)	**Bactericidal activity** in 25 min at +15°C 1) In presence of 2 mg DOC/L (clean) : at **71 mg/L AC** 2) In presence of 15 mg DOC/L (dirty) : at **95 mg/L AC**	Doc. "4_EN 1276_15°C_25 min_2 mg_L DOC_clean_P2S1_Bacteria" Doc. "5_EN 1276_15°C_25 min_15 mg_L DOC_dirty_P2S1_Bacteria" **R.I. 1**
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** Obligatory test organisms: *Enterococcus hirae* *E.coli* *Pseudomonas*	**EN 1276 (2010)** Quantitative suspension test Temperature : +15°C ± 1°C Contact time : 25 min Concentrations tested : 10 => 1500 mg/L AC I.S. : BSA 3000 mg/L (dirty conditions)	**Bactericidal activity** At **477 mg/L AC** in 25 min at +15°C	***NEW*** 8/06/2020 Doc. "28_EN 1276_15°C_25 min_3g_L BSA_dirty_P2S1_bacteria" **R.I. 1**

<table>
<tr>
<td></td>
<td>aeruginosa
Staphylococcus aureus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorine as sodium hypochlorite or chlorine dioxide</td>
<td>BACTERIA :
Escherichia coli
Enterococcus faecium

BACTERIOPHAGES :

MS2 (ATCC 15597-B1) : coliphage with ssRNA genome, belonging to the family Leviviridae, icosahedral capsids (non-enveloped).

PRD1 (DSM 19107): somatic phage with a dsDNA genome belonging to Tectiviridae. With icosahedral capsids (non-enveloped) and inner protein-lipid membrane. This phage shares characteristic features with human</td>
<td>From publication “A new approach to testing the efficacy of drinking water disinfectants”:
Rig test in a flow-through mode, in which microorganisms and disinfectants are dosed continuously into the test water.

It consists of a PVC pipe with an inner diameter of 40mm and small stainless steel sampling taps.

Concentrations of bacteria = 10^5-5.10^6 cfu/100 mL
Concentrations of bacteriaphages = 10^6-10^8 pfu/100 mL

$Ct_{99\%}$ value ⇔ concentration/time needed to reduce the organisms by 99% ⇔ Log 2 reduction

+15°C
Contact time range: 0,2 min to 277 min
2 mg/L DOC (clean)
pH = 7.5</td>
<td>Output = $Ct_{99\%}$ values (the product of the disinfectant concentration and the time needed to reduce the microorganisms by 99% (= 2 Log_{10} reduction)) → lower Ct values = higher efficacy

<u>Effect of temperature:</u>

At pH 7,5 and 2 mg/L DOC:
<table>
<tr><th>Temp (°C)</th><th>Bacteria</th><th>bacteriophages</th></tr>
<tr><td>5</td><td>0,081</td><td>0,444</td></tr>
<tr><td>15</td><td>0,061</td><td>0,385</td></tr>
<tr><td>25</td><td>0,052</td><td>0,156</td></tr>
</table>
<u>Effect of pH:</u>

At 15-16°C and 2 mg/L DOC:
<table>
<tr><th>pH</th><th>Bacteria</th><th>bacteriophages</th></tr>
<tr><td>6,3</td><td>0,032</td><td>0,164</td></tr>
<tr><td>7,4</td><td>0,040</td><td>0,185</td></tr>
<tr><td>9,2</td><td>0,337</td><td>0,361</td></tr>
</table>
<u>Effect of soiling:</u>

At pH 7,4-7,6 and 15°C:
<table>
<tr><th>mg/L DOC</th><th>Bacteria</th><th>bacteriophages</th></tr>
<tr><td>0,4</td><td>0,040</td><td>0,185</td></tr>
<tr><td>2,0</td><td>0,061</td><td>0,385</td></tr>
</table>
</td>
<td>Doc. “13_UBA Test Rig_15°C_10 min_2 mg/L DOC_clean_P2S2_Bacteria”

Doc. “14_UBA Test Rig_15°C_10 min_2 mg/L DOC_clean_P2S2_Viruses”

R.I. 2

For simulated use tests, the BPR guidance for efficacy (Vol II Parts B+C) refers to the protocol developed by UBA. This protocol only refers to Escherichia coli and Enterococcus faecium as indicator organisms for testing.
In the study it was impossible to test all potential pathogens in drinking water and UBA therefore decided to focus on indicator organisms that are globally used to surveil drinking water quality. Since fecal contamination is the most problematic cause of poor drinking water quality, the two most common fecal indicators for bacteria were selected, i.e. E. coli and enterococci. E. faecium was selected instead of the normally standard E. hirae (enterococcal species to be used according BPR guidance) but to make sure it was</td>
</tr>
</table>

	adenoviruses.		**3,2** 0,075 0,543 In 10 min at +15°C in presence of 2 mg DOC/L (clean) : with Log 2 reduction **Bacteria : 0.0061 mg/L AC** **Bacteriophages : 0.0385 mg/L AC** **Applicant justification:** *This publication describes the development of the protocol used by the UBA test facility to evaluate the efficacy of disinfectants for drinking water.* *Since UBA is the only facility which is capable to perform this type of testing, resulting in very long waiting lists and high costs. Therefore, reference would be made to this publication, as a valid alternative for performing a new test, which would be practically the same as the one described in the publication.* Please note that the efficacy at 25 minutes was not presented in the reference, taking into account the difficulties to perform the UBA test. However, according to the Fig 2. in the UBA test publication, it shows with very high confidence that log 4 reduction of all the test organism is achieved within 25 min with the proposed application rate of 0.5 mg/L. As seen from the figure, log 4 reductions of all target organisms are achieved under test conditions (T = 15 °C and pH = 7.5 and DOC = 2.0 mg/l.) with much lower c×t (min mg/ml) than that resulting from	representative for all bacterial species, wild isolates were used since they show a higher tenacity to the realistic environmental standards typical for the drinking water disinfection use and therefore show a higher resistance and resilience against disinfectants.

			25 min exposure to 0.5 mg/L. We consider the evidence to be much more convincing than any single test with 25 min contact time.	
SH-BPF-640 product 47 619 mg/L AC	**Bactericidal activity** *Legionella pneumophila*	**EN 13623 (2010)** Quantitative suspension test Temperature : +15°C ± 1°C Contact time : 25 min Concentrations tested : 2.857 => 95 mg/L AC I.S. : 0.0005 % Yeast extract (clean conditions)	*Legionella pneumophila* (with Log 4 reduction) in 25 min at +15°C - Clean conditions : at **28.5714 mg/L AC**	Doc. "6_EN 13623_15°C_25 min_0,0005% yeast extract_clean_P2S1_Legionella" **R.I. 1**
Sodium hypochlorite NaOCl 15.2 % AC	**Bactericidal activity** *Legionella pneumophila*	**CSTB test - Simulated-use test** 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	Results showed the decrease of *Legionella* in water superior to 4 Log : Shock treatment at 50 ppm or 50 mg/ L AC (3x 2h) followed by a continuous treatment at 1 ppm for 10 days (clean conditions).	Doc "25_Sim use - CSTB_37°C_Natural soiling_clean_P2S2_Legionella" **R.I. 2**
Sodium hypochlorite NaOCl 15.2 % AC	**Bactericidal activity** *Legionella pneumophila*	**Literature study** Clean conditions Continuous treatment: 1 – 5.0 mg/L AC Shock dosing: 20 – 50 mg/L AC pH not reported	Continuous dosing: 1 – 5.0 mg/L AC Shock dosing: 20 – 50 mg/L AC during 1 – 2 hours	Doc "15_Literature Study__continuous__clean_P3 _Legionella" **R.I. 2** About this literature study, please find below some additional information
47 619 mg/L AC	**Virucidal activity** Adenovirus Murine norovirus	**EN 14476 (2013)** Quantitative suspension test Temperature : 10°C ± 1°C	**FULL virucidal activity** in 5 min at **238 mg/L AC** at +10°C in 20 mg/L DOC (dirty conditions)	Doc. "18_EN 14476_10°C_5 min_20 mg-L DOC_dirty_P2S1_Viruses_Adeno" Doc. "19_EN 14476_10°C_5

	Poliovirus	Contact time : 5 min Concentrations tested : 47.62 => 1190.47 mg/L AC I.S. : 20 mg/L DOC pH not reported		min_20 mg-L DOC_dirty_P2S1_Viruses_Murine" Doc. "20_EN 14476_10°C_5 min_20 mg-L DOC_dirty_P2S1_Viruses_Polio" **R.I. 1**
47 619 mg/L AC	**Virucidal activity** Murine norovirus Poliovirus	**EN 14476 (2013)** Quantitative suspension test Temperature : +15°C ± 1°C Contact time : 25 min Concentrations tested : 66.67 => 666.7 mg/L AC I.S. : 2 mg DOC/L adjusted with bovine albumin (clean conditions) pH not reported	Active against poliovirus and norovirus in 25 min at **477 mg/L AC** at +15°C in clean conditions.	Docs "10a_EN 14476_15°C_25 min_2 mg_l DOC_clean_P2S1_Viruses" "10b_EN 14476_15°C_25 min_2 mg_l DOC_clean_P2S1_Viruses" **R.I. 1**
47 619 mg/L AC	**Virucidal activity** Murine norovirus Poliovirus	**EN 14476 (2013)** Quantitative suspension test Temperature : +15°C ± 1°C Contact time : 25 min Concentrations tested : 66.67 => 666.7 mg/L AC I.S. : 15 mg DOC/L adjusted with bovine albumin (dirty conditions) pH not reported	Active against poliovirus and norovirus in 25 min at **477 mg/L AC** at +15°C in dirty conditions.	Docs "11a_EN 14476_15°C_25 min_15 mg_l DOC_dirty_P2S1_Viruses" "11b_EN 14476_15°C_25 min_15 mg_l DOC_dirty_P2S1_Viruses" **R.I. 1**

SUMMARY of RESULTS from VALIDATED STUDIES		
EN 1276	**4**	in 25 min at +15°C - In presence of 2 mg DOC/L (clean) : at **71.4285 mg/L AC**
	5	in 25 min at +15°C **-** In presence of 15 mg DOC/L (dirty) : at **95.238 mg/L AC**
UBA	**13**	**Bacteria**

Rig test		in 10 min at +15°C - In presence of 2 mg DOC/L (clean) : **0.0061 mg/L AC** (with 99% ⇔ Log 2 reduction)
SIM	**27a**	in 30 min at **477 mg/L AC** at +12-15°C in natural (dirty) conditions.
EN 14476	**10**	in 25 min at +15°C **-** In presence of 2 mg DOC/L (clean) : at **477 mg/L AC**
	11	in 25 min at +15°C **-** In presence of 15 mg DOC/L (dirty) : at **477 mg/L AC**
SIM	**27b**	in 30 min at **477 mg/L AC** at +12-15°C in natural (dirty) conditions.
UBA **Rig test**	**14**	**Bacteriophages** in 10 min at +15°C - In presence of 2 mg DOC/L (clean) : **0.0385 mg/L AC** (with 99% ⇔ Log 2 reduction)
EN 13623	**6**	*Legionella pneumophila* (with Log 4 reduction) in 25 min at +15°C - Clean conditions : at **28.5714 mg/L AC**
SIM (CSTB test)	**25**	*Legionella pneumophila* (with Log 4 reduction) – clean conditions **50 mg/L AC 3x 2h (applied in the system) + continuous 1 mg/L AC (residual concentration)**
Literature	**15**	*Legionella pneumophila* – clean conditions **Continuous 1-5 mg/L AC – shock 20-50 mg/L AC 1-2h**

For use #4 – *DISCUSSION & CONCLUSION* :

According to the ECHA EFF guidance (from April 2018) with Annex IV (p. 275), the products should have a bactericidal and a virucidal activity. P2S1 tests (i.e. efficacy tests performed according to modified EN 1276 and to EN 14476 standards) and SIM tests (10 and 25 min – at +15°C – with 2 mg DOC/L) should be provided.

Note from the Applicant (Nov. 2020) : At the time of dossier submission, UBA was the only test facility with a validated test rig to perform the required simulated use tests. We have been in contact with UBA, but due to the high number of requests, they did not accept any new projects at that time. Also in recent communication (May 2020) they indicated that no new tests could be planned.

UBA ring tests have been performed, but only at 10 min at +15°C in presence of 2 mg DOC/L (clean). Validation of the use conditions for bacteria/viruses is therefore questionable.

For primary disinfection, SIM tests (#27a and #27b test reports) were provided. The EFF expert made the decision to validate the use as follows :

Bacteria + Viruses : 477 mg/L AC in 30 min at +12-15°C at pH 7.4.

For secondary disinfection (continuous dosing), no SIM tests (performed with 2 mg DOC/L) have been submitted.

The Application rate validated for primary disinfection from SIM tests performed in "natural" dirty conditions (in dirty conditions) would be applied, but duly overestimated.

As a way-forward, the Applicant has therefore proposed to use the application rates derived from the WHO guideline *Guidelines for Drinking-Water Quality* (3rd edition from 2004) i.e. 0.5 mg/L AC. Please note that a 4st edition (from 2017) of the WHO guideline Guidelines for Drinking-Water Quality is available, but not taken into account by the Applicant. However, it seems that the proposed value of 0.5 mg/L AC is still recommended. Furthermore, it should be duly noted that this proposed value of 0.5 mg/L AC (as residual concentration at pH 7.4) has been used and accepted (based on several efficacy tests provided and the WHO guidelines) by the time of the AS approval, in the CAR for Active Chlorine released from chlorine for PT 5 applications.

The concentrations derived from the UBA ring tests showed that a concentration higher that 0.0385 mg/L AC would be efficacious against bacteria and bacteriophages. According to the Applicant. this value of 0.0385 mg/L AC seems much lower than the concentrations proposed in the WHO guideline (2004). Though poorly familiar about the susceptibility of bacteriophages besides other viruses, it seems that this value of 0.0385 mg/L AC is a little bit lower indeed and should be increased to have an acceptable margin of safety. As the conclusion, the EFF expert found the way-forward proposed by the Applicant acceptable.

Bacteria + Viruses : 0.5 mg/L AC final

For use #4 - FINAL conclusion after peer-review and WG discussion :

All the commenting MSs agreed not to grant the use #4 (for shock dosing), at the end of the peer-review phase.

About efficacy via continious dosing, it has been confirmed based on UBA tests results & on the WHO guideline but adapted for clarity taking into account the way-forward proposed by FR to describe the use more in line with the EFF guidance. Furthermore, considering that the pH value has a high influence on disinfection when using chlorine, it's very important to mention a pH range to be maintained.

⇨ About this use #4 "Disinfection of drinking water at drinking water suppliers", we agree about the way-forward proposed by FR and are of the opinion to grant the use #4 as follows :

Residual concentration in the system / primary disinfection (effective against bacteria and viruses): 0.5 mg/L AC (continuous application – at pH 7.4) :
By adding an additional statement in section "Use-specific instructions for use" (or in : "*Please note that some member states after primary disinfection, request to maintain a residual level of available chlorine in drinking water in the pipes as a precautionary measure. This additional amount, claimed by the applicant as "Secondary disinfection: 0,1 to 0.5 mg/L available chlorine (residual)" has been considered as covered by the primary disinfection*".

For use #5 – *DISCUSSION & CONCLUSION* :

For use #7 – *DISCUSSION & CONCLUSION* :

According to the ECHA EFF guidance (from April 2018) with Annex IV (p. 275), the products should have a bactericidal and a virucidal (mandatory for use #5 but additional claim for use #7) activity. P2S1 tests (i.e. efficacy tests performed according to modified EN 1276 and to EN 14476 standards) and SIM tests (wo clear criteria to be achieved) should be provided.

For secondary disinfection (continuous dosing), no SIM tests (performed with 2 mg DOC/L) have been submitted.
The Application rate validated for primary disinfection from SIM tests performed in "natural" dirty conditions (in dirty conditions) would be applied, but duly overestimated.
As a way-forward, the Applicant has therefore proposed to use the application rates derived from the WHO guideline *Guidelines for Drinking-Water Quality* (3rd edition from 2004) i.e. 0.5 mg/L AC. Please note that a 4st edition (from 2017) of the WHO guideline Guidelines for Drinking-Water Quality is available, but not taken into account by the Applicant. However, it seems that the proposed value of 0.5 mg/L AC is still recommended. Furthermore, it should be duly noted that this proposed value of 0.5 mg/L AC (as residual

concentration at pH 7.4) has been used and accepted (based on several efficacy tests provided and the WHO guidelines) by the time of the AS approval, in the CAR for Active Chlorine released from chlorine for PT 5 applications.

The concentrations derived from the UBA ring tests showed that a concentration higher that 0.0385 mg/L AC would be efficacious against bacteria and bacteriophages. According to the Applicant. this value of 0.0385 mg/L AC seems much lower than the concentrations proposed in the WHO guideline (2004). Though poorly familiar about the susceptibility of bacteriophages besides other viruses, it seems that this value of 0.0385 mg/L AC is a little bit lower indeed and should be increased to have an acceptable margin of safety. As the conclusion, the EFF expert found the way-forward proposed by the Applicant acceptable.

Bacteria + Viruses : 0.5 mg/L AC final at +12-15°C at pH 7.4.

For use #5 - <u>FINAL conclusion after peer-review and WG discussion :</u>

As confirmed by the Applicant, the disinfection is carried out in the inlet of the reservoir, in order to assure proper distribution of the disinfectant in the water.

Conclusion about Efficacy confirmed by adapted for clarity based on the cMS comments :

- ⇨ Residual concentration in the system / primary disinfection (effective against bacteria and viruses): **0.5 mg/L AC** (continuous application – at pH 7.4)

For use #7 - <u>FINAL conclusion after peer-review and WG discussion :</u>

Conclusion about Efficacy confirmed by adapted for clarity based on the cMS comments :

- ⇨ Residual concentration in the system / primary disinfection (effective against bacteria and viruses): **0.5 mg/L AC** (continuous application – at pH 7.4)

For use #6 – *DISCUSSION & CONCLUSION* :

According to the ECHA EFF guidance (from April 2018), P2S1 tests for bacteria (including *Legionella pneumophila*) and viruses (as additional claim) and a field test with *Legionella pneumophila* (SIM test optional) should be submitted.

For shock dosing, in-use concentrations are derived from a SIM test (#25) with information from a literature search (#15). Comparing the results from the SIM test with *Legionella pneumophila* and the information from literature, the EFF expert made the decision to use the following values i.e. 50 mg/L AC (3 times 2h) for shock dosing against *Legionella pneumophila* (in clean water), followed by 1 mg/L AC final for continuous dosing.

***Legionella pneumophila* (for shock dosing) : 50 mg/L AC (3 times 2h) (in clean water)**
& **1 mg/L AC final for continuous dosing.**

For secondary disinfection, values derived from UBA ring tests could be applied. However, the Applicant has proposed to use the application rates, derived from the WHO guideline *Guidelines for Drinking-Water Quality* (3rd edition from 2004) i.e. **0.5 mg/L AC (Bacteria + Viruses)** since the concentrations derived from UBA ring tests seem much lower than the concentrations proposed in the WHO guideline (2004).
However, since *Legionella pneumophila* is a mandatory target organism as basic requirement, the application rate to be validated must take into account the effective dosing for *Legionella pneumophila* i.e. 1 mg/L AC. Then as the conclusion, the application rate should be raised at 1 mg/L AC instead of 0.5 mg/L AC.
Bacteria (including *Legionella pneumophila*) + Viruses : + V : 1 mg/L AC final at +12-15°C at pH 7.4.

For use #6 - FINAL conclusion after peer-review and WG discussion :

Considering the comments from FR #36 & #37 about the literature study (⇔ Doc. N°15), please find below some additional information :
An extensive literature search was conducted in order to identify (semi-)field trials or monitoring studies of chlorine disinfection in the different PT5 drinking water use categories. A review of scientific peer-reviewed open literature has been performed, to identify potential field trials or monitoring studies of interest. In order to target the literature search to studies relevant to the efficacy of active chlorine (released from sodium hypochlorite) in drinking water disinfection with relevant criteria : Field trials or monitoring data of drinking water (systems) for human consumption/ Studies using sodium hypochlorite, calcium hypochlorite or chlorine as disinfectant

(study material well defined)/ Relevant target organisms (Legionella, bacteria) /Clear reporting of dosage levels and contamination levels for the duration of the study (incl. zero measurement).
In total **50 publications** concerning disinfection of drinking water (systems) by chlorine were found in the public literature, for the different PT5 use categories (see Annex 1 for details).
After the relevance assessment, **10 field trials** were retrieved for a full assessment.
Sources include local drinking water suppliers, wells, natural springs, water courses. The disinfectant is applied by automated dosing, both continuous and shock dosing.

From the literature search, **6 articles describing field trials of drinking water disinfection with chlorine** (sodium hypochlorite, or source not specified) in collective systems were retrieved. The field trials span different geographical locations (Italy, United Kingdom and USA) and time periods (monitoring between 1980 and 2011). Field trials were initiated in hospitals or care facilities, after contamination with Legionella or an outbreak of Legionnaires' disease.
In 4 out of the 6 studies, initially shock dosing was performed with high chlorine levels (free chlorine 0.0015 – 0.0050%; 15 – 50 mg/L), followed by continuous chlorination with lower levels (free chlorine 0.00005 – 0.0008%; 0,5 – 8 mg/L). In all studies contamination by Legionella decreased significantly or disappeared after chlorine treatment.

⇨ **CONCLUSION** / **SHOCK DOSING :**

Considering the comments received during the peer-review, it's not possible to validate the use because efficacy against "vegetative" bacteria at 50 ppm since not supported by this literature study.

As the consequence, shock treatment should not be granted for this use #6

⇨ **CONCLUSION** / **CONTINUOUS DOSING** :

1) Field trials covering a wide range of locations (6 studies, 3 countries) demonstrate that chlorine is an effective disinfectant for collective drinking water systems contaminated with Legionella. For shock treatment, a concentration of 0.002 – 0.005% free chlorine (20 – 50 mg/L) during 1 – 2 hours, allows to sufficiently reduce the contamination with Legionella. Shock dosing can only take place when the system is not in use (temporarily). A rinsing step, to flush the system after shock dosing is performed. In order to avoid recurrence after shock treatment, a continuous chlorination of the drinking water is required.

2) For continuous dosing alone, in the literature review six field trials of drinking water disinfection with chlorine in Legionella infected collective systems are described. In these studies a rinsing step is performed after shock dosing to flush the system before continuous chlorination. In two out of the six studies, continuous dosing was performed with low levels of free chlorine (1-2 mg/L).

Making a read-across from P2S1 tests to set up an AR for Legionella pneumophila since mandatory target organism for "Disinfection of water in collective systems" as follows : the P2S1 tests performed against bacteria (EN 1276 – Study N°4 => 71 mg/L AC), Legionella (EN 13624 – Study N°6 => 28 mg/L AC), and viruses (EN 14476 – Study N°10 => 476 mg/L AC) all performed under the same test conditions (i.e. in 25 min at +15°C in presence of 2 mg DOC/L (clean) are validated and allow to conclude that Legionella seems to be more susceptible to chlorine that bacteria and viruses. Taking into account the UBA ring tests, efficacy against bacteria & viruses is proven in same "proportions" : 71 => 0.0061 for bacteria & 476 => 0.0385 for viruses) and indicate that chlorine is effective against Legionella at the AR validated for bacteria and viruses, the efficacy of such a continious dosing for Legionella is relevant to prove the efficacy.

The information mentioned above are tangible evidence that efficacy against bacteria (including Legionella) and viruses via continuous dosing is proven at 1 mg/L and the use #6 via continuous dosing should be accepted.

Conclusion about Efficacy confirmed by adapted for clarity based on the cMS comments :

⇨ **CONTINUOUS DOSING :** against bacteria (including *Legionella pneumophila*) + viruses : **1 mg/L AC** (as residual concentration in the system) at +12-15°C at pH 7.4.

Conclusion on the efficacy of the product & validated claims

The BE eCA have performed the EFF assessment according to the efficacy data and arguments provided by the Applicant.

The following claimed uses could be granted :

Use #2 : **Disinfection of waste water (post-STP)**
SHOCK DOSING = In case of contamination (effective against bacteria and viruses) – in 30 min contact time, with 477 mg/L AC (at +12-15°C at pH 7.4.)

Use #4 : **Disinfection of drinking water suppliers**
Residual concentration in the system / primary disinfection (effective against bacteria and viruses): 0.5 mg/L AC (continuous application - at +12-15°C at pH 7.4.)

Use #5 : **Disinfection of water (coming from tap water network) in reservoirs/tanks**
Addition of the disinfectant product in the inlet of the reservoir, in order to assure its proper distribution in the water :
Residual concentration in the system / primary disinfection (effective against bacteria and viruses): 0.5 mg/L AC (continuous application - at +12-15°C at pH 7.4.)

Use #6 **: Disinfection in collective drinking water systems**
CONTINUOUS DOSING : against bacteria (including *Legionella pneumophila*) + viruses : 1 mg/L AC (as residual concentration in the system)

Use #7 : **Disinfection of drinking water (coming from tap water network) for animals**
Residual concentration in the system / primary disinfection (effective against bacteria and viruses): 0.5 mg/L AC (continuous application - at +12-15°C at pH 7.4.)

2.2.5.4 Occurrence of resistance and resistance management

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.

2.2.5.5 Known limitations

The activity of hypochlorite ion can be reduced by the presence of organic load and in general by the presence of particles.

2.2.5.6 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

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

2.2.6 Risk assessment for human health

The product in this dossier is pure chlorine gas, without the addition of co-formulants. The effects on human health are derived from the AR of Chlorine (2017, Italy).

According to the AR, the adverse effects of the active substance active chlorine in humans are limited to local effects at the site of first contact. In the absence of clear systemic adverse effects, the risk characterization will mainly focus on local effects.

Please keep in mind that according to the APCP conclusion: the product in this dossier is liquefied chlorine under pressure (≥ 99.5 % w/w), and is identical to the reference product described in the Assessment Report (AR) of Chlorine (Italy, 2017).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product is classified for skin irritation 2.
Justification for the value/conclusion	The product consists out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is classified for skin irritation 2 (H315).

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product is classified for eye irritation 2.
Justification for the value/conclusion	The product consists out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is classified for eye irritation 2 (H319).

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The product consists out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is classified for respiratory tract irritation (STOT SE 3, H335).

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	The product is not classified for skin sensitisation.
Justification for the value/conclusion	The products consist out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is not classified for skin sensitisation.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The product is not classified for respiratory sensitisation.
Justification for the value/conclusion	The product consists out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is not classified for respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	The product is not classified for acute oral toxicity.
Justification for the selected value	The product consists out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is not classified for acute oral toxicity.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The product is classified for acute inhalation toxicity.
Justification for the selected value	The product consists out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is classified for acute inhalation toxicity (H331).

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	The product is not classified for acute dermal toxicity.
Justification for the selected value	The product consists out of pure chlorine gas. The harmonized CLP classification is followed.
Classification of the product according to CLP and DSD	The product is not classified for acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Active chlorine
Value(s)	Not applicable
Justification for the selected value(s)	The following text is included in the assessment report in the LoEP: BPC TOX-WGIII-2016 agreed that human health effects are primarily due to the local mode of action of chlorine gas (and related chlorine species) and potential systemic effects are secondary to its direct irritating reactivity. Moreover, chorine is a gas, and thus not available for dermal absorption Consequently, dermal absorption of chlorine is not relevant

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Not applicable, the product consists only out of chlorine gas.

Available toxicological data relating to a mixture

Not applicable, the product consists only out of chlorine gas.

Other

Regarding the assessment of endocrine disruptor properties, see section 2.2.9.

2.2.6.2 Exposure assessment

Only local exposure for the risk assessment is performed for all relevant routes of exposure (i.e. oral, dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

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

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

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

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	Yes	No	Yes	Yes	Yes	n.a.
Dermal	n.a.	No	No	Yes	Yes	Yes	n.a.
Oral	n.a.	No	No	n.a.	No	Yes	Yes

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	Mixing and loading	Users may be exposed by inhalation route to the gaseous product (Cl2) when connecting and disconnecting the canisters containing the product to the automatic dosing system.	Industrial Professionals
-	Application	No relevant exposure, the application takes place automatically in the water system. Therefore no contact with the concentrated and/or diluted product is expected.	Automatic process
2	Post-application - Maintenance work	When repairing the dosing system or the feed line, the repairer can be exposed by dermal and inhalation route with the product (concentrate and/or diluted).	Industrial Professionals
-	Post-application – Handling of empty containers	Empty containers are stored and restored to the distributor. Negligible risk of exposure due to the packaging.	Industrial Professionals
-	Bystanders during M&L tasks	Secondary inhalation exposure of professional bystanders during M&L tasks, risk covered by the scenario 1.	Professionals, bystanders

		Please refer to the scenario 1.	
3	Swim instructor	Secondary exposure - swim instructor A professional is exposed via inhalation to evaporating substance from the swimming pool during disinfection. Since the swim instructor only stands near the pool for giving instructions, no dermal or oral exposure is considered The risk of exposure for the professional swimmers is covered by the risk assessment performed for swim instructors (inhalation route) and general public (dermal route).	Professionals
4	SPA (adult)	Secondary exposure An adult is exposed during swimming in SPA (hot tube). Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water.	General public
5	Swimmer (adult)	Secondary exposure An adult is exposed during swimming. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water.	General public
6	Swimmer (child)	Secondary exposure A child is exposed during swimming. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water.	General public
7	Swimmer (baby)	Secondary exposure A baby is exposed during swimming. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water.	General public
8	Showering	Secondary exposure A person takes a shower with chlorinated water.	General public
9	Drinking water	Secondary exposure Exposure to the drinking chlorinated water.	General public

Industrial exposure

The product is intended for the following industrial sectors:

- "*Disinfection of raw water from rivers or wells for the production of industrial water (not to be used in food production or processing).*"
- *"Disinfection of waste water after the waste-water plant"*

The mixing and loading, maintenance process are performed by industrial/professional (see above. Scenario 1 and 3).

The application rate of 475 mg/L (use #3) of AC has not been validate by the efficacy expert (use #3 not granted by the efficacy expert).

Professional exposure

Scenario 1: Mixing and loading – Connecting chlorine gas cylinders to the automated dosing system

According to the CAR of active substance, for which a human health risk assessment has been conducted on a representative product identical to the product in application "Arche Chlorine".

The exposure to chlorine gas can occur only during mixing and loading, i.e. during connecting/disconnecting chlorine containing vessels to a dosing system. During exchange of chlorine containers, empty containers are closed, and the pressure of connecting circuit is lowered until a low-pressure or vacuum is achieved. It is only allowed to change the cylinder/drum when the system is under low-pressure in order to avoid any chlorine emission. The new cylinder/drum is connected to the system with a flexible, stainless steel pipe. The new cylinder/drum is checked for possible leaks with an ammonia "detector".
During these tasks, PPE is at hand and alarm systems are placed in the area where the vessels are connected to the system. In case of a leak, the presence of chlorine in the atmosphere is detected, turning red light and buzzer are switched on and operators shall wear the appropriate PPE.
Regarding the exposure assessment, no models are available to estimate the exposure during mixing and loading of a gaseous substance. However, measured exposure data of chlorine concentrations in different workplaces of chlor-alkali plants are available as detailed in Doc. IIIA, Section A2.
Workers exposure to chlorine in the atmosphere during chlorine production as measured by Euro Chlor, 2001 is given in table A.2.10-4 of Doc. IIIA, Section A2.
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 was 0.166 ppm (0.498 mg/m³ this value is lower than the AEC present in the CAR of active substance AEC= 0.5 mg/m³).
The bottles are connected in parallel to the piping system that leads to the dosing (injection) unit. This piping system is at low pressure (< 1 bar), which has the effect that in case of a leak in the piping system the pressure there will rise to atmospheric pressure and the connection valves to the bottles will close.

Taking into account that :

- an alarm system is in place which initiates safety procedures and RPE (EN141B),
- application of LEV (according to the national regulation)and low-pressure/vacuum are in place to avoid chlorine emission,
- the electrochemical sensors used for measurements detect various chlorinated species additional to chlorine itself,
- sensors are measuring exposure also when the operators are using RPE (EN141B), these values can be seen as conservative estimates of exposure towards chlorine gas during connection/disconnection of chlorine vessels.

Calculations for Scenario [1]

Summary table: estimated of local exposure from professional uses				
Scenario	**Tier/PPE**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Scenario [1]	1/no PPE	0.498	n.r.	n.r.

Further information and considerations on scenario [1]

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Scenario 2: Post-application – Maintenance

During maintenance/repair process of the dosing system the worker may come into contact with the concentrated product (in gaseous form) and the diluted product (in liquid form).

Gas exposure:

Regarding the worker exposure to the concentrated product (in gaseous form), the only relevant exposure route is the inhalation. Regarding the exposure assessment, no models are available to estimate the exposure during maintenance procedure of a gaseous substance. However, measured exposure data of chlorine concentrations in different workplaces of chlor-alkali plants are available as detailed in Doc. IIIA, Section A2 (CAR of active substance PT2).
Workers exposure to chlorine in the atmosphere during chlorine production as measured by Euro Chlor, 2001 is given in table A.2.10-4 of Doc. IIIA, Section A2. 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, this value is lower than the AEC present in the CAR of active substance AEC= 0.5 mg/m³).

Exposure to in use solution:
The contact with water just after chlorination is not likely as the dosing system is usually shut down during the work. During replacement of chlorine bottles and maintenance process no exposure to water is possible as the chlorine unit is in a separate room, so that the formation of chlorine in the form of an aerosol is not possible during normal use.

This justification is also valid for exposure of professional user by dermal route.

Calculations for Scenario [2]

Summary table: estimated of local exposure from professional uses				
Scenario	**Tier/PPE**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]

Scenario 2 (exposure to gas)	1/no PPE	0.480	n.r.	n.r.

Further information and considerations on scenario [2]

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Scenario 3: Swim instructor

Description of Scenario 3		
Secondary exposure - swim instructor A professional swim instructor is exposed via inhalation to evaporating substances from the swimming pool during disinfection. Since the swim instructor only stands near the pool for giving instructions, no dermal or oral 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 the swimming pool water will be mainly available as hypochlorous acid (HClO). This chlorine species evaporates easily, and therefore, 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 the inhalation exposure of the swim instructor will be similar or less than adult competitive swimmer. Therefore, the same parameters are used in the ConsExpo estimation. The exposure estimations are based on a use concentration of 5 mg avCl/L (continuous dosing). This is the maximal concentration of free chlorine (in hot tubs) allowed according to WHO recommendations[4] and is above the norms set by national authorities for the concentrations of free chlorine in swimming pool water[5], and can therefore be considered as worst case (knowing that free chlorine levels of less than 1 mg/l are considered acceptable in some countries, while in other countries allowable levels may be considerably higher).		
	Parameters	Value
Tier 1	Weight fraction compounds-avCl	0.0005% (or 5 mg/L)
	Molecular weight HClO	52.5 g/mol CAR active substance DocIIB
	Vapour pressure HClO	337 Pascal CAR active substance DocIIB, at 28°C (table 1., p.75)

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

[5] Evaluation des risques sanitaires liés aux piscines. Parti I: piscines réglementées. ANSES, 2012.

	Exposure duration	480 min
	Product amount	5.6 E8 gram
	Room volume	188 m^3
	Ventilation rate	2/hr
	Release area	375 m^2 (surface swimming pool with 25 m (length) x 15 m (width))
	Application duration	480 min
	Temperature	28 °C
	Mass transfer rate	Langmuir's method[6]
	Molecular weight matrix	18 g/mol

Calculations for Scenario [3]

Summary table: estimated of local exposure from Swim instructor				
Scenario	**Tier/PPE**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Scenario [3]	1/no PPE	0.012	n.r.	n.r.

Further information and considerations on scenario [3]
/

Combined scenarios

Not relevant

Non-professional exposure

Non-professional use is not foreseen for the product.

Exposure of the general public

Scenario 4: Adult swimmer in SPA

6 RIVM report 320005003/2006 Disinfectant Products Fact Sheet To assess the risks for the consumer (p.91)

Description of Scenario 4

Secondary exposure
An adult is exposed to the chlorine species in the swimming pool water during swimming. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water.

pH of swimming pool water is around 7.2-7.4 according to applicant company information. 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 (adult) competitive swimmer swims 2 hours in a pool 5 times a week. The temperature of the spa water is 40°C.

Aerosol exposure is also possible (whirlpool bath or hot tub), the risk 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. Annex 3.2.

The exposure estimations are based on a use concentration of 5 mg avCl/L (continuous dosing).This is the maximal concentration of free chlorine (in hot tubs) allowed according to WHO recommendations[7] and is above the norms set by national[8] authorities for the concentrations of free chlorine in swimming pool water[9], and can therefore be considered as worst case (knowing that free chlorine levels ≤ 1 mg/l are considered acceptable in some countries, while in other countries allowable levels may be considerably higher).

	Parameters	Value
Tier 1	Molecular weight HClO	52.5 g/mol CAR active substance DocIIB
	Vapour pressure HClO	725 Pascal CAR active substance DocIIB at 40°C (table 1., p.75)
	Exposure/application duration	120 min
	Product amount	5.6 E8 gram (with swimming pool water volume of 562 m^3)
	Weight fraction compound	0.0005%

7 Guidelines for safe recreational water environments. Volume 2: swimming pools and similar environments. WHO, 2006.
8 Please refer to appendix 3.7.1.1 for an overview of national/regional norms in several member states.
9 Evaluation des risques sanitaires liés aux piscines. Parti I: piscines réglementées. ANSES, 2012.

Room volume	188 m^3
Ventilation rate	2/hr
Release area	375 m^2 (surface swimming pool with 25 m (length) x 15 m (width))
Temperature	40 °C
Mass transfer rate	Langmuir's method[10]
Molecular weight matrix	18 g/mol

Calculations for Scenario [4]

Summary table: estimated of local exposure from adult swimmer 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	0.057	0.00005	0.0005	0.0005

Further information and considerations on scenario [4]
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Scenario 5: Adult swimmer

Description of Scenario 5
Secondary exposure An adult is exposed to the chlorine species in the swimming pool water during swimming. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water. pH of swimming pool water is around 7.2-7.4 according to applicant company information. 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 (adult) competitive swimmer swims 2 hours in a pool 5 times a week. The temperature of the swimming pool water is 28°C.

10 RIVM report 320005003/2006 Disinfectant Products Fact Sheet To assess the risks for the consumer (p.91)

The exposure estimations are based on a use concentration of 5 mg avCl/L (continuous dosing).This is the maximal concentration of free chlorine (in hot tubs) allowed according to WHO recommendations[11] and is above the norms set by national[12] authorities for the concentrations of free chlorine in swimming pool water[13], and can therefore be considered as worst case (knowing that free chlorine levels ≤ 1 mg/l are considered acceptable in some countries, while in other countries allowable levels may be considerably higher).

	Parameters	Value
Tier 1	Molecular weight HClO	52.5 g/mol CAR active substance DocIIB
	Vapour pressure HClO	337 Pascal CAR active substance Doc IIB at 28°C, (table 1., p.75)
	Exposure/application duration	120 min
	Product amount	5.6 E8 gram (with swimming pool water volume of 562 m^3)
	Weight fraction compound	0.0005%
	Room volume	188 m^3
	Ventilation rate	2/hr
	Release area	375 m^2 (surface swimming pool with 25 m (length) x 15 m (width))
	Temperature	28 °C
	Mass transfer rate	Langmuir's method[14]
	Molecular weight matrix	18 g/mol

Calculations for Scenario [5]

Summary table: estimated of local exposure from adult swimmer				
Scenario	**Tier**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]

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

12 Please refer to appendix 3.7.1.1 for an overview of national/regional norms in several member states.

13 Evaluation des risques sanitaires liés aux piscines. Parti I: piscines réglementées. ANSES, 2012.

14 RIVM report 320005003/2006 Disinfectant Products Fact Sheet To assess the risks for the consumer (p.91)

Scenario [5]	1	0.012	0.0005	0.0005

Further information and considerations on scenario [5]
/

Scenario 6: Child swimmer

Description of Scenario 6		
Secondary exposure A child is exposed to the chlorine species in the swimming pool water during swimming. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water. pH of swimming pool water is around 7.2-7.4 according to applicant company information. 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 child swims 2 times a week for 60 minutes. The temperature of the swimming pool water is 28°C. The exposure estimations are based on a use concentration of 5 mg avCl/L (continuous dosing). This is the maximal concentration of free chlorine (in hot tubs) allowed according to WHO recommendations[15] and is above the norms set by national authorities for the concentrations of free chlorine in swimming pool water[16], and can therefore be considered as worst case (knowing that free chlorine levels ≤ 1 mg/l are considered acceptable in some countries, while in other countries allowable levels may be considerably higher).		
	Parameters	Value
Tier 1	Molecular weight HClO	52.5 g/mol CAR active substance DocII B
	Vapour pressure HClO	337 Pascal CAR active substance DocII B at 28°C, (table 1., p.75)
	Exposure/application duration	60 min
	Product amount	5.6 E8 gram (with

15 Guidelines for safe recreational water environments. Volume 2: swimming pools and similar environments. WHO, 2006.
16 Evaluation des risques sanitaires liés aux piscines. Parti I: piscines réglementées. ANSES, 2012.

	swimming pool water volume of 562 m^3)
Weight fraction compound	0.0005%
Room volume	188 m^3
Ventilation rate	2/hr
Release area	375 m^2 (surface swimming pool with 25 m (length) x 15 m (width))
Temperature	28 °C
Mass transfer rate	Langmuir's method
Molecular weight matrix	18 g/mol

Calculations for Scenario [6]

Summary table: estimated of local exposure from child swimmer				
Scenario	**Tier**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Scenario [6]	1	0.012	0.0005	0.0005

Further information and considerations on scenario [6]

/

Scenario 7: - Baby swimmer

Description of Scenario 7
Secondary exposure A baby is exposed to the chlorine species in the swimming pool water during swimming. Exposure can occur via dermal and inhalation route as well as by accidental swallowing of the swimming pool water. pH of swimming pool water is around 7.2-7.4 according to applicant company information. 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 baby 'swims' 30 minutes in a pool 1 time a week for a period of 3 months (= 13 times/year). The temperature of the swimming pool water is 32°C.

The exposure estimations are based on a use concentration of 5 mg avCl/L (continuous dosing) This is the maximal concentration of free chlorine (in hot tubs) allowed according to WHO recommendations[17] and is above the norms set by national authorities for the concentrations of free chlorine in swimming pool water[18], and can therefore be considered as worst case (knowing that free chlorine levels ≤1 mg/l are considered acceptable in some countries, while in other countries allowable levels may be considerably higher).

	Parameters	Value
Tier 1	Molecular weight HClO	52.5 g/mol CAR active substance DocII B
	Vapour pressure HClO	438 Pascal CAR active substance DoII B at 32°C, (table 1., p.75)
	Exposure/application duration	30 min
	Product amount	10E8 gram
	Weight fraction compound	0.0005%
	Room volume	50 m^3
	Ventilation rate	2/hr
	Release area	100 m^2 (surface swimming pool with 10 m (length) x 10 m (width))
	Temperature	32 °C
	Mass transfer rate	Langmuir's method
	Molecular weight matrix	18 g/mol

Calculations for Scenario [7]

Summary table: estimated of local exposure from baby swimmer				
Scenario	**Tier**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Scenario [7]	1	0.015	0.0005	0.0005

Further information and considerations on scenario [7]

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

18 Evaluation des risques sanitaires liés aux piscines. Parti I: piscines réglementées. ANSES, 2012.

/

Scenario 8: Showering

Description of Scenario 8		
Secondary exposure: A person takes a shower with chlorinated water. In analogy to the method used in the AR of the active substance, the following models will be used to estimate the exposure during showering with chlorinated drinking water: Aerosol exposure: Consumer product spraying and dusting model 2 – Handheld trigger spray (Biocides Human Health Exposure Methodology, vers. 1, 2015, p. 220) Vapour exposure: ConsExpo 4.1 evaporation from constant surface model (in analogy to ConsExpo Disinfectant Products FactSheet, 2006, p. 87f, Appendix "Exposure in public swimming pools") Pre-chlorination is a shock dose (50 mg/L) which takes place on site (station, industry, etc.) and whose aim is to eliminate the microorganisms present in the water in order to make it drinkable. Continuous treatment (1 mg/L) aims to maintain the quality of drinking water. Monitoring is carried out in order to measure the levels of active chlorine present in the water. The WHO sets the use of chlorine to disinfect drinking water at 5 mg/L (max), the admissible quantities of free available chlorine in drinking water for different European countries generally vary between 0.1 and 0.5 mg/l. Therefore, it is unlikely that consumers will be exposed to a shock dose of active chlorine. Exposure estimations are based on a use concentration of 1 mg avCl/L, which corresponds to the highest in-use concentration for drinking water applications (continuous dosing, use #6).		
	Parameters	Value
Tier 1	Molecular weight HClO	52.5 g/mol CAR active substance DocIIB
	Vapour pressure HClO	725 Pascal CAR active substance DocIIB, at 40°C, (table 1., p.75)
	Exposure/application duration	15 min AR active substance
	Product amount	50 kg AR active substance
	Weight fraction compound	0.0001%
	Room volume	2.5 m^3
	Ventilation rate	2/hr

Release area	1 m^2
Temperature	40 °C
Mass transfer rate	Langmuir's method
Molecular weight matrix	18 g/mol
Indicative exposure value (aerosol exposure)	10.5 mg/m^3

Calculations for Scenario [8]

Summary table: estimated of local exposure from showering (adult, child, baby)					
Scenario	**Tier**	**Local inhalation exposure** [mg avCl/m^3]		**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
		Vapor	**Aerosol**		
Secnario [8]	1	0.005	0.00001	0.0001	0.0001

Further information and considerations on scenario [7]
/

Scenario 8: Drinking water

"Arche Chlorine" is a product intended to be used to disinfect drinking water therefore secondary oral exposure is considered relevant.

Calculations for Scenario [8]

Summary table: estimated of local exposure from showering (adult, child, baby)				
Scenario	**Tier**	**Local inhalation exposure** [mg avCl/m3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Scenario [8]	1	-	-	0.0001

Further information and considerations on scenario [8]
/

Combined scenarios
Not relevant for local exposure.

Monitoring data

No monitoring data available

Dietary exposure

The following is included in the AR of the active substance, no systemic assessment is required for substances such as chlorine which act by a local mode of action only.

The chlorate could be formed upon decomposition of chlorine in aqueous solution when using biocidal product.

Please keep in mind that during the product assessment, there was no available analytical method to measure the levels of chlorates in water (an analytical method has been recently approved, CAR December 2020), so we did not have any measurements on the "Arche Chlorine" product.

There is no chlorate formation during storage of chlorine gas but the chlorate formation occurs during application, mainly from disproportioning of free HOCl. But as the HOCl concentration is low, typically 1 mg/l for drinking water (continuous dosing, use#6), the chlorate concentration is much smaller as the formation rate is slow compared to the fast disinfection action of HOCl on target organisms and oxidation of organic matter. Gaseous chlorine is applied at the point of application, at the required concentration. Build-up of chlorate levels due to disproportionation occurs essentially in concentrated active chlorine solutions. The rate of HOCl/OCl- disproportionation in aqueous solution is highly dependent on pH and concentration and can be estimated based on the model of Adam et al 1992[19]. The highest rate of disproportionation occurs at pH ~ 7.2.

Based on the reaction rate constant reported in Adam et al (1992), the DBP Consortium has created an Excel tool (see. Confidential annex "DBP risk assessment (bibliographic data)") to estimate the amount of chlorate formed per day in function of the applied concentration active chlorine, pH and temperature.

Pre-chlorination is a shock dose (50 mg/L) which takes place on site (station, industry, etc.) and whose aim is to eliminate the microorganisms present in the water in order to make it drinkable. Continuous treatment (1 mg/L) aims to maintain the quality of drinking water. Monitoring is carried out in order to measure the levels of active chlorine present in the water.

The WHO sets the use of chlorine to disinfect drinking water at 5 mg/L (max), the admissible quantities of free available chlorine in drinking water for different European countries generally vary between 0.1 and 0.5 mg/l.

Therefore, it is unlikely that consumers will be exposed to a shock dose of active chlorine.

The highest in-use concentration active chlorine for drinking water is 1 mg/L active chlorine (continuous dosing, use#6). The rate of disproportionation is very low for at this concentration: 1.33×10^{-7} mg/L chlorate per day at a temperature of 40°C (spa) and pH of 7.25 as worst case.

19 Adam, L. C., Suzuki, K., Gordon, G., & Fábián, I. (1992). Hypochlorous Acid Decomposition in the pH 5-8 Region. Inorganic Chemistry, 31(17), 3534–3541.

In order to gather information on other factors contributing to the formation of chlorate following application of hypochlorite-based products, the DBP Consortium has undertaken studies at the University of Nottingham, measuring chlorate formation upon contact with food material (UoN 2019, see IUCLID section 13). Levels of chlorate, free chlorine and pH were measured in samples of sodium hypochlorite solutions (2,000 and 30,000 ppm active chlorine/L) exposed to different foodstuffs. After contact at ambient temperature for 5 or 30 minutes, the chlorate concentration in the recovered solution was measured and compared to the chlorate concentration measured in the original product. The results suggest that there was no significant formation of chlorate due to contact with foodstuffs (organic material).
Reaction of active chlorine with foodstuffs or most other organic materials does not generate chlorate, which is a more oxidized form than hypochlorous acid (HOCl). Instead, active chlorine is normally reduced to chloride ion by reaction with most organic materials. Thus, organic materials cannot oxidize HOCl (where the Cl atom has an oxidation state of +1) to chlorate ion (where the Cl atom has an oxidation state of +5).

At the moment these information or data provided by the DBP Consortium are still being evaluated by the RefMS (NL), so we can't take into account in the dietary risk assessment.

Occurrence data for chlorate residues in food have been summarized in an EFSA CONTAM Panel Scientific Opinion[20] (EFSA, 2015). In "drinking water (453 samples, essentially in germany) chlorate concentrations ranged from 0.028 mg/l (lower bound) and 0.039 mg/l (upper bound), the 99th percentile UB concentration was 0.196 mg/l.

Recent studies on data on municipal potable water taken at 39 sampling points across Europe showed chlorate to range from < 0.003 to 0.803 mg/l with a mean of 0.145 mg/l (Beate Kettlitz et al 2016[21]). In Belgium this rate is one of the highest in Europe mean = 0.378 ± 0.216 mg/l) followed by France (mean = 0.184 ± 0.276 mg/l), Spain (mean = 0.148 ± 0.22 mg/l), and the UK (mean = 0.07 ± 0.009 mg/l).

Available parametric values:

There is a provisional guideline provided by WHO for drinking water for chlorate is 0.7 mg/L., but this value is questioned by EU experts, as it is considered insufficient, especially for the most vulnerable population groups, i.e. infants and young children.

That's why EU commission[22] proposed to refine this limit value taking into account of a toxicological reference value of 0.01 mg/ kg bw /d (0.01 mg/ kg bw /d * 60 kg bw/2.5 l = 0.24 mg/l ≈ 0.25 mg/l).

The EU commission has recently published document[23] setting temporary the parametric value for chlorate present in the drinking water at 0.25 mg/l.

20 SCIENTIFIC OPINION; Risks for public health related to the presence of chlorate in food; EFSA Panel on Contaminants in the Food Chain (CONTAM); EFSA Journal 2015;13(6):4135

21 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

22 Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the quality of water intended for human consumption (recast), 1 February 2018

23 DIRECTIVE (EU) 2020/2184 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2020

The directive also mentions that the parametric value of 0.70 mg/l is applied when a disinfection method that generates chlorates, in particular chlorine dioxide, is used for the disinfection of water intended for human consumption. Where possible, without compromising disinfection, Member States shall endeavour to achieve a lower value. This parameter shall be measured only in cases where such disinfection methods are used.

In February 2020, the Standing Committee on Pesticide Residues (SCoPAFF) discussed about the EU draft regulation setting specific maximum residue levels (MRLs) for chlorate by qualified majority. This provides binding MRL for chlorate in various products and product groups in accordance with Regulation (EC) No. 396/2005.

The EU commission has recently published document[24] setting temporary MRLs (4 June 2020) for food until June 2025.

Estimating Livestock Exposure to Active Substances used in Biocidal Products:

During product assessment no analytical method to measure chlorate levels in water was available (an analytical method has been recently approved, CAR December 2020) and the WG-I-2021 agreed that no dietary risk assessment should be conducted in the absence of product-specific measurement data. In order to reduce the consumer risk of exposure to chlorate residues in food commodities of animal origin the following RMM is to be added to the SPC: "For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Regulation 2020/749".

To conclude:

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

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

• "Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Regulation 2020/2184."

• "For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Regulation 2020/749."

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant, the product is intended to be use by the professional/industrial.

24 COMMISSION REGULATION (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products

Exposure associated with production, formulation and disposal of the biocidal product

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Calculations for Scenario [n]/

Further information and considerations on scenario [n]

/

Combined scenarios

/

Aggregated exposure

Not relevant

Summary of exposure assessment

Scenario number	**Exposed group** (e.g. professionals, general publics, bystanders)	**Local oral exposure** [concentration, % avCl]	**Local dermal exposure** [concentration, % avCl]	**Local inhalation exposure** [mg avCl/m^3]		
				Aerosol (NaOCl as avCl)	**Vapour** (HClO as avCl)	**Total** (avCl)
1.	professionals	n.r.	n.r.	0.498 (tier1/no RPE)	negligible	0.498 (no RPE)
2.	professionals	n.r.	n.r.	0.480 (tier1/no RPE)	negligible	0.480 (no RPE)
3.	professionals (swim instructor)	n.r.	0.0476 (tier1)	negligible	0.012 (tier1)	0.012
4.	general public	0.0005 (tier1)	0.0005 (tier1)	0.00005 (tier1)	0.057 (tier1)	0.057
5.	general public	0.0005 (tier1)	0.0005 (tier1)	negligible	0.012 (tier1)	0.012
6.	general public	0.0005 (tier1)	0.0005 (tier1)	negligible	0.012 (tier1/no RPE)	0.012

7.	general public	0.0005 (tier1)	0.0005 (tier1)	negligible	0.015 (tier1)	0.012
8.	general public	0.0001 (tier1)	0.0001 (tier1)	0.0001 (tier1)	0.005 (tier1)	0.005
9.	general public	0.0001 (tier1)	n.r.	n.r.	n.r.	n.r.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
NOAECoral	rat 90-d subchronic repeated dose oral (drinking water) study rat 104-wks chronic repeated dose oral (drinking water) study	0.1%	1	-	0.1% avCl
NOAECdermal	human (dermatitis patients) 48 h-patch test study	1%	1	-	1% avCl
AECinhalation (chlorine)	monkey 52-wks subchronic repeated dose inhalation study human volunteer single dose inhalation study (4-8 h) human volunteer repeated dose inhalation study (3 d, 6 h/d)	NOAEC 1.5 mg/m3	3.2 (intra-species toxicodynamic factor)	-	0.5 mg avCl/m³
AEC inhalation (HClO)	No repeated dose inhalation toxicity study on HClO is available since HClO does not exist as such but is only formed in aqueous solutions of chlorine. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an AECinhalation based on chlorine data (please see above)				0.5 mg avCl/m³
ADI	A tolerable daily intake (TDI) of 3 µg chlorate/kg body weight (b.w.) was set by read-across from a TDI of 0.3 µg/kg b.w. derived	-	-		3 µg/kg bw/d

	for this effect for perchlorate, multiplied by a factor of 10 to account for the lower potency of chlorate.				
ArfD	An acute reference dose (ARfD) of 36 µg chlorate/kg b.w. was derived from a no-observed-effect-level for chlorate in a controlled clinical study.	-	-	-	36 µg/kg bw/d

Maximum residue limits or equivalent

Residue definitions

MRLs or other relevant reference values	Reference	Relevant commodities	Value
Chlorate	WHO	Drinking water	0.7 mg/L (provisional)
Chlorate	EU commission	Drinking water	0.25 mg/L (lower bound) and 0.7 mg/L (upper bound)
Chlorate	EU commission	Food	0.05 mg/kg (lowest value)

Specific reference value for groundwater

No data

Risk for industrial users

Systemic effects
Not relevant only local effect has been considered.

Local effects

See "Risk for professional users" section.

Risk for professional users

Systemic effects

Not relevant only local effect has been considered
Local effects

Only local exposure for the risk assessment is performed for all relevant routes of exposure (i.e. oral, dermal, inhalation).

Inhalation:

Scenario	Tier/PPE	AEC (mg/m³)	Estimated exposure concentration (mg/m³)	Ratio (%)	Acceptable (yes/no)
1	1/No RPE	0.5	0.498	99.6	Yes
2	1/No RPE	0.5	0.480	96	Yes
3	1/No RPE	0.5	0.012	2.4	Yes

Qualitative risk assessment:

Exposure during handling and maintenance process:

Hazard			Exposure						
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**
Low	STOT SE 3	Although the product is also classified as skin/eye irritant, this routes of exposure are considered negligible due to the form in which the product is presented	2 and 5	Professional users	M&L: Connecting containers containing the biocidal product to automated dosing system Maintenance of dosing system	Inhalation	M&L: few minutes per day Maintenance: More than few minutes but equal to or less than few hours per day	Accidental exposure > 0.5 ppm	**Organisation** • Training for staff on good practice • Procedures and training for emergency decontamination and disposal • Good standard of personal hygiene **RMM** Labelling: • Labelling according to CLP regulation Formulation: • Packaging reduce the risk of exposure Monitoring tool:

									• <u>Local exhaust ventilation (according to the national legislation)</u> • Presence of Chlorine detectors can detect 0.1 ppm (0.3 mg/m³) as a theoretical minimum. In case of a leak, the presence of chlorine in the atmosphere is detected, turning red light and buzzer are switched on and operators shall wear the appropriate RPE • Measuring device used for chlorine monitoring is an electrochemical sensor, which is sensible not

									only to chlorine, but also to other chlorinated substances present in the air. It could be assumed that the chlorine concentration measured in the atmosphere of a chlor-alkali plant is a worst case for inhalation exposure, because The measured value takes into account the exposure coming from several production plants (chlorine and other chlorinated chemicals). The measured level is the sum of chlorine and

									other chlorinated substances. The sensors are also measuring exposure when the operators are using RPE (they are indeed wearing a mask if the alarm threshold of 0.5 ppm (1.5 mg/m3) is exceeded). **RPE** EN141B

Conclusion

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

- an alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m³) is in place with initiates safety procedures like wearing RPE (EN141B),
- application of LEV (according to the national regulation) and low-pressure/vacuum are in place to avoid chlorine emission,
- the electrochemical sensors used for measurements detect various chlorinated species additional to chlorine itself,
- sensors are measuring exposure also when the operators are using RPE (EN141B)

The product use according to the use instructions will not lead to adverse effects for human health.

Risk for non-professional users

Not relevant

Risk for the general public

Systemic effects

Not relevant only local effect has been considered

Local effects

Inhalation:

Scenario	Tier	AEC (mg/m³)	Estimated exposure concentration (mg/m³)		Ratio (%)	Acceptable (yes/no)
4	1	0.5	Vapor	0.057	1.14	Yes
			Aerosol	0.00005		
5	1	0.5	0.012		2.4	Yes
6	1	0.5	0.012		2.4	Yes
7	1	0.5	0.015		3	Yes
8	1	0.5	Vapor	0.005	1	Yes
			Aerosol	0.0001		

Dermal:

Scenario	Tier	NOAEC (%)	Estimated exposure concentration (%)	Ratio (%)	Acceptable (yes/no)
4	1	1	0.0005	0.05	Yes
5	1	1	0.0005	0.05	Yes
6	1	1	0.0005	0.05	Yes
7	1	1	0.0005	0.05	Yes
8	1	1	0.0001	0.01	Yes

Oral:

Scenario	Tier	NOAEC (%)	Estimated exposure concentration	Ratio (%)	Acceptable (yes/no)
4	1	0.1	0.0005	0.5	Yes
5	1	0.1	0.0005	0.5	Yes
6	1	0.1	0.0005	0.5	Yes
7	1	0.1	0.0005	0.5	Yes
8	1	0.1	0.0001	0.1	Yes
9	1	0.1	0.0001	0.1	Yes

Qualitative risk assessment:

Regarding exposure to the concentrate product (gas form), the biocidal product is only intended to be use 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 we cannot exclude that systems with chlorine are also used for instance in larger houses with many tenants, which have a common swimming pool, spa's or hot tubs, that's why eCA considers relevant the following RMM:

- "Apply only in areas inaccessible to the general public."
- "Keep out of reach of children."

Regarding exposure during 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.

For secondary exposure via drinking water disinfection no unacceptable risk was identified.

Conclusion

The product use did not lead to an unacceptable exposure. The product use according to the use instructions will not lead to adverse effects for human health.

However eCA cannot exclude that systems with chlorine are also used for instance in larger houses with many tenants, which have a common swimming pool, spa's or hot tubs, that's why eCA considers relevant the following RMM for the use #1:

- "Apply only in areas inaccessible to the general public."
- "Keep out of reach of children."

Furthermore in order to inform the users the BE CA suggest to add the following RMMs:

For use #1: "After a shock dosing, swimmers can only enter the water once the concentration of chlorine is decreased to the national chlorine limit ."

For uses #4, #5, #6: Ensure that the concentration of chlorine in the drinking water does not exceed national chlorine limits before consumption.

Risk for consumers via residues in food

During disinfection, chlorate can be formed. This substance is relevant for dietary exposure. But at this stage the eCA does not have the necessary information about chlorate measurements generated from the use of the product in demand in order to carry out the dietary risk assessment following the disinfection of drinking water.

In order to ensure consumers safety, BE CA suggests adding the following RMM :

- "Ensure that the concentration of chlorate present in the drinking water does not exceed the parametric values set in Directive 2020/2184."

- "For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Regulation 2020/749."

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

/

2.2.7 Risk assessment for animal health

The biocidal product is only intended to be use in the dedicate installations specifically designed for a specific site, according to local requirements and regulations so that no exposure to the pets should be expected. However we cannot exclude that systems with chlorine are also used for instance in larger houses (which have a swimming pool, spa's or hot tubs,) that can accommodate pets, that's why eCA considers relevant the following RMM:

- "Apply only in areas inaccessible to the pets."
- "Keep out of reach of pets."

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

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

Therefore, no effects of the active substance on animals are expected. Furthermore we can expect that the risk of local exposure is also covered by the risk assessment made for human.

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

However at this stage the eCA does not have the necessary information, about the chlorate measurements generated from the use of the product in demand. To carry out the animal risk assessment following the disinfection of drinking water.

DBP risk assessment for swimming pool application:

PT2-swimming pool disinfection:

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

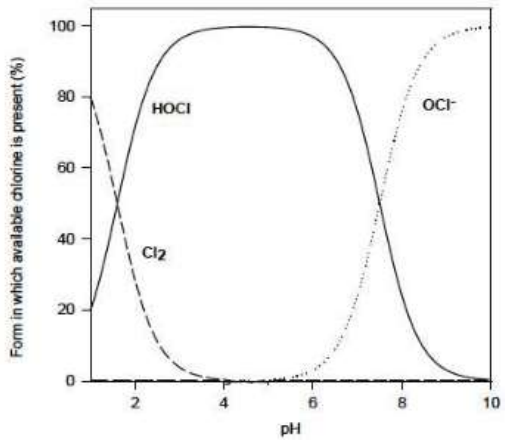
For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out.

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 confidential annex, section "DBP risk assessment".

2.2.8 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 (Cl2). 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 taken 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 use of the product Arche Chlorine, when used as described in the authorised uses section of this product assessment report, only lead to a direct release to the surface water compartment for the Use # 2 – "Disinfection of waste water after the sewage treatment plants" and potentially for the Use # 3 – "Disinfection of raw water from rivers or wells for the preparation of industrial water (direct release to surface water)". Therefore, a quantitative assessment for the active substance has only been performed for these 2 uses and a qualitative assessment has been performed for the other uses of the product.

(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 PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment."*

See section 2.2.8.3 for further details.

2.2.8.1 Effects assessment on the environment

Short and long term toxicity data from literature are available for fish, invertebrates, algae and micro-organisms, resulting from flow-through or static tests. Most tests with a static test design result in a factor of 100-500 higher end-points (NOEC, LC50) than studies performed according to a flow-through design. Due to very fast hypochlorite decay, a dynamic test system is continuously exposed to the same hypochlorite concentration. When data from literature were considered not valid or incomplete for the risk assessment, new toxicity laboratory studies were performed and included in the CAR. TRC (total residual chlorine) is a measurement of both free and combined chlorine (such as chloramines). It is difficult to separate the contribution to toxicity of the FAC (free available chlorine) such as HClO/ClO- from that of the combined chlorine species. For studies where the percentage of FAC (free available chlorine) in TRC (total residual chlorine) was measured, the toxicity endpoints were expressed as FAC/L as well.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No studies have been conducted on the product, as it is identical to the pure active substance. Effects are based on data on the active substance. The applied endpoints are taken from the assessment report and summarised below.

PNEC	Lowest endpoint	AF	PNEC	Test/species
Free available chlorine (FAC)				
STP	NOEC: 41.1 mg/L*	10	4.11 mg FAC/L	Respiration inhibition test
fresh water	NOEC: 2.1 µg/L	50	0.042 FAC µg/L	Algae
sediment	-	-	0.045 µg FAC/kg wwt	Equilibrium partioning from aquatic data using a theoretical K_{oc} of 13.22 L/kg. Calculated according to the Guidance part B, vol. IV.
soil	-	-	0.015 µg FAC/kg wwt	
groundwater	Reference value for groundwater = 0.1 µg/L			
atmosphere	At environmental pH (6.5-8.5) half of the active chlorine is available as the unvolatile hypochlorite ion; half as hypochlorous acid with a Henry's law constant as 0.11 Pa m^3/mol. Hence, the concentration in air will be very low and the air is not an environmental compartment of concern.			
birds	No data available for birds and mammals as primary and secondary poisoning is not considered relevant (see paragraph 2.2.8.2			
mammals				

FAC: Free available chorine, Wwt wet weight; bw body weight; * endpoint is converted to standard soil

According to the harmonised classification of chlorine (according to annex VI of Regulation (EC) No 1272/2008), the product in this dossier is classified as aquatic acute tox. cat. 1. (H400).

Further Ecotoxicological studies

No further ecotoxicological studies have been conducted on active chlorine or the active chlorine releasing product supported in this document.

Data waiving	
Information requirement	Not relevant
Justification	The product in this dossier is identical to the reference product described in the Assessment Report "Active chlorine released from chlorine" (Italy, 2017).

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on other target organisms is needed on the basis of intended uses, data available on the active substance or risk assessment.

Supervised trials to assess risks to non-target organisms under field conditions

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	Chlorine is not in the form of bait or granules

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	Chlorine is not in the form of bait or granules

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Foreseeable routes of entry into the environment on the basis of the use envisaged

See section "Fate and distribution in exposed environmental compartments".

Further studies on fate and behaviour in the environment (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	No additional test is needed on the basis of intended uses, data available on the active substance or risk assessment.

Leaching behaviour (ADS)

The performance of a study on leaching (e.g. from treated surfaces) is neither applicable nor relevant for the intended uses within PT1-5.

Testing for distribution and dissipation in soil (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	No additional test is needed on the basis of intended uses, data available on the active substance or risk assessment.

Testing for distribution and dissipation in water and sediment (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	No additional test is needed on the basis of intended uses, data available on the active substance or risk assessment.

Testing for distribution and dissipation in air (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	No additional test is needed on the basis of intended uses, data available on the active substance or risk assessment.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	The product is not intended to be sprayed near to surface waters.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

No new data is available for the chlorine BP in this dossier.

Data waiving	
Information requirement	Not relevant
Justification	The product is not intended to be sprayed outside.

2.2.8.2 Exposure assessment

General information

Chlorine is used as a water disinfectant for PT2 or PT5 (see section 2.2.1) in dedicated, often large-scale, installations, and only handled by (trained) professionals.

Use code	Use
Use # 1	PT2: Disinfection of swimming pool water and hot tubs
Use # 2	PT2: Disinfection of waste water after the waste-water plant
Use # 3	PT2: Disinfection of raw water from rivers or wells for the production of industrial water
Use # 4	PT5: Disinfection of drinking water at drinking water suppliers
Use # 5	PT5: Disinfection of stationary water in reservoirs
Use # 6	PT5: Disinfection of water in collective systems
Use # 7	PT5: Disinfection of drinking water for animals

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, when used as described in the authorised uses section of this product assessment report, only lead to a direct release to the surface water compartment for the Use # 2 – "Disinfection of waste water after the sewage treatment plants" and potentially for the Use # 3 – "Disinfection of raw water from rivers or wells for the preparation of industrial water" (See "Fate and distribution in exposed environmental compartments" below). Therefore, a quantitative assessment for the active substance has only been performed for these 2 uses.

A qualitative assessment has been performed for the other uses of the product.

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

Emission estimation

Qualitative assessment:

As indicated above, as the product is evaluated qualitatively for the uses #1, #3 (release via STP), #4, #5, #6 and #7, no calculation of the emission to the environment is necessary for these specific uses.

PT2:

- *For the use #1 "Disinfection of swimming pool water and hot tubs" (release via STP)*: As chlorine is always applied in specific, professional installations, it will only be used 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.
- *For the use #3 "Disinfection of raw water from rivers or wells for the production of industrial water" (release via STP)*: After disinfection, water can be used for different processes. Depending on the process and the contamination level of the water, it can be re-used as it is, disinfected again, released directly to surface water (quantitative assessment) or discharged via the municipal or an on-site STP.
  Specific conclusions of the ENV WG-I-2020 concerning this last way of discharge (on-site STP): "In case of an on-site STP, waste water from the different plant units is collected in a collecting tank and the pH is adapted before release either to the public sewer system or to an onsite STP. Therefore, degradation is also taken into account in case of an on-site STP, considering a residence time of 1 hour."

PT5:

- *For the uses #4 "Disinfection of drinking water at drinking water suppliers", #5 "Disinfection of stationary water in reservoirs", #6 "Disinfection of water in collective systems" and #7 "Disinfection of drinking water for animals":* Drinking water for use by humans and animals holding the residues is mainly discharged to the sewer system, purified in a sewage treatment plant (STP). However, the majority of farms are not connected to the sewer because of the distance to the nearest pipeline. Farms that are not connected to the sewer systems may purify their (domestic) waste water locally in an individual sewage treatment plants, but domestic waste water may be discharged to the slurry pit as well.

Quantitative assessment:

A quantitative assessment for the active substance has only been performed for the *PT2 Use # 2 – "Disinfection of waste water after the sewage treatment plants"* and for the *PT2 Use # 3 – "Disinfection of raw water from rivers or wells for the preparation of industrial water (direct release to surface water)"*.

For the intended uses, emission scenarios are based on average consumption. Therefore, all PEC values in this dossier were calculated using the consumption based approach.
The in-use concentrations for the environmental risk assessment are based on the worst-case use conditions (highest concentrations) currently used.

Representative scenario	Intended use description	Indoor/ outdoor use
PT2: Disinfection of waste water effluent	Use #2 - Disinfection of waste water after the sewage treatment plants Use #3 - Disinfection of raw water from rivers or wells for the preparation of industrial water • direct release to surface water (occasionally)	Indoor/ outdoor

Assessed PT	**PT 2**
Assessed scenario	**Scenario: Disinfection of waste water effluent**
ESD(s) used	– Scenario agreed at AHEE-4 (6 February 2020) and agreed at WG-I-2020 (ENV_7-3) – Emission Scenario Document for Biocides: Emission scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC), RIVM report 601450009, P. van der Poel and J. Bakker, 2001 – TAB (version 2.1, December 2019) – Volume IV Environment Part B and C (2017)
Approach	Consumption based
Distribution in the environment	Calculated based on BPR Guidance, Volume IV Environment – Part B
Groundwater simulation	According to the guidance based on a Koc of 13.22 L/kg. Additional PEARL simulations were not run as the model is not suitable for inorganic compounds.
Confidential Annexes	No
Life cycle steps assessed	All scenarios: Production: No Formulation : No Use: Yes Service life: No

- **Use #2: Disinfection of waste water after the waste-water plant**

Post-chlorination at the sewage treatment plant (STP) is assessed in the AR for Chlorine (PT2b- Disinfection of sewage/waste water in the effluent stream of the STP) at concentrations of 7.5 mg/L for continuous or 40 mg/L for shock dosing.
The highest in-use concentrations described in this dossier is 476.19 mg/L AC. Therefore, an assessment is made based on this concentration and with the adapted scenario.

Input parameters for calculating the local emission – Active Substance				
Input	**Value**	**Unit**	**Symbol**	**Remarks**
Use #2: *Disinfection of waste water after the waste-water plant*				
Maximum concentration of disinfectant in waste-water	476.19	[mg/L]	$C_{(0)}$	Highest in-use concentration
Reaction rate constant in sewer system	0.743	[h^{-1}]	k	AR chlorine: The DT50 used is the $DT50_{surfacewater}$=56 min
Residence time in STP (contact time)	0.5	[hr]	t	Based on efficacy tests, 30 min contact time
Dilution factor (at the point of complete mixing)	10	[-]	DIL	BPR (2017, chapter 2.3.7.3.1)

Output:		
C(t) = Concentration at the release point to surface water [mg/L] $C(t) = C(0) \cdot e^{-k \cdot t} = C(0) \cdot e^{-\frac{\ln 2}{DT50} \cdot t}$ $Clocal_{water}$ = local concentration in surface water during emission period [mg/L] $Clocal_{water} = \frac{C(t)}{DIL}$		
C(t) : Emission rate to surface water	[mg/L]	**328.43**
$Clocal_{water}$: local concentration in surface water during emission period	[mg/L]	**32.84**

- **Use #3: Disinfection of water from rivers or wells for industrial processes**

After disinfection, water can be used for different processes. Depending on the process and the contamination level of the water, it can be re-used as it is, disinfected again, discharged via the municipal or an on-site STP (*****), or released directly to surface water.
In case the chlorinated water is released directly to surface water, the exposure scenario is comparable to the one used for the use #2 "disinfection of waste water after the waste-water plant".
The highest in-use concentrations proposed by the applicant is 475 mg/L AC. It is important to note that this application rate is not validated by the efficacy expertise.
Despite this, an assessment is made based on this concentration and with the adapted scenario.

***** *During the WG-I-2020-Part A (ENV_7-3) two adapted scenarios for "releases via STP" (via on-site STP and via municipal STP) were agreed in the context of the UA evaluation of the ARCHE Chlorine dossier.*
Later, during the WG-I-2020-Part B (ENV_7-7) 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.
Consequently, for the specific use "Disinfection of water for industrial processes" of the product "Arche Chlorine", a quantitative assessment remains necessary in the context of direct release to surface water but following this later agreement during the Part B WG, qualitative assessments are considered sufficient for the 2 ways of releases via STP.
Thus in order to ensure harmonization between dossiers, in the end these two scenarios validated during the WG-I-2020-Part A (ENV_7-3) are no longer applied in the particular case of the Arche Chlorine dossier and is not included in the PAR. However, of course, the scenarios can still be used later in the context of dossiers with other type of disinfectant active substances if so inclined.

- *See Confidential annex.*

Input parameters for calculating the local emission – Active Substance				
Input	**Value**	**Unit**	**Symbol**	**Remarks**
Use #3: Disinfection of water from rivers or wells for industrial processes - direct release to surface water				

Maximum concentration of disinfectant in waste-water	475	[mg/L]	$C_{(0)}$	Highest in-use concentration proposed by the applicant **-> not validated by EFF**
Reaction rate constant in surface water	0.743	[h^{-1}]	k	AR chlorine: The DT50 used is the $DT50_{surfacewater}$=56 min
Residence time (contact time)	0	[hr]	t	Worst case
Dilution factor (at the point of complete mixing)	10	[-]	DIL	BPR (2017, chapter 2.3.7.3.1)
Output: C(t) = Concentration at the release point to surface water [mg/L] $C(t) = C(0) \cdot e^{-k \cdot t} = C(0) \cdot e^{-\frac{\ln 2}{DT50} \cdot t}$ $Clocal_{water}$ = local concentration in surface water during emission period [mg/L] $Clocal_{water} = \frac{C(t)}{DIL}$				
C(t) : Emission rate to surface water	[mg/L]	**475**		
$Clocal_{water}$: local concentration in surface water during emission period	[mg/L]	**47.5**		

Fate and distribution in exposed environmental compartments

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) 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. 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.

Overview of input parameters

Input parameters (only set values) for calculating the fate and distribution in the environment*			
Input	*Value*	*Unit*	*Remarks*
Molecular weight	52.5	g/mol	
Melting point	0	°C	Estimated, the substance should be treated as a liquid at environmental temperature.
Boiling point	Not available	°C	
Vapour pressure (at 25°C)	276	Pa	
Water solubility (at 25°C)	1E+05	mg/L	
Log Octanol/water partition coefficient	-0.87	-	
Organic carbon/water partition coefficient (Koc)	13.22	L/kg	
Henry's Law Constant (at 20 °C)	0.11	Pa/m3/mol	Hypochlorous acid, measured
Biodegradability	Not applicable to inorganic substances	[-]	Due to rapid decomposition in organic matter, the default value for readily degradable substances can be used for the degradation constant in the STP (1 h^{-1}) can be used.
Rate constant for STP *[if measured data available]*	44.6	h^{-1} (at 15°C)	
DT_{50} for biodegradation in sewer system	56	S (at 12°C)	
DT_{50} for biodegradation in surface water/sediment	56	**min** (at 12°C)	
DT50 – hydrolysis	No hydrolysable groups	h (at 12°C)	Very rapid degradation in water in the presence of organic matter
DT50 – photo degradation	Stable	h (at 12°C)	
DT_{50} for degradation in soil	56	s (at 12°C)	
DT_{50} for degradation in air	114.6	days	Calculated (Atkinson calculation, 24-hour day)

***** Hypochlorite ion. Source: AR. Active chlorine released from sodium hypochlorite. Product-type 2(Food and feed area)January 2017. IT

The product in this dossier is only used (by professionals) for the disinfection of water, either for swimming pools, spa's and hot tubs, process water for industrial processes, waste water or drinking water. For all uses in this dossier, products are released to the STP via the sewer system after use. In case of disinfection of the effluent of the STP, treated water is released directly to surface water.
For the disinfection of drinking water, the product might be released to the manure or slurry tank. This could lead to indirect release to the soil compartment from spreading of manure/slurry on agricultural fields.

Identification of relevant receiving compartments based on the exposure pathway					
use	**STP**	**Freshwater incl. sediment**	**Marine**	**Soil incl. groundwater**	**Air**
PT2					

Identification of relevant receiving compartments based on the exposure pathway					
use	**STP**	**Freshwater incl. sediment**	**Marine**	**Soil incl. groundwater**	**Air**
#1: Disinfection of swimming pool water and hot tubs	Q (++)	Q (+)	-	Q (+)	Q
#2: Disinfection of waste water after the sewage treatment plants	-	++	-	-	Q
#3: Disinfection of raw water from rivers or wells for the production of industrial water.	Q (++)	Q (+)	-	Q (+)	Q
PT5					
#4: Disinfection of drinking water at drinking water suppliers	Q (++)	Q (+)	-	Q (+)	Q
#5: Disinfection of stationary water in reservoirs	Q (++)	Q (+)	-	Q (+)	Q
#6: Disinfection of water in collective systems	Q (++)	Q (+)	-	Q (+)	Q
#7: Disinfection of drinking water for animals	Q (++)	Q (+)	-	Q (+)	Q

++ compartment directly exposed; + compartment indirectly exposed; - compartment not exposed; Q will be assessed qualitatively

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Hypochlorite ion	
Air	0.04107	Calculated with SimpleTreat v4.
Water	8.002	
Primary settler	0.1194	
Surplus sludge	0.004165	
Degraded in STP	91.83	

Calculated PEC values

As indicated above, a quantitative assessment for the active substance has only been performed for the PT2 Use # 2 – "Disinfection of waste water after the sewage treatment plants" and for the PT2 Use # 3 – "Disinfection of raw water from rivers or wells for the preparation of industrial water (direct release to surface water)".

Summary table on calculated PEC values

Scenario: Disinfection of waste water effluent	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/m^3]	[µg/l]
Use # 2 - Disinfection of waste water after the sewage treatment plants	n.r.	32.84	n.r.(*)	n.r.	n.r.
Use # 3 - Disinfection of raw water from rivers or wells for the preparation of industrial water ➔ direct release to surface water	n.r.	47.50	n.r.(*)	n.r.	n.r.
n.r.: Not relevant (*): $PNEC_{sed}$ is calculated with EPM & log Kow ≤ 5 => RCR for surface water = RCR for sediment					

Primary and secondary poisoning

Active chlorine does not bio-accumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. Hence the product meets the standards for the risk to birds and mammals. Primary poisoning is not expected for the intended uses. Hence primary and secondary poisoning are not of concern.

2.2.8.3 Risk characterisation

Atmosphere

As indicated above, the risk characterisation presented for the Atmosphere is only qualitative :

Conclusion: Hypochlorite might enter the atmosphere due to volatilisation from the STP. Exposure assessment in the AR showed emission to air via this pathway is negligible. 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)

As indicated above, the risk characterisation presented for the STP is only qualitative :

The measured DT50 of the active substance in the sewer is equal to 56 seconds i.e. a degradation rate of 44.6 h^{-1}. This rapid degradation is allowed 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 showing that the concentrations of active substance are divided by approximately $1x10^{20}$.

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 (incl. sediments)

As indicated above, the risk characterisation presented for the aquatic compartment is quantitative for uses with direct release to surface water and qualitative for uses with indirect release to surface water (via STP):

- Direct release to surface water:

Summary table on calculated PEC/PNEC values		
Scenario: Disinfection of waste water effluent	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$***
Use # 2 - Disinfection of waste water after the sewage treatment plants	**7.82 E+05**	**7.82 E+05**
Use # 3 - Disinfection of raw water from rivers or wells for the preparation of industrial water ➔ direct release to surface water	**1.13 E+06**	**1.13 E+06**

***** PNECsed is calculated with EPM & log Kow ≤ 5 → RCR for surface water = RCR for sediment

- Indirect release to surface water (via STP):

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 degradation of the active substance is be expected to be very rapid in the STP taking into account the high amount of organic substance and the long residence times. Indeed, into a standard STP the retention times are estimated to be : 2 h in the primary settler, 6.9 h in the activated sludge tank, 6 h in solid-liquids separator and 9.2 d for the sewage sludge in the aeration tank. (Sodium Hypochlorite CAR doc IIB).

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.

Conclusions: 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:

- #1: PT2: "Disinfection of swimming pool water and hot tubs";
- #3: PT2: "Disinfection of raw water from rivers or wells for the production of industrial water" - release via STP;
- #4: PT5: "Disinfection of drinking water at drinking water suppliers";
- #5: PT5: "Disinfection of stationary water in reservoirs";
- #6: PT5: "Disinfection of water in collective systems";
- #7: PT5: "Disinfection of drinking water for animals";

But unacceptable risks are expected for the following proposed uses:

- #2: PT2: "disinfection of waste water after the waste-water plant".
- #3: PT2: "Disinfection of raw water from rivers or wells for the preparation of industrial water" - direct release to surface water.

➔ For this uses, the following RMMs is proposed:

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

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

(See Confidential annex for more details.)

Terrestrial compartment

As indicated above, the risk characterisation presented for the terrestrial compartment is only qualitative :

The active chlorine concentration in the pore water of agricultural soil (after application of sewage sludge to agricultural land) is taken as an indication of potential groundwater levels. According to the Guidance Vol IV part B, 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: Based on the highest (provisional) in-use concentrations, and taking into account degradation of active chlorine in the sewer system, no unacceptable risk is expected for the proposed uses.

Groundwater

As indicated above, the risk characterisation presented for the groundwater is only qualitative :

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.

Primary and secondary poisoning

Primary and secondary poisoning is not considered relevant for this active substance and PTs, see paragraph 2.2.8.2.

Mixture toxicity

Non-relevant for this product as the product contains only one active substance and no co-formulants.

Assessment of disinfection-by-products (DBPs)

As explained at the beginning of the environmental assessment section, the assessment of DPBs cannot be performed for the time being due to the lack of guidance and agreed parameters.
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 PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment."*

The applicant submitted the following information regarding the DBPs :

See section 3.6 "confidential annex".

Aggregated exposure (combined for relevant emission sources)

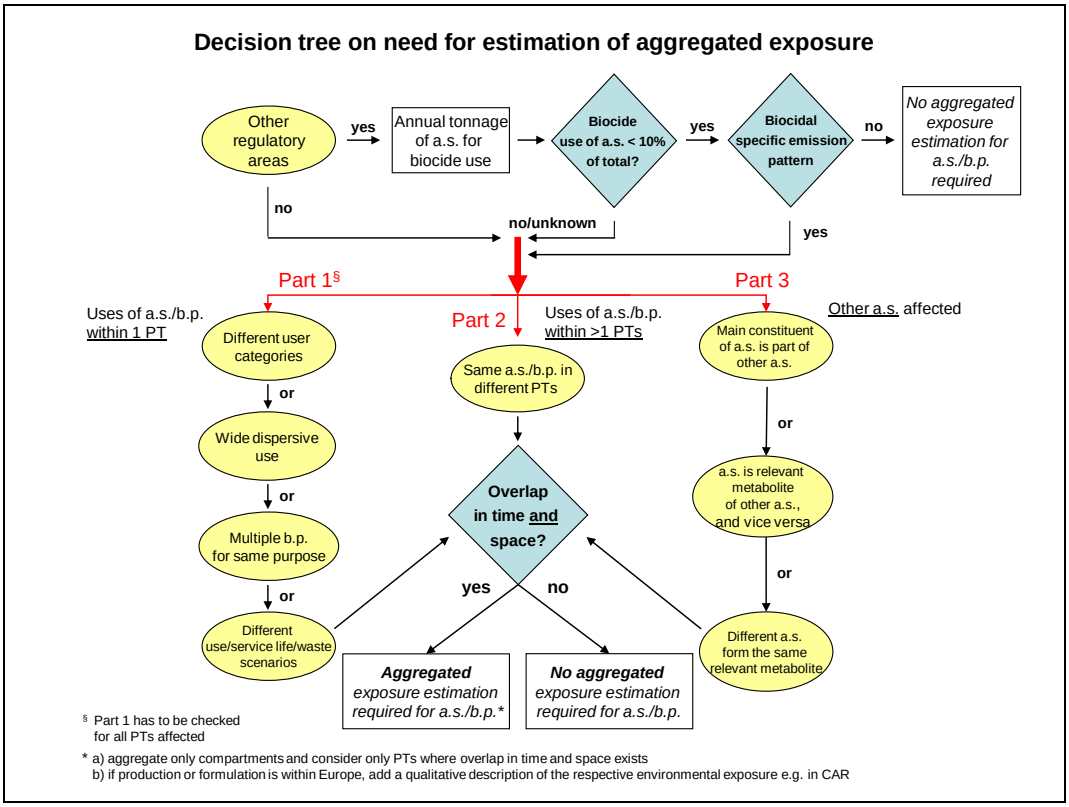


Figure 1: Decision tree on the need for estimation of aggregated exposure

According to the decision tree an aggregate exposure assessment is not required if the "biocide use of the active substance is < 10% of total" and if the biocidal use does not have a biocidal specific emission pattern.

All compartments exposed via the STP route are relevant for the aggregated exposure assessment.The environmental exposure calculations are based on free available chlorine (FAC) independent from whether the exposure is based on sodium hypochlorite, calcium hypochlorite or chlorine. Therefore, the total tonnage of the active substance and the two precusors should be considered to decide whether an aggregate exposure assessment is needed.

No information on the tonnage of Cl_2 produced as an intermediate and the total tonnage for biocidal uses for all three actives is available to the applicant. Nevertheless, considering the fast degradation of active chlorine in the sewer system and in the soil, no unacceptable risk is expected due to aggregated exposure.

Conclusion: No unacceptable risks for the environment are expected from the aggregated exposure.

Conclusion on the risk assessment for the environment of the product

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

-Use#1: PT2: "Disinfection of swimming pool water and hot tubs";

-Use#3: PT2: "Disinfection of raw water from rivers or wells for the production of industrial water" - release via STP;

-Use#4: PT5: "Disinfection of drinking water at drinking water suppliers";

-Use#5: PT5: "Disinfection of stationary water in reservoirs";

-Use#6: PT5: "Disinfection of water in collective systems";

-Use#7: PT5: "Disinfection of drinking water for animals";

In case chlorine is used for the disinfection of waste water effluent or raw water, direct release to surface water could lead to unacceptable risk for the aquatic compartment:

-Use#2: PT2: "disinfection of waste water after the waste-water plant".

-Use#3: PT2: "Disinfection of raw water from rivers or wells for the preparation of industrial water" - direct release to surface water.

Therefore, risk mitigation measures are proposed for this uses:

"Reduce residual concentrations of active chlorine by active carbon filtration or addition of reducing agents (e.g. ascorbic acid or sodium ascorbate) before discharging the wastewater to surface water. Alternatively, the water should be retained in a buffer after disinfection."

"Regular water quality assessment should be performed to assure the effluent meets all required quality standards".

2.2.9 Assessment of 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:

1. Assessment of the ED properties of the active substances in Arche Chlorine:
   - 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[2] 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

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

endocrine disrupting properties. Active chlorine released from sodium hypochlorite does not fulfil criterion (d) of Article 5(1)."

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[25], published in 2020, refers to the EFSA Scientific Opinion on "*Risks for public health related to the presence of chlorate in food*"[26], 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[27].

No CoRAP procedure has been launched for Sodium chlorate, unlike Perchlorate which has a similar mode of action[21] and for which a conclusion is available[28]. 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, BE 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.

2. Assessment of the ED properties of non-active substances (co-formulants) in Arche Chlorine:
   - Since Arche Chlorine 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.

Overall conclusion on the biocidal product regarding ED properties:
Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product Active chlorine released from chlorine.
If, in the future, Sodium chlorate is identified as an endocrine disrupting substance, the conditions for granting the biocidal product authorization will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

25 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

26 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.

27 https://echa.europa.eu/registration-dossier/-/registered-dossier/10580/7/1

28 https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807ea4f2

2.2.10 Measures to protect man, animals and the environment

First aid instructions:

Contact with skin: Wash immediately with plenty of water. Seek medical advice. On inhalation of chlorine gas: Move affected person into fresh air, keep warm and allow to rest. Call a physician immediately. As soon as practicable treat initially with a cortisone spray metered dose inhaler. If there is difficulty in breathing, give oxygen. In case of respiratory arrest, apply ventilation with respiratory device or perform mouth to nose or mouth to mouth respiration.

For other measures , please see relevant sections of the risk assessment.

2.2.11 Assessment of a combination of biocidal products

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

2.2.12 Comparative assessment

Not relevant. The Active substance of the product "Arche Chlorine" is not a candidate for substitution.

3 Annexes

3.1 List of studies for the biocidal product

A reference is made to the list of studies of the active substance dossier for the
- Physical, chemical and technical properties
- Physical hazards and respective characteristics
- Methods for detection and identification

The applicant has provided the following data for the pH monitoring:

Analysis report: Dependency of pH-value from chlorine content in water	December 2019	(See Confidential PAR)
Drinking water disinfection	19/05/20	(See Confidential PAR)
Report chlorine dosage [29]		(See Confidential PAR)
Disinfection of swimming pools – monitoring data	June 2020	(See Confidential PAR)
Drinking water disinfection	29/05/20	(See Confidential PAR)
Waste water disinfection	29/05/20	(See Confidential PAR)

3.2 Output tables from exposure assessment tools

Scenario 1 : Mixing and loading – Connecting chlorine gas cylinders to the automated dosing system

Mixing & Loading (connecting chlorine gas cylinders to the automated dosing system)
Model for inhalation exposure: - aerosol: Mixing & Loading Model 7, manual loading, pouring of liquid (according to HEEG opinion 1, 2008)

		Units	**Tier 1: no PPE**
Product: Arche Chlorine			
Active substance [avCl] – Cl2 gaz		% W/W	100%
Oral exposure:			
Active substance [avCl]		% W/W	n.r.
$NOAEC_{oral}$ [avCl]		**%**	**0.1**
% $NOAEC_{oral}$		**%**	**n.r.**

[29] Remark : test unsigned , not dated, incomplete. For information only.

Dermal exposure: Active substance [avCl]	% W/W	n.r
NOAEC$_{dermal}$ [avCl]	**%**	**1**
% NOAEC$_{dermal}$	**%**	**n.r.**
Inhalation exposure: **Exposure to aerosol [dissolved Cl_2 as avCl]** Indicative value mg/m³ Potential air concentration [avCl] Penetration through RPE Actual air conecntration **Exposure to vapour [dissolved HOCl as avCl]** Not relevant		 0.498 0.498 100 0.498
Total inhalation exposure [avCl]	**mg/m³**	**0.498**
AEC$_{inhal}$	**mg/m³**	**0.5**
% AEC$_{inhal}$	**%**	**99.6**

Scenario 3: Swim instructor exposure

Substance	
Name	HClO
CAS number	7601-90-3
Molecular weight	52.5 g/mol
K_{OW}	–
Product	
Name	Arche chlorine
Weight fraction substance	0.0005 %
Population	
Name	EU framework Biocides adult
Body weight	60 kg

Label	**Value**
Frequency	260 per year
Description	

Inhalation

Label	**Value**
Exposure model	Exposure to vapour - Evaporation
Exposure duration	480 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol

Label	Value
The product is used in dilution	No
Amount of solution used	560000000 g
Weight fraction substance	0.0005 %
Room volume	188 m³
Ventilation rate	2 per hour
Inhalation rate	1.37 m³/hr
Application temperature	28 °C
Vapour pressure	337 Pa
Molecular weight	52.5 g/mol
Mass transfer coefficient	5200 m/min
Release area mode	Constant
Release area	375 m²
Emission duration	480 minute
Absorption model	Fixed fraction
Absorption fraction	100 %

Results for scenario 3: Swim instructor exposure
Inhalation

Mean event concentration: 1.2×10^{-2} mg/m³

Disinfection of public swimming pool – Professional (swim instructor)

Model for inhalation exposure: ConsExpo Evaporation from constant surface model (ConsExpo Disinfectant Products Factsheet,2006, 87f, appendix "Exposure in public swimming pools")

	Units	Swim instructor
Product: Arche Chlorine Active substance [avCl] – in use dilution (continuous disinfection) W/W	%	0.0005
Oral exposure: Active substance [avCl] – in the pool (continuous disinfection)	% W/W	n.r.
NOAEC$_{oral}$ [avCl]	**%**	**0.1**
% NOAEC$_{oral}$	**%**	**n.r.**
Dermal exposure: Active substance [avCl] – in the pool (continuous disinfection)	% W/W	n.r.
NOAEC$_{dermal}$ [avCl]	**%**	**1**
% NOAEC$_{dermal}$	**%**	**n.r.**

Inhalation exposure:		
Exposure to aerosol [dissolved Cl_2 as avCl]		
Not relevant		
Exposure to vapour [dissolved HOCl as avCl]		
Mean event concentration	mg/m³	0.012
Penetration through RPE	%	100
Actual air concentration [avCl]	mg/m³	0.012
Total inhalation exposure [avCl]	**mg/m³**	**0.012**
AEC_{inhal}	**mg/m³**	**0.5**
% AEC_{inhal}	**%**	**2.4**

Scenario [4] : Adult swimmer (SPA)

Label	***Value***
Substance	
Name	*HClO*
CAS number	
Molecular weight	*52.5 g/mol*
K_{ow}	*–*
Product	
Name	*Arche Chlorine*
Weight fraction substance	*0.0005 %*
Population	
Name	*EU framework Biocides adult*
Body weight	*60 kg*

Scenarios

- ***Scenario - Adult swimmer (SPA)***

Scenario- Adult swimmer (SPA)

Label	***Value***
Frequency	*5 per week*

Inhalation

Label	***Value***
Exposure model	*Exposure to vapour - Evaporation*
Exposure duration	*120 minute*
Product is substance in pure form	*No*
Molecular weight matrix	*52.5 g/mol*
The product is used in dilution	*No*

Label	***Value***
Amount of solution used	*560000000 g*
Weight fraction substance	*0.0005 %*
Room volume	*188 m³*
Ventilation rate	*2 per hour*
Inhalation rate	*1.25 m³/hr*
Application temperature	*40 °C*
Vapour pressure	*725 Pa*
Molecular weight	*52.5 g/mol*
Mass transfer coefficient	*320000 m/hr*
Release area mode	*Constant*
Release area	*375 m²*
Emission duration	*120 minute*
Absorption model	*Fixed fraction*
Absorption fraction	*100 %*

Results for scenario - Adult swimmer (SPA)

Inhalation

Mean event concentration (average air concentration on exposure event. Note: depends strongly on chosen exposure duration)	*5.7×10^{-2} mg/m³*

Disinfection of public swimming pool – Adult swimmer (SPA)

Model for inhalation exposure:
- to aerosol: Consumer product spraying and dusting model 2-Handheld Trigger Spray (Biocides Human Health Exposure Methodology, vers1, 2015, p.220)
- to vapour: ConsExpo Evaporation from constant surface model (in analogy to ConsExpo Disinfectant Products Factsheet,2006, 87f, appendix "Exposure in public swimming pools")

	Units	Tier 1: no PPE
Product: Arche Chlorine		
Active substance [avCl] – in use dilution (continuous disinfection) W/W	%	0.0005

Inhalation exposure:		
Exposure to aerosol [dissolved Cl_2 as avCl]		
Indicative value	mg/m³	10.5
Potential concentration [avCl]	mg/m³	0.00005
Penetration through RPE	%	100
Actual air concentration [avCl]	mg/m³	0.00005
Exposure to vapour [dissolved HOCl as avCl]		
Mean event concentration	mg/m³	0.057

Penetration through RPE	%	100
Actual air concentration [avCl]	mg/m³	0.057
Total inhalation exposure [avCl]	**mg/m³**	**0.057**
AEC_{inhal}	**mg/m³**	**0.5**
% AEC_{inhal}	**%**	**1.14**

Scenario 5: Adult swimmer exposure

Substance	
Name	HClO
CAS number	7601-90-3
Molecular weight	52.5 g/mol
K_{ow}	–
Product	
Name	Arche chlorine
Weight fraction substance	0.0005 %
Population	
Name	EU framework Biocides adult
Body weight	60 kg

Label	Value
Frequency	260 per year
Description	

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	120 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	560000000 g
Weight fraction substance	0.0005 %
Room volume	188 m³
Ventilation rate	2 per hour
Inhalation rate	2.89 m³/hr

Label	Value
Application temperature	28 °C
Vapour pressure	337 Pa
Molecular weight	52.5 g/mol
Mass transfer coefficient	5200 m/min
Release area mode	Constant
Release area	375 m²
Emission duration	120 minute
Absorption model	Fixed fraction
Absorption fraction	100 %

Results for scenario 5: Adult swimmer exposure
Inhalation

Mean event concentration: 1.2×10^{-2} mg/m³

Disinfection of public swimming pool – General Public (swimmer: adult)
Model for inhalation exposure: ConsExpo Evaporation from constant surface model (ConsExpo Disinfectant Products Factsheet,2006, 87f, appendix "Exposure in public swimming pools")

		Units	**Swim instructor**
Product: Arche Chlorine Active substance [avCl] – in use dilution (continuous disinfection) W/W		%	0.0005
Oral exposure: Active substance [avCl] – in the pool (continuous disinfection)		% W/W	0.0005
NOAEC$_{oral}$ [avCl]	**%**		**0.1**
% NOAEC$_{oral}$	**%**		**0.5**
Dermal exposure: Active substance [avCl] – in the pool (continuous disinfection)		% W/W	0.0005
NOAEC$_{dermal}$ [avCl]	**%**		**1**
% NOAEC$_{dermal}$	**%**		**0.05**
Inhalation exposure: **Exposure to aerosol [dissolved Cl_2 as avCl]** Not relevant			
Exposure to vapour [dissolved HOCl as avCl]			
Mean event concentration	mg/m³		0.012
Penetration through RPE	%		100
Actual air concentration [avCl]	mg/m³		0.012
Total inhalation exposure [avCl]	**mg/m³**		**0.012**
AEC$_{inhal}$	**mg/m³**		**0.5**
% AEC$_{inhal}$	**%**		**2.4**

Scenario 6: Child swimmer exposure

Substance	
Name	HClO
CAS number	7601-90-3
Molecular weight	52.5 g/mol
K_{ow}	–
Product	
Name	Arche chlorine
Weight fraction substance	0.0005 %
Population	
Name	EU framework Biocides child
Body weight	15.6 kg

Label	Value
Frequency	104 per year
Description	

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	60 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	560000000 g
Weight fraction substance	0.0005 %
Room volume	188 m³
Ventilation rate	2 per hour
Inhalation rate	1.58 m³/hr
Application temperature	28 °C
Vapour pressure	337 Pa
Molecular weight	52.5 g/mol
Mass transfer coefficient	5200 m/min
Release area mode	Constant
Release area	375 m²
Emission duration	60 minute
Absorption model	Fixed fraction
Absorption fraction	100 %

Results for scenario 6: Child swimmer exposure

Inhalation

Mean event concentration: 1.2×10^{-2} mg/m³

Disinfection of public swimming pool – General Public (swimmer: child)
Model for inhalation exposure: ConsExpo Evaporation from constant surface model (ConsExpo Disinfectant Products Factsheet,2006, 87f, appendix "Exposure in public swimming pools")

		Units	Child swimmer
Product: Arche Chlorine Active substance [avCl] – in use dilution (continuous disinfection) W/W		%	0.0005
Oral exposure: Active substance [avCl] – in the pool (continuous disinfection)		% W/W	0.0005
$NOAEC_{oral}$ [avCl]		**%**	**0.1**
% $NOAEC_{oral}$		**%**	**0.5**
Dermal exposure: Active substance [avCl] – in the pool (continuous disinfection)		% W/W	0.0005
$NOAEC_{dermal}$ [avCl]		**%**	**1**
% $NOAEC_{dermal}$		**%**	**0.05**
Inhalation exposure: **Exposure to aerosol [dissolved Cl_2 as avCl]** Not relevant **Exposure to vapour [dissolved HOCl as avCl]**			
Mean event concentration		mg/m³	0.012
Penetration through RPE		%	100
Actual air concentration [avCl]		mg/m³	0.012
Total inhalation exposure [avCl]		**mg/m³**	**0.012**
AEC_{inhal}		**mg/m³**	**0.5**
% AEC_{inhal}		**%**	**2.4**

Scenario 7: Baby swimmer exposure

Substance	
Name	HClO
CAS number	7601-90-3
Molecular weight	52.5 g/mol
K_{OW}	–
Product	
Name	Arche chlorine
Weight fraction substance	0.0005 %
Population	
Name	EU framework Biocides infant

Body weight	8 kg

Label	Value
Frequency	13 per year
Description	

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	30 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	100000000 g
Weight fraction substance	0.0005 %
Room volume	50 m^3
Ventilation rate	2 per hour
Inhalation rate	0.84 m^3/hr
Application temperature	32 °C
Vapour pressure	438 Pa
Molecular weight	52.5 g/mol
Mass transfer coefficient	5200 m/min
Release area mode	Constant
Release area	100 m^2
Emission duration	30 minute
Absorption model	Fixed fraction
Absorption fraction	100 %

Results for scenario 7: Baby swimmer exposure
Inhalation
Mean event concentration: 1.5×10^{-2} mg/m^3

Disinfection of public swimming pool – General Public (swimmer: baby)

Model for inhalation exposure: ConsExpo Evaporation from constant surface model (ConsExpo Disinfectant Products Factsheet,2006, 87f, appendix "Exposure in public swimming pools")

	Units	Baby swimmer
Product: Arche Chlorine Active substance [avCl] – in use dilution (continuous disinfection) W/W	%	0.0005

Oral exposure: Active substance [avCl] – in the pool (continuous disinfection)	% W/W	0.0005
$NOAEC_{oral}$ [avCl]	**%**	**0.1**
% $NOAEC_{oral}$	**%**	**0.5**
Dermal exposure: Active substance [avCl] – in the pool (continuous disinfection)	% W/W	0.0005
$NOAEC_{dermal}$ [avCl]	**%**	**1**
% $NOAEC_{dermal}$	**%**	**0.05**
Inhalation exposure: **Exposure to aerosol [dissolved Cl_2 as avCl]** Not relevant **Exposure to vapour [dissolved HOCl as avCl]**		
Mean event concentration	mg/m^3	0.015
Penetration through RPE	%	100
Actual air concentration [avCl]	mg/m^3	0.015
Total inhalation exposure [avCl]	**mg/m^3**	**0.015**
AEC_{inhal}	**mg/m^3**	**0.5**
% AEC_{inhal}	**%**	**3**

Scenario 8: Showering

Substance	
Name	HClO
CAS number	7601-90-3
Molecular weight	52.5 g/mol
K_{OW}	–
Product	
Name	Arche chlorine
Weight fraction substance	0.0005 %
Population	
Name	EU framework Biocide Adult
Body weight	60 kg

Label	**Value**
Frequency	1 per day
Description	

Inhalation

Label	**Value**
Exposure model	Exposure to vapour - Evaporation

Label	Value
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	50000 g
Weight fraction substance	0.0001 %
Room volume	2.5 m³
Ventilation rate	2 per hour
Inhalation rate	1.25 m³/h
Application temperature	40 °C
Vapour pressure	725 Pa
Molecular weight	52.5 g/mol
Mass transfer coefficient	5330 m/min
Release area mode	Constant
Release area	1 m²
Emission duration	15 minute
Absorption model	Fixed fraction
Absorption fraction	100 %

Results for scenario 8: Post-application – showering (adult)
Inhalation
Mean event concentration: 5×10^{-3} mg/m³

Substance	
Name	HClO
CAS number	7601-90-3
Molecular weight	52.5 g/mol
K_{ow}	–
Product	
Name	Arche chlorine
Weight fraction substance	0.0001 %
Population	
Name	Toddlers
Body weight	10 kg

Label	Value
Frequency	1 per day
Description	

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	50000 g
Weight fraction substance	0.0001 %
Room volume	2.5 m³
Ventilation rate	2 per hour
Inhalation rate	1.32 m³/h
Application temperature	40 °C
Vapour pressure	725 Pa
Molecular weight	52.5 g/mol
Mass transfer coefficient	5330 m/min
Release area mode	Constant
Release area	1 m²
Emission duration	15 minute
Absorption model	Fixed fraction
Absorption fraction	100 %

Results for scenario 8: Showering (toddlers)
Inhalation

Mean event concentration: 5×10^{-3} mg/m³

Substance	
Name	HClO
CAS number	7601-90-3
Molecular weight	52.5 g/mol
K_{ow}	–
Product	
Name	Arche chlorine
Weight fraction substance	0.0001 %
Population	
Name	EU framework Biocide baby
Body weight	8 kg

Label	Value

Label	Value
Frequency	1 per day
Description	

Inhalation

Label	Value
Exposure model	Exposure to vapour - Evaporation
Exposure duration	15 minute
Product is substance in pure form	No
Molecular weight matrix	18 g/mol
The product is used in dilution	No
Amount of solution used	50000 g
Weight fraction substance	0.0005 %
Room volume	2.5 m³
Ventilation rate	2 per hour
Inhalation rate	0.84 m³/h
Application temperature	40 °C
Vapour pressure	725 Pa
Molecular weight	52.5 g/mol
Mass transfer coefficient	5330 m/min
Release area mode	Constant
Release area	1 m²
Emission duration	15 minute
Absorption model	Fixed fraction
Absorption fraction	100 %

Results for scenario 8: Showering (infant)
Inhalation
Mean event concentration: 5×10^{-3} mg/m³

Human drinking water disinfection – showering (adult, toddlers, infants)

Model for inhalation exposure:
- to aerosol: Consumer product spraying and dusting model 2-Handheld Trigger Spray (Biocides Human Health Exposure Methodology, vers1, 2015, p.220)
- to vapour: ConsExpo Evaporation from constant surface model (in analogy to ConsExpo Disinfectant Products Factsheet,2006, 87f, appendix "Exposure in public swimming pools")

	Units	Tier 1: no PPE
Product: Arche Chlorine Active substance [avCl] – in use dilution (continuous disinfection) W/W	%	0.0001

Oral exposure: Active substance [avCl] – in water (continuous disinfection)		% W/W	0.0001
$NOAEC_{oral}$ [avCl]	**%**		**0.1**
% $NOAEC_{oral}$	**%**		**0.1**
Dermal exposure: Active substance [avCl] – in water (continuous disinfection)		% W/W	0.0001
$NOAEC_{dermal}$ [avCl]	**%**		**1**
% $NOAEC_{dermal}$	**%**		**0.01**
Inhalation exposure:			
Exposure to aerosol [dissolved Cl_2 as avCl]			
Indicative value	mg/m³		10.5
Potential concentration [avCl]	mg/m³		0.00001
Penetration through RPE	%		100
Actual air concentration [avCl]	mg/m³		0.00001
Exposure to vapour [dissolved HOCl as avCl]			
Mean event concentration	mg/m³		
Penetration through RPE	%		0.005
Actual air concentration [avCl]	mg/m³		100
			0.005
Total inhalation exposure [avCl]	**mg/m³**		**0.005**
AEC_{inhal}	**mg/m³**		**0.5**
% AEC_{inhal}	**%**		**1**

Scenario 9: Drinking water

	Units	Tier 1: no PPE
Product: Arche Chlorine Active substance [avCl] – in use dilution (continuous disinfection, use#6) % W/W		0.0001
Oral exposure: Active substance [avCl] – in drinking water (continuous disinfection, use#6) % W/W		0.0001
$NOAEC_{oral}$ [avCl]	**%**	**0.1**
% $NOAEC_{oral}$	**%**	**0.1**

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

(See Confidential PAR)

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Reference is made to the IUCLID file.

3.6 Confidential annex

The confidential annex is included in the dossier as a separate file.

3.7 Other

3.7.1 Overview national chlorine limits

3.7.1.1 Swimming pools

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
Austria	≤	1,2	mg/L	free chlorine		Residual	Bäderhygieneverordnung 2012 – BHygV 2012 (BGBl. II Nr. 321/2012, §7 (1) 2. c)cc))	indoor pools
Austria	≤	2	mg/L	free chlorine		Residual	Bäderhygieneverordnung 2012 – BHygV 2012 (BGBl. II Nr. 321/2012, §7 (1) 2. c)cc))	outdoor pools
Austria	≤	0,3	mg/l	combined chlorine		Residual	Bäderhygieneverordnung 2012 – BHygV 2012 (BGBl. II Nr. 321/2012, §7 (1) 2. d))	
Austria	≥	0,3	mg/l	free chlorine		Residual	Bäderhygieneverordnung 2012 – BHygV 2012 (BGBl. II Nr. 321/2012, §7 (1) 2. c)aa))	pH 6,5 - 7,4
Austria	≥	0,5	mg/L	free chlorine		Residual	Bäderhygieneverordnung 2012 – BHygV 2012 (BGBl. II Nr. 321/2012, §7 (1) 2. c)aa))	pH 7,4-7,8
Belgium		0,5 - 1,5	mg/L	free chlorine		Residual	VLAREM II Art. 5.32.8.1.9	in door pools, therapy bath
Belgium	<	0,6	mg/L	combined chlorine		Residual	VLAREM II Art. 5.32.8.1.9	in door pools, therapy bath, dip bath
Belg		0,5	mg	free		Resid	VLAREM II Art. 5.32.8.1.9	out door pools, splash bath (plonsbad)

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
ium		- 3,0	/L	chlorine		ual		
Belgium	<	0,6 / 1,0	mg /L	combined chlorine		Residual	VLAREM II Art. 5.32.8.1.9	out door pools, splash bath (plonsbad)
Belgium		1 - 3	mg /L	free chlorine		Residual	VLAREM II Art. 5.32.8.1.9	hot whirlpool
Belgium	<	0,6	mg /L	combined chlorine		Residual	VLAREM II Art. 5.32.8.1.9	hot whirlpool
Belgium		1 - 2	mg /L	free chlorine		Residual	VLAREM II Art. 5.32.8.1.9	dip bath (dompelbad)
Czech Republic		0,3 - 0,6	mg /L	free chlorine		Residual	National legislation - Decree No. 238/2011 Coll.	swimming pools and pools with a water temperature not exceeding 28 ° C
Czech Republic		0,5 - 0,8	mg /L	free chlorine		Residual	National legislation - Decree No. 238/2011 Coll.	swimming pools and pools with a temperature not exceeding 32 ° C
Czech Republic		0,7 - 1,0	mg /L	free chlorine		Residual	National legislation - Decree No. 238/2011 Coll.	swimming pools and pools with a temperature higher than 32 ° C
Czech Republic	≤	0,3	mg /L	combined chlorine		Residual	National legislation - Decree No. 238/2011 Coll.	
Germany	>	0,3	mg /L	free chlorine		Residual	DIN 19643-1 : 2012-11	in feed water
Germany	>	0,3	mg /L	free chlorine		Residual	DIN 19643-1 : 2012-11	in pool
Germany	<	0,6	mg /L	free chlorine		Residual	DIN 19643-1 : 2012-11	in pool
Germany	<	1,2	mg /L	free chlorine		Residual	DIN 19643-1 : 2012-11	in pool, maximum value if pool is highly contaminated
Germany	>	0,7	mg /L	free chlorine		Residual	DIN 19643-1 : 2012-11	hot tubes, in feed water
German	>	0,7	mg /L	free chlorine		Residual	DIN 19643-1 : 2012-11	hot tubes, in pool

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
y								
Germany	<	1,0	mg/L	free chlorine		Residual	DIN 19643-1 : 2012-11	hot tubes, in pool
Hungary	≤	1	mg/L	free chlorine		Residual	37/1996. (X. 18.) NM decree, Annex 1, Section 4, Table A) (page 8)	In case of disinfection with chlorine (chlorine gas, sodium hypoclorite or chlorine dioxide), measured from circulated, treated pool water
Hungary	≤	0,5	mg/L	combined chlorine		Residual	37/1996. (X. 18.) NM decree, Annex 1, Section 4, Table A) (page 8)	In case of disinfection with chlorine (chlorine gas, sodium hypoclorite or chlorine dioxide), measured from circulated, treated pool water
Hungary	=	300	mg/L	other	Chloride	Dosing	37/1996. (X. 18.) NM decree, Annex 1, Section 4, Table A) (page 8)	In addition to the concentration measured in influent water of swimming pool
Hungary	≤	1	mg/L	other	Chlorite	Residual	37/1996. (X. 18.) NM decree, Annex 1, Section 4, Table A) (page 8)	In case of disinfection with chlorine dioxide, measured from circulated, treated pool water
Poland	≤	0,3	mg/L	combined chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2015	water in the swimming area and shower tray for children
Poland		0,3 - 0,6	mg/L	free chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2016	water in the swimming area and shower tray for children
Poland	≤	0,3	mg/L	combined chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2017	water in area equipped with water-and-air aerosol generating devices
Poland		0,7 - 1,0	mg/L	free chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2018	water in area equipped with water-and-air aerosol generating devices
Poland	≤	0,3	mg/L	combined chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2019	water in swimming area provided for swimming instruction for infants and young children up to the age of 3
Poland		0,3 - 0,4	mg/L	free chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2020	water in swimming area provided for swimming instruction for infants and young children up to the age of 3
Poland		-	mg/L	combined chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2021	water in the shower tray to rinse feet
Poland		1,0 -	mg/L	free chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra	water in the shower tray to rinse feet

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
		2,0					Zdrowia z dnia 9 listopada 2022	
Poland	≤	0,2	mg/L	combined chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2023	water introduced into the swimming area from the circulation system
Poland		-	mg/L	free chlorine		Residual	Dz.U. 2015 poz. 2016, Rozporządzenie Ministra Zdrowia z dnia 9 listopada 2024	water introduced into the swimming area from the circulation system
Portugal		0,5 - 1,2	mg/L	free chlorine		Residual	Decreto Regulamentar n.o 5/97	pH 7 - 7,4
Portugal		1 - 2	mg/L	free chlorine		Residual	Decreto Regulamentar n.o 5/97	pH 7,4 - 8
Portugal		1 - 3	mg/L	free chlorine		Residual	Decreto Regulamentar n.o 5/97	another pool activities
Portugal		free chlorine + 0,6	mg/L	other	total	Residual	Decreto Regulamentar n.o 5/97	
Portugal		0,5 - 1,2	mg/L	free chlorine		Residual	Circular Normativa nº 14/DA (Portuguese Health Authority)	pH 6,9 - 7,4
Portugal		1 - 2	mg/L	free chlorine		Residual	Circular Normativa nº 14/DA (Portuguese Health Authority)	pH 7,5 - 8
Portugal	≤	0,5	mg/L	combined chlorine		Residual	Circular Normativa nº 14/DA (Portuguese Health Authority)	
Portugal		máx free chlorine + 0,5 (1 - 2,5)	mg/L	other	total	Residual	Circular Normativa nº 14/DA (Portuguese Health Authority)	

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
Slovakia	<	0,6	mg/L	free chlorine		Residual	Vyhláška č. 308/2012 Z. z. Vyhláška Ministerstva zdravotníctva Slovenskej republiky o požiadavkách na kvalitu vody, kontrolu kvality vody a o požiadavkách na prevádzku, vybavenie prevádzkových plôch, priestorov a zariadení na prírodnom kúpalisku a na umelom kúpalisku	Examination frequency: three times a day and always after filling a new volume of water residual: to 1 mg / l at a pool water above 28 ° C, not more than 0,3 mg / l in the pool for infants and toddlers and in the pool for children is regardless of the water temperature
Slovakia	<	0,3	mg/L	other	bound chlorine	Residual	Vyhláška č. 308/2012 Z. z. Vyhláška Ministerstva zdravotníctva Slovenskej republiky o požiadavkách na kvalitu vody, kontrolu kvality vody a o požiadavkách na prevádzku, vybavenie prevádzkových plôch, priestorov a zariadení na prírodnom kúpalisku a na umelom kúpalisku	Examination frequency: three times a day and always after filling a new volume of water residual: to 1 mg / l at a pool water above 28 ° C, not more than 0,3 mg / l in the pool for infants and toddlers and in the pool for children is regardless of the water temperature,
Spain		0,5 - 2	mg/L	free chlorine		Residual	Real Decreto 742/2013	
Spain	≤	0,6	mg/L	combined chlorine		Residual	Real Decreto 742/2013	
Switzerland	>	0,2	mg/L	free chlorine		Residual	SIA 385/9	in pool
Switzerland	<	0,8	mg/L	free chlorine		Residual	SIA 385/9	in pool
Switzerland	>	0,7	mg/L	free chlorine		Residual	SIA 385/9	hot tubes, in pool
Switzerland	<	1,5	mg/L	free chlorine		Residual	SIA 385/9	hot tubes, in pool
Slovenia		0,3-0,6	mg/L	free chlorine		Residual	Rules on minimum hygiene requirements to be met by baths and bathing water in swimming pools (Uradni list RS, št. 59/15, 86/15 –	Field measurement.

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
							popr. in 52/18).	
Slovenia		0,7-1,0	mg/L	free chlorine		Residual	Rules on minimum hygiene requirements to be met by baths and bathing water in swimming pools (Uradni list RS, št. 59/15, 86/15 – popr. in 52/18).	Field measurement. Pool water ≥ 23 ° C and possibility of water aerosolization.
Slovenia	≤	1,2	mg/L	free chlorine		Residual	Rules on minimum hygiene requirements to be met by baths and bathing water in swimming pools (Uradni list RS, št. 59/15, 86/15 – popr. in 52/18).	Field measurement. Exceptionally, higher concentrations are permitted for a limited time to ensure compliance with the prescribed microbiological parameters for bathing water.
Slovenia	≤	0,3	mg/L	other	bound chlorine	Residual	Rules on minimum hygiene requirements to be met by baths and bathing water in swimming pools (Uradni list RS, št. 59/15, 86/15 – popr. in 52/18).	
Slovenia	≤	0,1	mg/L	other	chlorite	Residual	Rules on minimum hygiene requirements to be met by baths and bathing water in swimming pools (Uradni list RS, št. 59/15, 86/15 – popr. in 52/18).	Field or laboratory measurement. In case of disinfection with chlorine dioxide.
Slovenia	≤	0,050	mg/L	other	total trihalomethanes	Residual	Rules on minimum hygiene requirements to be met by baths and bathing water in swimming pools (Uradni list RS, št. 59/15, 86/15 – popr. in 52/18).	Total concentration of chloroform, bromoform, dibromochloromethane, bromodichloromethane.

3.7.1.2 Disinfection of waste water

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
Austria	≤	0,4	mg/L	combined chlorine		Residual	Allgemeine Abwasseremissionsverordnung 1996, BGBl. Nr. 186/1996	
Austria	≤	0,2	mg/L	free chlorine		Residual	Allgemeine Abwasseremissionsverordnung 1996, BGBl. Nr. 186/1996	
Belgium	≤	0,5	mg/L	free chlorine		Residual	VLAREM bijlage 5.3.2	(non-ferro)metal industry, effluent for surface water
Belgium	≤	1	mg/L	free chlorine		Residual	VLAREM bijlage 5.3.2	other; effluent for surface water or sewage system
Germany							AbwV - Abwasserverordnung (Wate-Water-Regulation)	no reference towards chlorine, just CSB, BSB_5, NH_4-N, N_{ges}, P_{ges}
Germany							Emissionserklärungsverordnung - Abwasser (Immission deklaration regulation - waste water)	no reference towards chlorine, just DCE, DCM, Chloralkane, HCB, HCBD, HCH, AOX
Hungary	≤	2	mg/L	free chlorine		Residual	28/2004. (XII. 25.) KvVM decree, Annex (page 64)	Wastewater treatment, measured in effluent prior to receiving body, general limit
Hungary	≤	0,3	mg/L	free chlorine		Residual	28/2004. (XII. 25.) KvVM decree, Annex 5 (page 69)	Wastewater treatment, measured in effluent prior to receiving body, minimum of individual limit that can be set by the appropriate authority
Hungary	≤	10	mg/L	free chlorine		Residual	28/2004. (XII. 25.) KvVM decree, Annex 5 (page 69)	Wastewater treatment, measured in effluent prior to receiving body, maximum of individual limit that can be set by the appropriate authority
Hungary	≤	30	mg/L	free chlorine		Residual	28/2004. (XII. 25.) KvVM decree, Annex 4 (page 67)	Wastewater treatment, influent wastewaters into communal sewer system
Poland	≤	0,2	mg/L	free chlorine		Residual	Dz.U. 2019 poz. 1311, Rozporządzenie Ministra Gospodarki Morskiej i Żeglugi Śródlądowej z dnia 12 lipca 2019	waste water after treatment discharged into waters or ground

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
Poland	≤	0,4	mg/L	other	total chlorine	Residual	Dz.U. 2019 poz. 1311, Rozporządzenie Ministra Gospodarki Morskiej i Żeglugi Śródlądowej z dnia 12 lipca 2019	waste water after treatment discharged into waters or ground
Poland	≤	1	mg/L	free chlorine		Dosing	Dz.U. 2016 poz. 1757, Obwieszczenie Ministra Infrastruktury i Budownictwa z dnia 28 września 2016	industrial waste water dicharged into wastewater plant
Poland	≤	4	mg/L	other	total chlorine	Dosing	Dz.U. 2016 poz. 1757, Obwieszczenie Ministra Infrastruktury i Budownictwa z dnia 28 września 2016	industrial waste water dicharged into wastewater plant
Portugal	≤	0,5	mg/L	free chlorine		Residual	Decreto-Lei n.o 236/98	
Portugal	≤	1	mg/L	other	total	Residual	Decreto-Lei n.o 236/98	
Slovenia	≤	0,2	mg/L	free chlorine	Residual	Decree on the emission of substances and heat when discharging waste water into waters and the public sewage system (Uradni list RS, št. 64/12, 64/14 in	Discharge directly and indirectly into water.	Slovenia

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
						98/15)		
Slovenia	≤	0,5	mg/L	free chlorine	Residual	Decree on the emission of substances and heat when discharging waste water into waters and the public sewage system (Uradni list RS, št. 64/12, 64/14 in 98/15)	Discharge into public sewers.	Slovenia
Slovenia	≤	0,5	mg/L	combined chlorine	Residual	Decree on the emission of substances and heat when discharging waste water into	Discharge directly and indirectly into water.	Slovenia

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
						waters and the public sewage system (Uradni list RS, št. 64/12, 64/14 in 98/15)		
Slovenia	≤	1,0	mg/L	combined chlorine	Residual	Decree on the emission of substances and heat when discharging waste water into waters and the public sewage system (Uradni list RS, št. 64/12, 64/14 in 98/15)	Discharge into public sewers.	Slovenia

3.7.1.3 industrial water

Country		Value	Unit	Compound	Dosing/residual	Reference	Remarks
Czech Republic	≤	0,2	mg/L	free chlorine	Residual	National legislation - Government Regulation No. 401/2015 Coll.	Manufacture of other inorganic basic chemicals
Hungary	≤	0,3	mg/L	free chlorine	Residual	28/2004. (XII. 25.) KvVM decree, Annex 1, Part 3, Chapter 15 (page 24)	Textile production, measured in effluent prior to receiving body
Hungary	≤	0,2	mg/L	free chlorine	Residual	28/2004. (XII. 25.) KvVM decree, Annex 1, Part 3, Chapter 22 (page 33)	Alkali chloride electrolysis, measued in effluent technological wastewater
Hungary	≤	0,5	mg/L	free chlorine	Residual	28/2004. (XII. 25.) KvVM decree, Annex 1, Part 3, Chapter 32 (page 52)	Aluminium refining with chlorine, measured in effluent of wet air scrubber
Hungary	≤	0,5	mg/L	free chlorine	Residual	28/2004. (XII. 25.) KvVM decree, Annex 1, Part 3, Chapter 33 (page 55)	Metal works and metal surface treatment (processes collected in A/(1) section of page 53.) , measured in wastewater prior to its mixture with other wastewaters

3.7.1.4 Drinking water

Country		Value	Unit	Compound	Other	Dosing/ residual	Reference	Remarks
	≥	0,5	mg/L	free chlorine		Residual	WHO recommendation	concentration at water works
	<	5	mg/L	free chlorine		Residual	WHO recommendation	concentration at water works
	>	0,2	mg/L	free		Residual	WHO recommendation	concentration at user

				chlorine				
	<	1	mg/L	free chlorine		Residual	DIN EN 937 : 2016-09	
Austria	≤	1,2	mg/l	free chlorine		Dosing	Österreichisches Lebensmittelbuch IV. Auflage Codexkapitel / B 1 / Trinkwasser	https://www.verbrauchergesundheit.gv.at/lebensmittel/buch/codex/B1_Trinkwasser.pdf?7a1iyg
Austria	≥	0,1	mg/l	free chlorine		Residual	Österreichisches Lebensmittelbuch IV. Auflage Codexkapitel / B 1 / Trinkwasser	at the end of the treatment process
Austria	≤	0,3	mg/L	free chlorine		Residual	Österreichisches Lebensmittelbuch IV. Auflage Codexkapitel / B 1 / Trinkwasser	at the end of the treatment process
Belgium		0,25	mg/L	free chlorine		Residual	Besluit van de Vlaamse Regering van 13 december 2002	
Czech Republic	≤	0,3	mg/L	free chlorine		Residual	National legislation - Decree No. 252/2004 Coll.	
Czech Republic	≤	0,4	mg/L	other	total chlorine	Residual	National legislation - Decree No. 252/2004 Coll.	
Germany	>	0,1	mg/L	free chlorine		Residual	TrinkwW - Trinkwasserverordnung (drinking water regulation) - Bekanntmachung der Liste der Aufbereitungsstoffe und Desinfektionsvefahren gemäß § 11 der Trinkwasserverordnung - 17.1 Änderung- (Stand: November 2012)	
Germany	<	0,3	mg/L	free chlorine		Residual	TrinkwW - Trinkwasserverordnung (drinking water regulation) - Bekanntmachung der Liste der	

							Aufbereitungsstoffe und Desinfektionsvefahren gemäß § 11 der Trinkwasserverordnung - 17.1 Änderung- (Stand: November 2012)	
Germany	<	0,6	mg/L	free chlorine		Residual	TrinkwW - Trinkwasserverordnung (drinking water regulation) - Bekanntmachung der Liste der Aufbereitungsstoffe und Desinfektionsvefahren gemäß § 11 der Trinkwasserverordnung - 17.1 Änderung- (Stand: November 2012)	If water is highly contaminated or ammonia is present
Germany	<	6	mg/L	free chlorine		Dosing	TrinkwW - Trinkwasserverordnung (drinking water regulation) - Bekanntmachung der Liste der Aufbereitungsstoffe und Desinfektionsvefahren gemäß § 11 der Trinkwasserverordnung - 17.1 Änderung- (Stand: November 2012)	If water is highly contaminated or ammonia is present
Germany	≤	1,2	mg/l	free chlorine		Dosing	Liste der Aufbereitungsstoffe und Desinfektionsverfahren gemäß § 11 der Trinkwasserverordnung	https://www.umweltbundesamt.de/sites/default/files/medien/3521/dokumente/20011 4_21._bekanntmachung_der_liste_der_aufb ereitungsstoffe_und_desinfektionsverfahren _gemaess_ss_11_der_trinkwasserverordnun g_0.pdf
Germany	≥	0,1	mg/l	free chlorine		Residual	Liste der Aufbereitungsstoffe und Desinfektionsverfahren gemäß § 11 der Trinkwasserverordnung	at the end of the treatment process
Germany	≤	0,3	mg/L	free chlorine		Residual	Liste der Aufbereitungsstoffe und Desinfektionsverfahren gemäß § 11 der Trinkwasserverordnung	at the end of the treatment process

Hungary	≤	0,2	mg/L	other	Chlorite	Residual	201/2001. (X. 25.) Gov. decree, Annex 1, Table B) (page 21)	Required to aim at a value as low as possible without the risk of inappropriate disinfection
Hungary	≤	3	mg/L	combined chlorine		Residual	201/2001. (X. 25.) Gov. decree, Annex 1, Table B) (page 21)	Required to aim at a value as low as possible without the risk of inappropriate disinfection
Hungary	≤	250	mg/L	other	Chloride	Residual	201/2001. (X. 25.) Gov. decree, Annex 1, Table C) (page 23)	Water is required not to be agressive
Hungary	≤	100	mg/L	other	Chloride	Residual	201/2001. (X. 25.) Gov. decree, Annex 1, Table D) (page 25)	In case of karstic waters, groundwaters and bank filtered waters
Poland		0 - 0,3	mg/L	free chlorine		Residual	Dz.U. 2017 poz. 2294, Rozporządzenie Ministra Zdrowia z dnia 7 grudnia 2017 r. w sprawie jakości wody przeznaczonej do spożycia przez ludzi	at the point of inlet to the consumer
Poland		0,3-0,5	mg/L	free chlorine		Residual	Dz.U. 2017 poz. 2294, Rozporządzenie Ministra Zdrowia z dnia 7 grudnia 2017 r. w sprawie jakości wody przeznaczonej do spożycia przez ludzi	permissible concentration of free chlorine in the water storage tank in land, air or water transport
Portugal		0,2-0,6	mg/L	free chlorine		Residual	Decreto-Lei n.º 306/2007 (changed by Decreto-Lei n.º 152/2017)	Tap
Portugal		0,1-0,4	mg/L	other	chlorine dioxide	Residual	Decreto-Lei n.º 306/2007 (changed by Decreto-Lei n.º 152/2017)	Tap
Slovakia	<	0,3	mg/L	free chlorine		Residual	Vyhláška č. 247/2017 Z. z. Vyhláška Ministerstva zdravotníctva Slovenskej republiky, ktorou sa ustanovujú podrobnosti o kvalite pitnej vody, kontrole kvality pitnej vody, programe monitorovania a manažmente rizík pri zásobovaní pitnou vodou	Indicators investigated for disinfection and chemical treatment of drinking water

Slovakia	<	250	mg/L	other	Chlorides	Residual	Vyhláška č. 247/2017 Z. z. Vyhláška Ministerstva zdravotníctva Slovenskej republiky, ktorou sa ustanovujú podrobnosti o kvalite pitnej vody, kontrole kvality pitnej vody, programe monitorovania a manažmente rizík pri zásobovaní pitnou vodou	Indicators that may adversely affect the properties of drinking water: Drinking water must not be aggressive.
Spain	≤	2	mg/L	combined chlorine		Residual	Real Decreto 140/2003	Tap
Spain	≤	1	mg/L	free chlorine		Residual	Real Decreto 140/2003	Tap
Spain	≤	250	mg/L	other	chloride	Residual	Real Decreto 140/2003	Tap
Slovenia	≤	250	mg/L	other	chloride	Residual	Rules on drinking water, Annex I (Pravilnik o pitni vodi (Uradni list RS, št. 19/04, 35/04, 26/06, 92/06, 25/09, 74/15 in 51/17))	Water is required not to be aggressive.