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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATION

(submitted by the applicant, revised by refMS)

ACIW

Product type 2

Active chlorine released from chlorine

Case Number in R4BP: BC-LG080460-47

Competent Authority: Switzerland

December 2023

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Changes history table

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	Switzerland	BC-LG080460-47	dd.mm.yyyy	Initial assessment	

For national authorisation, future changes will be introduced in the PAR *via* an addendum. The addendum will be a standalone document, displaying the same chapters' structure of the PAR and reporting only the changes under the relevant chapters. At the renewal stage of the national authorisation, the PAR will be consolidated by incorporating all the changes.

1 Conclusion

The biocidal product ACIW is a gaseous biocidal product containing "active chlorine released from chlorine" as active substance. The product is used as a water disinfectant for PT 2 by industrial users for the control of bacteria and algae. The product is composed of 100% active substance.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the use as disinfectant of raw water from wells or rivers for the preparation of industrial water by industrial users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

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

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

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.8 of the PAR. The hazard and precautionary statements of the biocidal product according to Regulation (EC) No 1272/2008 are available in the SPC.

Because the biocidal product consists of 100% active substance, it does not contain any non-active substances (so called "co-formulants"). Therefore, no substances of concern are contained in the biocidal product.

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

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

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

Because the biocidal product consists of 100% active substance, no non-active substances are contained in the biocidal product. Hence, the evaluation of endocrine-disrupting properties according to Regulation (EU) 2017/2100 for the non-active substances is not deemed neccesary.

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

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

Composition

The qualitative and quantitative information on the non-confidential composition of the

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer of the biocidal product is listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

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

Physical, chemical and technical properties

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

Physical hazards and respective characteristics

Physical hazards were assessed. The product is classified as Oxidising Gas Cat. 1 (H270) and Gases under pressure: Liquefied gas (H280). More information is available in section 3.3 of the PAR.

Methods for detection and identification

The product in this dossier is identical to the reference product described in the Assessment Report (AR) of active chlorine released from chlorine (Italy, 2017, revised 2020) (hereafter referred to as AR of Chlorine). Validated analytical methods for the analysis of the active substance and validated analytical methods for monitoring the active substance and residues are available in the active substance dossier (see section 3.4 of the PAR).

Efficacy against target organisms

The biocidal product has been shown to be efficacious against bacteria and algae for the intended use. More information is available in section 3.5 of the PAR.

Risk assessment for human health

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

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

Based on the risk assessment, it is unlikely that the intended use causes any unacceptable acute or chronic risk to industrial users and industrial bystanders, if the directions for use as well as the RMMs, as specified in the SPC, are followed.

Dietary risk assessment

Considering the use, food or feed contamination is not expected. As a consequence, the

exposure via food, via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

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

Risk assessment for the environment

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

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

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

Post-authorisation conditions

No post-authorisation conditions are set for this application.

2 Information on the biocidal product

2.1 Product type and type of formulation

Table 2.1 Product type and type of formulation

Product type	PT2
Type of formulation	GA (gas)

2.2 Uses

The intended use as applied for by the applicant and the conclusions by the evaluating competent authority is provided in the table below.

The use "Disinfection of raw water from wells or rivers for the preparation of industrial water" can be very different depending on the individual industrial site and application. The source of the water used for the production of industrial water can come from rivers, wells or reservoirs. And although chlorination helps to control biological growth in filters and decanters (bactericidal action) and removes the color from water (algaecidal action), it is also used to reduce the organic load of the water and improve chemical coagulation.

Chlorine is injected in the water stream via a vacuum system when the water is passing through a pipe. Although this chlorination can be continuous (constant stream of chlorine and water), the water passes the chlorine injector only once, and hence chlorine is added only once, after which its concentration will gradually go down due to oxidation.

After chlorination, the water may be used as such, or undergo further treatment such as chemical coagulation, flocculation/decantation, settling and filtration. After treatment, the water can be stored, used on site, or distributed to different sites. In these cases, the original treatment may be not sufficient to combat new contaminations of the water.

The industrial water can be used for a large variety of applications. However, industrial water should not be used in food production or processing facilities.

The application of chlorine is done in automated, closed installations, dedicated for the use with chlorine gas, and only performed by industrial users. These installations are designed for a specific site, according to local requirements and regulations. Also the storage and handling of chlorine cylinders is highly regulated. An example of a chlorination installation is given in section 6.2 of the confidential annex.

For detailed description of the authorised uses and use instructions, refer to the respective sections of the SPC.

Table 2.2 Overview of uses of the biocidal product

Use number[1]	Use description[2]	PT[3]	Target organisms[4]	Application method[5]	Application rate[6] (min-max)	User category[7]	Conclusion (refMS)[8]	Comment (refMS)[9]
1	Disinfection of raw water from wells or rivers for the preparation of industrial water	PT2	Bacteria Algae	Automated, closed dosing system	5 ppm active chlorine (avCl) ($HClO/OCl^-/Cl_2$)	Industrial	R	The RMMs are based on the human health and the environmenal risk assessment.

[1] Use number (as applied for), as indicated in the SPC
[2] Title of the specific use (as applied for), as indicated in the SPC
[3] Product type(s) of the use(s)
[4] Target organisms, group of organisms
[5] Application method for the specific use
[6] Min-max. application rate of the product for the specific use
[7] User categor(y/ies), e.g. general public, non-professional, professional, industrial
[8] eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

Codes for indicating the acceptability for each use

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

[9] If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

2.3 Identity and composition

The identity and composition of the biocidal product are

identical ☒
not identical ☐

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

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

2.4 Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

Active substance	
ISO name	Active chlorine released from chlorine
Remarks	As per the AR of Chlorine (2017, rev. 2020): *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 and temperature dependent (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.).*
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

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

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

☐ Yes
☒ No

The source has been subject to an assessment of technical equivalence and has been found to be technically equivalent (TE-APP decision number: TAP-D-1382106-34-00/F).

2.6 Candidate(s) for substitution

Active chlorine released from 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.

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

A stepwise approach based on CA-March23-Doc.4.13 was followed to assess the ED properties of the product in this dossier:

1. Assessment of the ED properties of the active substance:
   Since, according to section 2.1. of the above-mentioned CA document, the evaluation of the ED properties of an active substance is carried out under the relevant active substance procedures, no additional data should be requested to assess the ED properties of the active substance in the context of the biocidal product authorisation procedure. As active chlorine released from chlorine is not part of the list of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

   According to the BPC opinion on active chlorine released from chlorine (2016): "Active chlorine released from chlorine is not considered to have endocrine disrupting properties. Active chlorine released from chlorine does not fulfil criterion (d) of Article 5(1)."

2. Assessment of the ED properties of non-active substances (co-formulants):
   Since the product only contains 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.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data available, 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 ACIW.

2.8 Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

	Classification	Labelling
Hazard Class and Category code	Oxidising Gas 1 Press. Gas (Liq. Gas) Acute Toxicity (inhal.) 3 Eye Irritation 2 STOT SE 3 Skin Irritation 2 Aquatic Acute 1	
Hazard Pictograms	GHS03; GHS06; GHS09	GHS03; GHS06; GHS09
Signal word(s)	Danger	Danger
Hazard statements	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.	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.
Precautionary statements*	P220 Keep away from clothing and other combustible materials. P244 Keep valves and fittings free from oil and grease. P273 Avoid release to the environment. P261 Avoid breathing gas. P264 Wash hands thoroughly after handling P271 Use only outdoors or in a well-ventilated area P280: Wear protective gloves/protective clothing/eye protection/face protection. P370 + P376: In case of fire: Stop leak if safe to do so P302 + P352 IF ON SKIN: Wash with plenty of water. P321 Specific treatment (see ... on this label) P332 + P313 If skin irritation occurs: Get medical advice/attention. P362 + P364 Take off contaminated clothing and wash it before reuse. P304+P340+P311 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a doctor P312: Call a doctor if you feel unwell. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/attention	The authorisation holder is responsible to choose the relevant P-statements to be included on the label.

	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.	
Supplemental hazard statements	/	
Notes	According to CLP guidance: *Pictogram GHS04 is not required for gases under pressure where pictogram GHS02 or pictogram GHS06 appears.* Based on AR of Chlorine (2017, rev. 2020) and Harmonised classification.	

*****P-statements that are excluded based on the risk assessment or the intended use of the product[2], are indicated with a strikethrough and possibly different colour. All P-statements listed under the first column have also been listed in the SPC.

[2] Section 3 of the CA note of Q&A concerning the content of some SPC sections. Document is available at https://circabc.europa.eu/w/browse/0179339e-57cc-4f66-b49f-c0b32c21779b.

2.9 Letter of access

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

2.10 Data submitted in relation to product authorisation

No new data on the active substance available.

2.11 Similar conditions of use across the Union

This section is not relevant.

3 Assessment 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 and Switzerland should be constructed and labelled according to the Transportable Pressure Equipment Directive (TPED)/Ordinance on the placing on the market and market surveillance of dangerous goods containers (GGUV) and ADR/SDR. 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.

3.1 Packaging

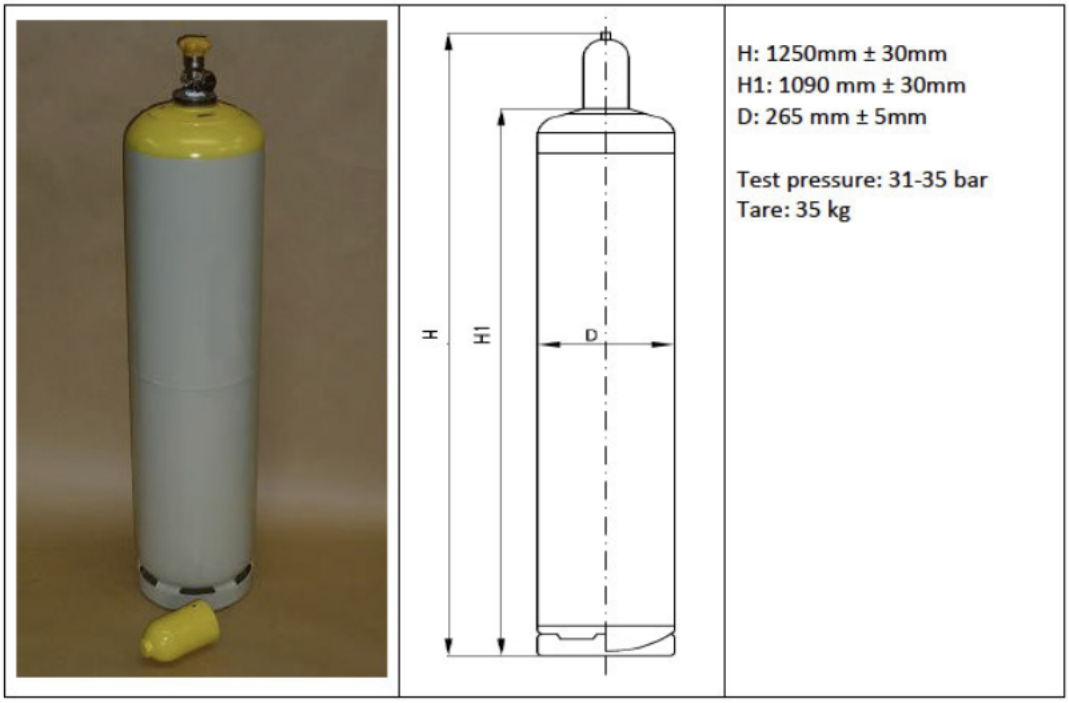
The Assessment Report for chlorine (2017, rev. 2020) states that "container materials must be chosen to suit the conditions under which chlorine is being handled." Compatibility of chlorine with cylinder and valve materials is described in industrial and international standards (e.g., GEST 79/82, ISO 11114-1).
The Assessment Report mentions amongst others steel, fine grain carbon steel and PVDF as usual materials for container materials. ISO 11114-1 further mentions compatibitility with stainless steel for cylinder and valve material, and nickel or brass for valve material.

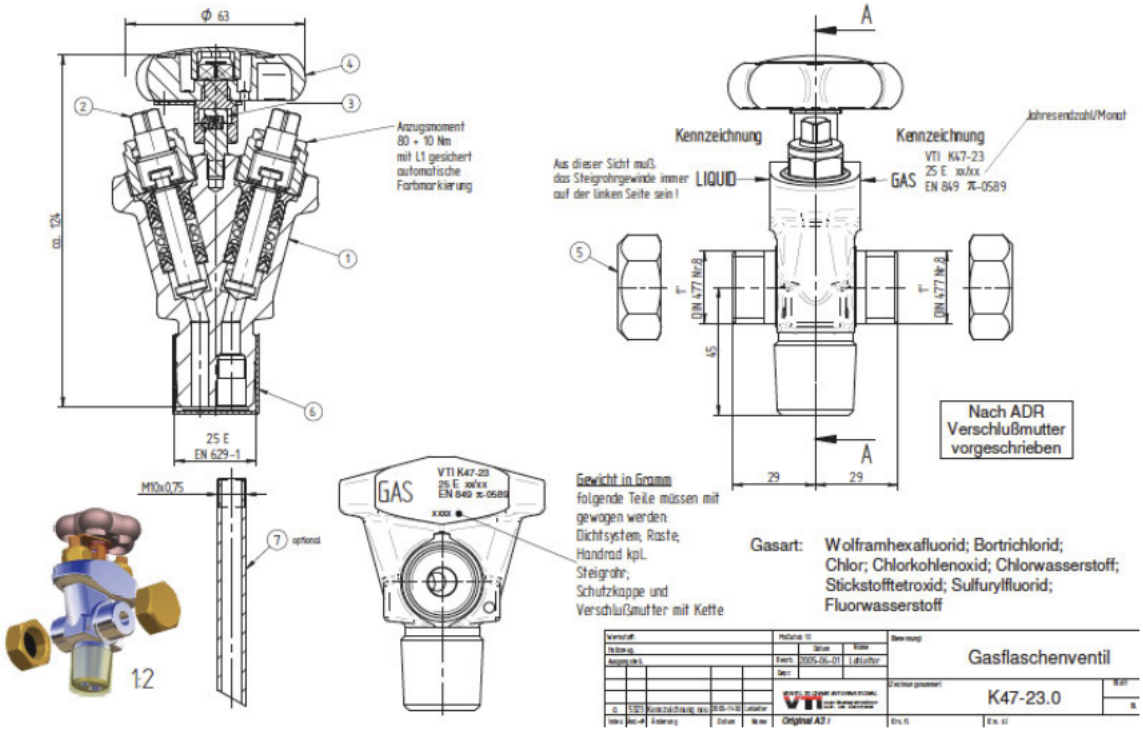
Table 3.1 Packaging

Type of packaging[1]	Size/ volume of the packaging[2]	Material of the packaging[3]	Type and material of closure(s)	Intended user[4]	Compatibility of the product with the proposed packaging materials (Yes/No)
Cylinder	4.8 – 140 L (6-175 kg Cl_2)	Carbon/ stainless steel	Carbon steel/stainless steel/brass/PVDF/ nickel pressure resisting valve	industrial	Yes
Drum	400 – 1,000 L (500-1,250 kg Cl_2)	Carbon/ stainless steel	Carbon steel/ stainless steel/brass/PVDF/ nickel pressure resisting valve	industrial	Yes

[1] Type of packaging e.g. bottle, rolls, can, barrel, tank.
[2] Size for primary packaging (closed packaging that preserves the biocidal product, prevents leakage during storage and is removed or opened before use) and detailed volume in the case of individual packaging intended to be used to prevent human exposure and facilitate the use of the product.
For rolls or individual products such as wipes, the dimension of product / amount of individual products should be reported here: Height*Length*Width for rolls / number and weight of wipes.
[3] For metallic packaging, it should be indicated if there is a varnish layer; in the same way, the nature of plastic packaging should be reported. For sprayer sold with packaging, the nature of the material should be added.
[4] Intended user, e.g. professional, non-professional

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 15 bar for 30 sec.
9) Adding the new barcode and date of the next check.

Comment by the refMS:
In July 2018, the APCP working group decided that a storage stability test is not required for pressure cylinder/drums as such a test is technically not feasible. Therefore the packaging material of these pressure receptables and their closures are not in the scope of the evaluation conducted by the refMS. The applicant is responsible to ensure that the pressure vessels and the procedure used to handle them are compliant to (inter)national norms and regulations regarding safe handling of chlorine drums/cylinders.

3.2 Physical, chemical, and technical properties

The product in this dossier is liquefied chlorine under pressure (≥ 99.5% w/w, in compliance with EN 937:2009), and is identical to the reference product described in the AR of Chlorine (2017, rev. 2020). Therefore, reference is made to the AR of Chlorine for most physical-chemical properties. Furthermore, chlorine is a well-characterised basic chemical of which the physical-chemical properties are already extensively investigated and published.
According to the AR of Chlorine, physical-chemical data on e.g. density and acidity should be provided during product authorization, as well as a storage stability study (including reactivity towards container material) and a study on the effect of light, temperature and humidity on the product. However, as the product in this dossier is identical to the reference product, a rationale is given to waive these tests, or reference is made to available literature. This is in accordance with the conclusions of the APCP WG IV 2018.

Table 3.2 Physical, chemical, and technical properties

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Evaluation by the refMS
3.1.	Appearance at 20°C and 101.3 kPa	Refer to AR of Chlorine	≥99.5%	Greenish-yellow with characteristic stringent odour gas	AR of Chlorine (2017, rev. 2020)	Information acceptable.
3.1.1.	Physical state at 20°C and 101.3 kPa					
3.1.2.	Colour at 20°C and 101.3 kPa					
3.1.3.	Odour at 20°C and 101.3 kPa					
3.2.	Acidity, alkalinity and pH value	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 APCP of July 2018 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 use "raw industrial water from river water". The details are given below.			Information acceptable as agreed by the WG APCP of July 2018.
		Monitoring of pH value: Equipment for pH measurement: portable measuring equipment, CRISON, model MM40	Source of water: [redacted] river - Chlorination is performed in raw water in the Rapid Mixing Chamber right after entry in the WTP.	pH value is around 8.1 in the entrance of WTP (before chlorination) and around 7.9 in the Rapid Mixing Chamber (after chlorination) Overall, the pH remains between 7.7 to 8.3 for both	Process Control of [redacted] Water Treatment Plant - pH, 29/05/20, by [redacted]	Data acceptable. The data covers the intended use and the application rate specified.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Evaluation by the refMS
				measuring, with doses of 3 - 5 mg/L active chlorine		
3.3.	Relative density / bulk density	Refer to AR of Chlorine	The density of compressed liquid chlorine (purity: ≥99.5%) is reported in the AR to be 1.411 kg/dm3 (20°C, 10 kg/cm2 pressure). The density of chlorine varies with temperature and pressure, and is no constant value. Chlorine is stored in steel cylinders and tanks. Once connected to the chlorination installation, chlorine will start to flow from the receptacle. The flow rate will depend on the temperature and the amount of chlorine in the receptacle. As the volume of chlorine in the receptacle will decrease, also the pressure decreases and hence the density will decrease.		AR of Chlorine (2017, rev. 2020) Euro Chlor document GEST 91/168.	Information acceptable
3.4.1.1.	Storage stability test – **accelerated storage**	• Chlorine is stored under pressure in steel cylinders (6-175 kg) or drums (500-1250 kg). Chlorine packages for use in Switzerland or within the EU should be constructed according to the Ordinance on the placing on the market and market surveillance of dangerous goods containers (GGUV) and SDR or Transportable Pressure Equipment Directive (TPED) and ADR respectively. Compliance with GGUV/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			Guidance on the design and construction of chlorine packages is given in the GEST documents 88/138 and 79/76.	Information/Waiver acceptable as agreed by the WG APCP of July 2018.
3.4.1.2.	Storage stability test – **long-term storage at ambient temperature**					

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Evaluation by the refMS
		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. • As the product (chlorine) itself is stable, and a cylinder still may contain traces of product from previous fillings, a shelf-life is not considered relevant for this product. Furthermore, in case the current national and European regulations are followed, a chlorine cylinder (and his content) should not be used for more than 5 years.			

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Evaluation by the refMS
3.4.1.3.	Storage stability test – **low temperature stability test for liquids**	Waived	Storage should be done at temperatures >15°C to guarantee a good flow of chlorine from the gas bottle. Considering that this requirement is stricter than the default RMM "protect from frost", an adapted RMM "Store at a temperatures >15°C" will be added to the label.			Waiver based on label instruction acceptable.
3.4.2.1.	Effects on content of the active substance and technical characteristics of the biocidal product – **light**	Refer to AR of Chlorine	Not applicable: - container under pressure: exposure to elevated temperatures (max. 50°C) or direct sunlight during storage not allowed.[3] - dry chlorine at ambient temperature does not attack steel, copper or nickel, but reactivity of these metals is observed at higher temperatures (>200°C).[4]		AR of Chlorine (2017, rev. 2020)	Waiver acceptable as stainless steel containers are not transparent.
3.4.2.2.	Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**					Waiver acceptable based on statement provided above for the storage stability tests.
3.4.2.3.	Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Refer to AR of Chlorine and ISO 11114-1:2020[5]	Chlorine is compatible with all materials except aluminium, and 316 type stainless steels are recommended (Group 8 gasses).		AR of Chlorine (2017, rev. 2020) ISO 11114-1:2020[5]	Waiver acceptable based on statement provided above for the storage stability tests.
3.5.1.	Wettability	Waived	Not applicable since biocidal product is not a solid			Waiver based on

[3] According to EN 937:2016
[4] "Safe handling of chlorine from drums and cylinders" (2nd edition), HSE 1999
[5] ISO 11114-1 third edition (2020-05): Gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 1: Metallic materials

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Evaluation by the refMS
			preparations to be dispersed in water.			product formulation/physical state acceptable.
3.5.2.	Suspensibility, spontaneity, and dispersion stability	Waived	Not applicable since biocidal product does not need to be diluted.			Waiver based on product formulation acceptable.
3.5.3.	Wet sieve analysis and dry sieve test	Waived	Not applicable since biocidal product is a gas.			Waiver based on physical state acceptable.
3.5.4.	Emulsifiability, re-emulsifiability and emulsion stability	Waived	Not applicable since biocidal product does not need to be emulsified.			Waiver based on product formulation acceptable.
3.5.5.	Disintegration time	Waived	Not applicable since biocidal product is not a tablet and is not used in a water-soluble bag.			Waiver based on product formulation acceptable.
3.5.6.	Particle size distribution, content of dust/fines, attrition, friability	Waived	Not applicable since biocidal product is not a granule or tablet.			Waiver based on product formulation acceptable.
3.5.7.	Persistent foaming	Waived	Not applicable since biocidal product is a gas.			Waiver based on product formulation/physical state acceptable.
3.5.8.	Flowability/pourability/dustability	Waived	Not applicable since biocidal product is not granular/a suspension.			Waiver based on product formulation acceptable.
3.5.9.	Burning rate — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.			Waiver acceptable, product is not a smoke generator.
3.5.10.	Burning completeness — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.			Waiver acceptable, product is not a smoke generator.
3.5.11.	Composition of smoke — smoke generators	Waived	Not applicable since the biocidal product is no smoke generator.			Waiver acceptable, product is not a smoke generator.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product/batch (AS% w/w)	Results	Reference	Evaluation by the refMS
3.5.12.	Spraying pattern — aerosols / spray	Waived	Not applicable since the biocidal product is not an aerosol.			Waiver acceptable, product is not a smoke generator.
3.6.1.	Physical compatibility	Waived – see AR of Chlorine	Avoid heat or temperatures above 50°C. Do not expose to direct sunlight. The product is not intended to be used in combination with other products.			Waiver acceptable since the product is not intended to be used with other products.
3.6.2.	Chemical compatibility	Waived – see AR of Chlorine	The product is not intended to be used in combination with other products[6]			Waiver acceptable.
3.7.	Degree of dissolution and dilution stability	Waived	Not applicable since biocidal product is a gas.			Waiver based on product formulation/physical state acceptable.
3.8.	Surface tension	Refer to AR of Chlorine	≥99.5%	18.2 mN/m (20°C) (calculated for liquid chlorine)	AR of Chlorine (2017, rev. 2020)	Information acceptable.
3.9.	Viscosity	Refer to AR of Chlorine	≥99.5%	12.4×10^{-3} Pa.s (0°C) 13.3×10^{-3} Pa.s (20°C) (calculated for gaseous chlorine)	AR of Chlorine (2017, rev. 2020)	Information acceptable.

[6] Moreover, it is specified in the AR 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).

Table 3.3 Conclusion on physical, chemical, and technical properties

Conclusion on physical, chemical, and technical properties
The product in this dossier is identical to the active substance releaser chlorine described in the Assessment Report (2017, rev. 2020). It is a greenish-yellow gas with a characteristic stringent odour. The density of compressed liquid chlorine is reported in the AR to be 1.411 kg/dm^3 (20°C, 10 kg/cm^2 pressure). The density of chlorine varies with temperature and pressure, and is no constant value under the storage and use conditions of this product. Based on the chemical and technical properties of the product and the safety regulations in place for the transport, handling and storage of chlorine, the stability of the product is assured. Hence, no shelflife is defined. 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^{-3} Pa.s. **Implications for labelling:** Keep containers with chlorine tightly closed and store in a cool, dry and well-ventilated place. Tightly screw on the valve outlet protection seal and the valve protection cap when storing. Prevent cylinders from falling over. Protect from heat and direct sunlight, the temperature of the container should never be below 15°C and > 50°C. 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).

3.3 Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Evaluation by the refMS
4.1.	Explosives	Waiver	- There are no chemical groups associated with explosive properties present in the molecule of chlorine - According to the AR of Chlorine: not applicable to gases		Waiver acceptable based on evaluation in CAR: Waiver based on physical state acceptable.
4.2.	Flammable gases	Refer to AR of Chlorine (2017, rev. 2020)	≥99.5%	Flash-point: not applicable to gases Chlorine is known to be a non-flammable gas	Waiver based on CAR acceptable.
4.3.	Flammable aerosols	Waiver	Not relevant for the formulation type		Waiver based on formulation type acceptable.
4.4.	Oxidising gases	The applicant refers to the revised AR of Chlorine (November 2020). According to the AR 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.			Information acceptable. Classification as oxidizing gas required based on the revised assessment report.
4.5.	Gases under pressure	According to the harmonised classification and the AR of 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." The boiling point of chlorine is -34°C at 100 kPa and the critical			Information from harmonised classification is acceptable. Chlorine is a pressurised gas. Based on the properties of the gas (critical temperature), it needs to be classified as Liquefied Gas.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Evaluation by the refMS
		temperature is 144°C (EN937:2016)[7]. The vapour pressure at 50°C is > 300 kPa (GEST 79/76, 4th edition)[8]. Considering the CLP classification criteria, the product is therefore to be classified as a (low pressure) liquefied Gas: A gas which, when packaged under pressure, is partially liquid at temperatures above -50°C, with a critical temperature above +65°C. **H280: Contains gas under pressure; may explode if heated.**			
4.6.	Flammable liquids	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.7.	Flammable solids	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.8.	Self-reactive substances and mixtures	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.9.	Pyrophoric liquids	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.10.	Pyrophoric solids	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.11.	Self-heating substances and mixtures	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.12.	Substances and mixtures which in contact with water emit flammable gases	Waiver	Chlorine is a gas at room temperature and normal pressure, and upon contact with water forms hypochlorous acid (HClO), which is in equilibrium with the hypochlorite ion (ClO-). This means that chlorine (Cl2) itself is no longer available.		Waiver based on physical state acceptable.
4.13.	Oxidising liquids	Waiver	Not relevant for the formulation type		Waiver based on physical state

[7] NBN EN 937:2016 – Chemicals used for the treatment of water intended for human consumption – Chlorine.
[8] Euro Chlor, GEST 79/76, 4th edition, January 2009: Design and construction of fixed tanks and tank containers for the transport of liquid chlorine by road.

Numbering according to Annex III of BPR	Property	Guideline and Method	Tested product / batch (AS% (w/w)	Results	Evaluation by the refMS
					acceptable.
4.14.	Oxidising solids	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.15.	Organic peroxides	Waiver	No bivalent O – O - structure		Waiver based on chemical structure acceptable.
4.16.	Corrosive to metals	Waiver	According to the Guidance to Regulation (EC) No1272/2008 on CLP of substances and mixture), neither the corrosivity of gases nor the formation of corrosive gases is currently covered by CLP classes and are therefore not applicable here.		Waiver based on physical state acceptable.
4.17.1.	Auto-ignition temperatures of products (liquids and gases)	Waiver	According to the AR of Chlorine, the testing is not required for gases having no flammable range.		Waiver based on the information in the CAR acceptable.
4.17.2.	Relative self-ignition temperature for solids	Waiver	Not relevant for the formulation type		Waiver based on physical state acceptable.
4.17.3.	Dust explosion hazard	Waiver	Not relevant for the formulation type		Wavier based on formulation type acceptable.

Table 3.5 Conclusion on physical hazards and respective characteristics

Conclusion on physical hazards and respective characteristics
The physical hazards of the biocidal product have been assessed, the product is classified as - Oxidsing Gas Cat. 1 (H270) - Gases under pressure: Liquefied gas (H280)

3.4 Methods for detection and identification

The product in this dossier is identical to the reference product described in the AR of Chlorine (2017, rev. 2020). Therefore, reference is made to the available methods in the AR of 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.

Residues analysis

The active substance is active chlorine released from chlorine, which is thought to consist of chlorine (Cl_2), hypochlorous acid (HClO) and hypochlorite anion (ClO^-) in equilibrium. The predominant species will depend on pH value (chlorine is available only at pH < 4, hypochlorous acid is predominant in the range 4 to 5.5, whereas only hypochlorite anion is present at pH > 10).

At the in-use pH values in PT2, chlorine is virtually non-present at the equilibrium, whereas the predominant species are the hypochlorite anion and the hypochlorous acid.

Table 3.6 Analytical methods for soil

Analytical methods for soil
Residue definition: HClO/ClO^- Not required. For none of the intended uses, soil is the first receiving compartment. Environmental exposure is expected via the facility drain into the STP. Active chlorine (HClO/ClO^-) can reach the soil compartment only indirectly, via sewage sludge: rapid degradation occurs already with organic matter therein. In the event of contamination of soil, e.g. due to direct application of chlorinated water, active chlorine would react rapidly with organic matter in soil anyway. (Assessment Report (AR) of Chlorine (2017, rev. 2020)

Table 3.7 Analytical methods for air

Analytical methods for air
Residue definition: HClO/ClO^- Hypochlorite is a non-volatile species. Hypochlorous acid is volatile, but according to literature data, the Henry's Law constant is ≈ 0.1 Pa m^3 mol^{-1}, i.e. volatilization from the aqueous phase is expected to be slow. Furthermore, there are indications that the half-life is only a few hours, i.e. much shorter than the value derived by Atkinson calculation. So occurrence in air is not probable for this species either. In PT2, chlorine is handled exclusively in closed systems and exposure to the gas is not expected, but during connecting/disconnecting of chlorine vessels.

Two analytical methods[9,10] are available in the Assessment Report (AR) of Chlorine (2017, rev. 2020) to monitor human exposure, which allow the determination of chlorine in workplace air in the range 0.3 – 7.0 mg Cl_2/m^3. In principle, the range can be expanded. Though not validated, the two available methods are published methods, so they can still be concluded to be acceptable for the purpose (determination of chlorine in workspace air).

(Assessment Report (AR) of Chlorine (2017, rev. 2020)

Table 3.8 Analytical methods for water

Analytical methods for water
Drinking water Residue definition: $HClO/ClO^-$ and relevant metabolite chlorate (ClO_3^-) A fully-validated analytical method of active chlorine ($HClO/ClO^-$) residues in drinking water is available, using N,N-diethyl-p-phenylenediamine (DPD) and a double-beam photometer (λ = 510 nm), as specified in *DIN EN ISO 7393-2:2000 Water quality - determination of free chlorine and total chlorine - part 2: colorimetric method using n,n-diethyl-1,4-phenylenediamine, for routine control purposes*. The method enables the determination of active chlorine in water down to 30 µg/L, by formation of a red compound in the pH range 6.2 to 6.5. The method is a colorimetric method and, therefore, not 'highly specific' in the meaning of the BPR guidance Vol. I, Parts A+B+C (Version 2.0, May 2018). However, the test system given *by DIN EN ISO 7393-2:2000* is historically well-known and readily applicable to field testing (commercial kits are available for in-field determination, e.g. by potable water-network technicians), so it can be considered specific enough for the purpose. A fully validated analytical method is also available for the relevant metabolite chlorate (ClO_3^-), using HPLC coupled with tandem mass spectrometry. The method was validated at 0.1 µg/L and 1.0 µg/L according to SANCO/825/00 rev. 8.1. Residues of chlorate in drinking water were analysed by direct injection into the HPLC-MS/MS system. Detection was carried out by an ionspray tandem mass spectrometer in SRM mode. **Surface water** Residue definition: $HClO/ClO^-$ Not required. Environmental exposure is expected via the facility drain into the STP, but rapid degradation occurs with organic matter therein. Rapid degradation occurs also with the organic matter in surface water ($DT_{50surface\ water}$ = 56 min at environmental temperature). (Assessment Report (AR) of Chlorine (2017, rev. 2020)

Table 3.9 Analytical methods for animal and human body fluids and tissues

Analytical methods for animal and human body fluids and tissues
Residue definition: $HClO/ClO^-$ Not required. Hypochlorous acid/ hypochlorite anion are oxidizing agents and degrade rapidly with organic matter. Besides, due to corrosive properties, systemic toxicity would be secondary to local

[9] Reference: OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; Smith & Cochran Spectrophotometric determination of Free Chlorine in Air using Sulphamic acid/Tri-iodide procedure - Anal Chem 1986 Vol 58 pp 1591-1592

[10] Reference: OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; NIOSH free chlorine in air 01.01.75; ISO 7392/2 Water quality – Determination of free and total chlorine Part 2 Colorimetric method using DPD for routine control purposes 15.10.85

effects. Nevertheless, in case of an accidental release of chlorine, the analytical methods available for the monitoring of chlorine in workplace air are meaningful for monitoring human exposure.

Table 3.10 Analytical methods for monitoring of active substances and residues in food and feeding stuff

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Not required under PT2.

Table 3.11 Conclusion on methods for detection and identification

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

3.5 Assessment of efficacy against target organisms

The dossier covers the following use:

Use #1	Disinfection of raw water from wells or rivers for the preparation of industrial water (PT2)

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

MG 01: Disinfectants

PT2: Disinfectants and algaecides not intended for direct application to humans or animals. The products are used for protection of humans from pathogenic organisms which may result in spreading of contagious disease due to contact with contaminated surfaces or contaminated water (e.g. swimming pool or waste water).

Field of use: indoor. The chlorination is always done in a closed system (=indoor); the use of treated water can be both indoor and outdoor; industrial settings.

Target organisms: bacteria, algae

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

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

The active chlorine (or available chlorine) is the sum of three substances in equilibrium: hypochlorite ion (OCl^-), hypochlorous acid (HClO) and chlorine (Cl_2) The equilibrium depends 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.

Unacceptable suffering is not applicable for the intended uses.

The chlorination and the oxidation reactions 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) active chlorine is able to inhibit bacterial growth. In this case the proteins of the membrane are partly destroyed, and the bacteria and algae are not able to multiply.

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

3.5.3 Efficacy data

Upon dilution in water, chlorine will form active chlorine, also referred to as available chlorine (avCl), 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. To demonstrate the efficacy of the BP in this dossier, microbial efficacy tests are included which are performed on an aqueous dilution of NaOCl. The content of NaOCl can be converted from chlorine (Cl_2) content using the following conversion factor (Mw_{NaOCl}/Mw_{Cl2} = 74.44/70.91=1.05). Nevertheless, since the results are given as active chlorine, no conversion is needed.

The efficacy tests described in the table below are performed with an aqueous dilution of NaOCl, without adding any co-formulants. An efficacious concentration will be set per use and per target organism and is based on the requirements specified in the BPR guidance Vol. II: Efficacy, Parts B+C (Version 4.1, Feb. 2022)'.

Table 3.12 Efficacy data

PT and use number	Test product	Function / Test organism(s)	Test method / Test system / concentrations applied / exposure time	Test results: effects	Reference	Number in IUCLID section 6.7/Test report title
PT2 Use #1	Natriumhypochloridlsg. 5% Batch: 3610031115-006-006 5% NaOCl	Bactericide *S. aureus* *E. coli* *E. hirae* *P. aeruginosa*	P2S1 EN1276:2019 Temperature: 15°C ± 1°C Contact time: 25 min Dirty conditions: 3.0 g/L bovine albumin Test conc: 10 + 250 + 500 + 750 + 1500 ppm NaOCl pH 500 ppm = 8.9	Pass conc: 500 ppm NaOCl (=475 ppm avCl) Log R > 5 Dirty conditions (3.0 g/L bovine albumin) 25 min; 15°C Controls ok	Test report or test number: L20/0110.1 Author: H. Gabriel & A. Kampe Year: 2020	1_EN1276_bacteria_15°C_25min_3g/L BSA
PT2 Use #1	Sodium hypochlorite solution 5% Batch: 361003111	Algaecide *Chlorella vulgaris*	P2S1 Modified EN1276:2009 + OECD 201:2011 Temperature: 15°C ± 1°C	Pass conc: 250 ppm NaOCl (=237.5 ppm avCl) Log R > 3 Dirty conditions (20	Test report or test number: STULV20AA0745-1 Author: C. Giarei Year: 2020	2_EN1276_algae_15°C_25min_20 mg/L DOC

	5 5% NaOCl		Contact time: 25 min Dirty conditions: 20 mg/L DOC. (see 3.5.4) Test conc: 10 + 250 + 500 + 750 + 1500 ppm NaOCl	mg/L DOC) 25 min; 15°C Controls ok		
PT2 Use #1	Sodium hypochlorite solution 5% Batch: 361003111 55% NaOCl	Algaecide *Chlorella vulgaris* *Anabaena flos-aquae*	P2S1 Modified EN1276:2009 + OECD 201:2011 Temperature: 15°C ± 1°C Contact time: 25 min Dirty conditions: 20 mg/L DOC (see 3.5.4) Test conc: 500 ppm NaOCl	Pass conc: 500 ppm NaOCl (=475 ppm avCl) Log R > 3 Dirty conditions (20 mg/L DOC) 25 min; 15°C Controls ok	Test report or test number: STULV20AA1294-1 Author: C. Giarei Year: 2020	3_EN1276_algae_15°C_25min_20 mg/L DOC
PT2 Use #1	Sodium hypochlorite solution 5% Batch: 20200730_01 Sodium Hypochlorite as active chlorine 5.2% w/w	Bactericide *S. aureus*	**P2S2** **Simulated use test** ASTM E645-18 + EN1276:2019 (screening test) Temperature: 15°C ± 1°C Contact time: 10 min + 25 min Dirty conditions: Natural soiling (source 1) Test conc: 500 ppm + 250 ppm + 100 ppm + 50 ppm + 10 ppm + 5 ppm + 2.5 ppm active chlorine	Pass conc: 5 ppm avCl Log R > 2 after 10 min + Log R > 4 after 25 min Dirty conditions (Natural soiling); 10 min; 15°C Controls ok	Test report or test number: STULV20AA4289-1 Author: A. De Bortoli Year: 2022	4_sim-use_bacteria(screening)_15°C_10 &25min_natural soiling
PT2 Use #1	Sodium hypochlorite solution 5% Batch: 20200730_01	Bactericide *E. coli* *E. faecium*	P2S2 Simulated use test ASTM E645-18 + EN1276:2019 Temperature: 15°C ± 1°C	Pass conc: 5 ppm avCl Log R > 2 after 10 min + Log R > 4 after 25 min Dirty conditions	Test report or test number: STULV20AA4360-1 Author: C. Carloni Year: 2020	5_sim-use_bacteria_15°C_10&25min_natural soiling

	Sodium Hypochlorite as active chlorine 5.2% w/w	*S. aureus*	Contact time: 10 min + 25 min Natural soiling (source 1 = 30 ppm TOC + sources 2+3 approx. 3 ppm TOC) Test conc: 5 ppm active chlorine	(Natural soiling); 15°C Controls ok		
PT2 Use #1	Sodium hypochlorite solution 5% Batch: 20200730_01 Sodium Hypochlorite as active chlorine 5.2% w/w	Algaecide *Chlorella vulgaris* *Anabaena flos-aquae*	P2S2 Simulated use test ASTM E645-18 Dilution-neutralisation Temperature: 15°C Contact time: 25 min Natural soiling (source 1 = 30 ppm TOC and sources 2+3 = approx. 3 ppm TOC) Test conc: 5 ppm active chlorine	Pass conc: 5 ppm avCl Reduction >95% after 25 min contact time Dirty conditions (Natural soiling); 15°C Controls ok	Test report or test number: STULV20AA4368-1 Author: C. Giarei Year: 2020	6_sim-use_algae_15°C_10&25min_natural soiling

3.5.4 Efficacy assessment

Use #1	Disinfection of raw water from wells or rivers for the preparation of industrial water (PT2)

The product is intended for the disinfection of raw water from wells or rivers for the preparation of industrial water.

Target organisms: bacteria, algae

The BPR guidance Vol. II: Efficacy, Parts B+C (Version 4.1, Feb. 2022) does not make any recommendations for this use.
During EFF WG-V-19, the following test setup and pass criteria were agreed:

- P2S1:
  - Temperature: 15°C
  - Same contact time as simulated use test
  - Dirty conditions:
    - Bacteria: 3 g/L BSA
    - Algae: 15-20 mg/L DOC
  - Pass criteria:
    - Bacteria: 5 log reduction
    - Algae: 3 log reduction
- Simulated use:
  - Natural soiling
  - Pass criteria bacteria: 2 log R in 10 min AND 4 log R in 25 min
  - Pass criteria algae: surviving algae (CFU) decline >95%

For the simulated use test, 3 water samples were collected from 3 different water sources (reservoir – river – well). The samples were frozen immediately after sampling and analysed at the lab before start of the tests. Bioburden and physical-chemical characteristics (conductivity, salinity, TDS, pH, DO, TOC, DOC) were determined. More information on the origin of the samples is included in IUCLID section 6.7.

Parameter (average from 3 measurements)	**Source 1 (reservoir)**	**Source 2 (river)**	**Source 3 (well)**
Conductivity (mS/cm)	169.6	11.33	72.07
Salinity (g/kg)	>70.0	6.4	47.93
Total Dissolved Solids (mg/L)	>2000	>2000	>2000
pH	7.82	5.96	6.27
Dissolved oxygen (mg/L)	5.46	5.77	6.56
TOC (ppm)	29.97	3.869	2.901
DOC (ppm)	29.91	3.632	2.873
Bioburden (cfu/mL)	6.65×10^3	5.0×10^1	6.8×10^1

Water samples to be used for testing of bacteria were sterilized by autoclaving. Water samples to be used for testing of algae were sterilized by filtration.

Bacteria and algae that are relevant for industrial water were selected for the simulated use tests. For bacteria E. coli, E. faecium and S. aureus were tested. P. aeruginosa was not tested because this species was less tolerant in the P2S1 test than E. hirae and S. aureus.

The applicant has submitted modified P2S1 tests and simulated-use tests with sterilized water from 3 different sources for bacteria and algae. The following results were achieved:

- P2S1: bacteria and algae: 500 ppm NaOCl, 25 min, 15°C, dirty conditions
- Simulated use: bacteria and algae: 5 ppm active chlorine, 25 min, 15°C, dirty conditions

Justification for derivation of the efficacious concentration

The BPR guidance Vol. II: Efficacy, Parts B+C (Version 4.1, Feb. 2022) refers to the European standard EN 14885 for general information on the application and interpretation of standards for the testing of chemical disinfectants within PT 1-4. According to EN 14885:2022, Annex C.4, the following should be considered in defining a use dilution for the product and application:

"In defining a use dilution for the product and application the following should be considered:
When the product dilution required to pass one phase or step is significantly higher than that required to pass the other phases or steps, the recommended use dilution should be chosen taking into account the intended use of the product in relation to the design of the tests.
This can happen, for example where results from phase 2, step 1 and phase 2, step 2 tests are inconsistent with each other or with those of a valid field trial.
In such a case tests which are as close as possible to the practical application should be preferred to recommend a use dilution for the product. Therefore, where infection prevention is not indicated, it may be justified to support a claim based on the more relevant test result (phase 2, step 1 or phase 2, step 2) even if it was not the hardest to pass."

In the simulated use tests, raw water was used from 3 different sources (see details in PAR section 3.5.3 and IUCLID section 6.7). This is closer to the real use of the product and data from these tests are therefore more relevant to define the in-use concentration for the claimed use.

Below, the different concentrations obtained in the P2S1 (EN1276) suspension and simulated use tests are compared and discussed in detail.

Bacteria:

Soiling

The simulated use test was performed under realistic dirty soiling conditions (= natural soiling in water: min 3 mg/L, max 30 mg/L DOC), in comparison with a 100 – 1000 times higher amount of soiling (3000 mg/L bovine albumin) in the P2S1 test EN1276. As chlorine rapidly reacts with organic matter, the soiling has a major impact on the amount of residual active chlorine available for disinfection.

Pass criteria

The number of bacteria that was introduced for the P2S1 (EN1276) suspension test was 10^7 cfu/ml, and to pass the test with a Log 5 reduction implies that 10^5 of bacteria have to be killed. This amount is about 100 times higher than the maximal cellular density of naturally occurring bacteria in the water sources used. The bioburden/ cellular density in the natural water sources used was at minimum 5.0×10^1 cfu/ml and at maximum 6.65×10^3 cfu/ml (see above: table with the parameters of the 3 sources).

In the simulated use test against bacteria, performed under relevant dirty soiling conditions, the required Log 4 reduction was reached at a concentration of 5 ppm active chlorine. This implies that with 5 ppm active chlorine, 10^4 of bacteria are killed, which is at least 10 times more than the highest cellular density of naturally occurring bacteria in the water sources used.

Algae:

The number of cells that was introduced for the P2S1 (EN1276) suspension test (10^7 cfu/ml for Chlorella; 10^6 cfu/ml for Anabaena) is 100 times higher than the number of cells introduced during the simulated use testing (10^5 cfu/ml for Chlorella; 10^4 cfu/ml for Anabaena), implying that more cells must be killed in the P2S1 (EN1276) suspension test.

Further, it should be noted that the quantification of vitality/growth of algae in the P2S1 (EN1276) suspension test was performed using a spectrophotometer. Since the method used to evaluate the cell density by spectrophotometer is less accurate for the quantification of live microorganisms, CFUs growth is normally used as the standard method to assess efficacy in all EN tests.

In the simulated use test performed against algae, exact CFUs growth were determined, and the reduction required was reached at a concentration of 5 ppm active chlorine.

Conclusion
Considering that factors such as soiling, bioburden/cellular density in natural water source and method of detection have an impact on the efficacious concentration resulting from the testing, the simulated use tests provided have demonstrated efficacy under conditions most appropriate for the intended use of the product.
This conclusion is in line with the BPR guidance Vol. II: Efficacy, Parts B+C (Version 4.1, Feb. 2022) and the standard EN14885 which support the idea that tests which are as close as possible to the practical use should be preferred for recommending a use dilution and contact time for the product.

The conclusion above justifies the following dose determined by simulated use tests for both bacteria and Algae:

- Dirty conditions (natural soiling), 25 min, 15°C:
  - Mandatory target: bacteria: 5 ppm active chlorine
  - Optional target (but mandatory included): algae: 5 ppm active chlorine

3.5.5 Conclusion on efficacy

Based on the efficacy data and the justification provided in PAR section 3.5.3, the following conclusions are made:

Conditions of use	Mandatory target	Optional target (mandatory included)
Use #1 – Disinfection of raw water from wells or rivers for the preparation of industrial water (PT2)		
Dirty conditions (natural soiling), 25 min, 15°C	Bacteria: 5 ppm active chlorine	Algae: 5 ppm active chlorine

3.5.6 Occurrence of resistance and resistance management

Although different species vary in their sensitivity to chlorine, development of acquired

resistance is not expected since its multiple molecular sites of attack on the surface and within the microbial cells. 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.

3.5.7 Known limitations

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

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

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

3.6 Risk assessment for human health

The product in this dossier is pure chlorine gas, without the addition of co-formulants. The product is liquefied chlorine under pressure (≥ 99.5% w/w), and is identical to the reference product described in the AR of Chlorine (2017, rev. 2020). The effects on human health are derived from the AR.

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.

3.6.1 Assessment of effects on human health

There are no human health data available for the product. As the product in this dossier is identical to the reference product, the assessment, and classification and labelling are based on the agreed endpoint(s) for the active substance.

3.6.1.1 Skin corrosion and irritation

Table 3.13 Conclusion used in Risk Assessment – 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	The product is classified for skin irritation 2 (H315).

Table 3.14 Data waiving

Data waiving	
Information requirement	8.1. Skin corrosion or skin irritation
Justification	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. It consists of pure chlorine gas.

3.6.1.2 Eye irritation

Table 3.15 Conclusion used in Risk Assessment – 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	The product is classified for eye irritation 2 (H319).

Table 3.166 Data waiving

Data waiving	
Information requirement	8.2 Eye irritation
Justification	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. It consists of pure chlorine gas.

3.6.1.3 Respiratory tract irritation

Table 3.17 Conclusion used in the Risk Assessment – Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	The product is classified for 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	The product is classified for respiratory tract irritation (STOT SE 3, H335).

Table 3.18 Data waiving

Data waiving	
Information requirement	**8.10. Other tests**
Justification	Based on the "Guidance on Information Requirements" for biocides, there are currently no standard tests and no OECD test guidelines available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation.

3.6.1.4 Skin sensitization

Table 3.19 Conclusion used in Risk Assessment – Skin sensitisation

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	The product is not classified for skin sensitisation.

Table 3.20 Data waiving

Data waiving	
Information requirement	8.3 Skin sensitisation
Justification	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. It consists of pure chlorine gas.

3.6.1.5 Respiratory sensitization

Table 3.21 Conclusion used in Risk Assessment – Respiratory sensitisation

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	The product is not classified for respiratory sensitisation.

Table 3.22 Data waiving

Data waiving	
Information requirement	8.4 Respiratory sensitization (ADS)
Justification	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. It consists of pure chlorine gas.

3.6.1.6 Acute oral toxicity

Table 3.23 Value used in the Risk Assessment – Acute oral toxicity

Value used in the Risk Assessment – Acute oral toxicity	
Value/conclusion	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	The product is not classified for acute oral toxicity.

Table 3.24 Data waiving

Data waiving	
Information requirement	8.5.1 Acute toxicity by oral route
Justification	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. It consists of pure chlorine gas.

3.6.1.7 Acute inhalation toxicity

Table 3.25 Value used in the Risk Assessment – Acute inhalation toxicity

Value used in the Risk Assessment – Acute inhalation toxicity	
Value/conclusion	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	The product is classified for acute inhalation toxicity (H331).

Table 3.26 Data waiving

Data waiving	
Information requirement	8.5.2 Acute toxicity by inhalation
Justification	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."

	The composition of the biocidal product is known. It consists of pure chlorine gas.

3.6.1.8 Acute dermal toxicity

Table 3.27 Value used in the Risk Assessment – Acute dermal toxicity

Value used in the Risk Assessment – Acute dermal toxicity	
Value/conclusion	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	The product is not classified for acute dermal toxicity.

Table 3.28 Data waiving

Data waiving	
Information requirement	8.5.3 Acute toxicity by dermal route
Justification	According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), "testing on the product/mixture does not need to be conducted if: there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." The composition of the biocidal product is known. It consists of pure chlorine gas.

3.6.2 Information on dermal absorption

Table 3.29 Value(s) used in the Risk Assessment – 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.

Table 3.30 Data waiving

Data waiving	
Information requirement	8.6 Information on dermal absorption

Justification	No study has to be performed as dermal absorption is not relevant for chlorine gas.

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

The product consists only out of chlorine gas. There are no non-active substances present in the product.

3.6.4 Other

3.6.4.1 Food and feeding stuffs studies

Not relevant

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

Not relevant

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

Not relevant

3.6.5 Available toxicological data relating to endocrine disruption

Not relevant. The product consists only of chlorine gas. There are no non-active substances present in the product.

3.6.6 Exposure assessment and risk characterisation for human health

3.6.6.1 Introductory remarks

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, rev. 2020).

The product is intended for the use: "*Disinfection of raw water from rivers or wells for the preparation of industrial water".*

The application of the industrial water can cause secondary exposure to users as the biocidal product can still be present during the use of treated water. The exact concentration will depend on the initial concentration (5 ppm avCl), the organic load of the water (oxidation of chlorine), further treatments of the industrial water, and the time between chlorination and secondary use.

The following secondary exposure scenarios have been identified as possibly relevant:
1. Application of industrial water for cleaning of container terminals or ships by coarse spraying
2. General use as process water in industry: exposure to humified air containing the biocide

3. Rinsing of fabrics: dermal contact from workers with the fabrics. Only possible with low residual levels of chlorine as higher concentrations would lead to bleaching of the fabrics. Contact with the textiles will be limited as the processes are mostly automated.
4. Cleaning/maintenance of the process water system.
5. Taking samples for water quality check of the process water system.

The first scenario is selected as worst-case and most relevant for human exposure. During this scenario there is a high potential for both dermal and inhalation exposure. This worst-case scenario will be further assessed as secondary exposure scenario.

Note: The product is intended to be used by industrial users, i.e. professional users in an industrial environment. Therefore, where the terms professional users or professional uses are found in the PAR, they have to be understood as professional users or uses in an industrial environment.

Strategy for human health risk assessment

According to the AR of Chlorine (2017, rev. 2020), 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.

Only local exposure 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.

For primary exposure, only the inhalation route of exposure is considered relevant for the industrial users. For secondary exposure, also dermal exposure is considered relevant. Oral exposure is not considered applicable for the exposure of industrial workers in these scenarios.

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 (as avCl) and vapour (HClO as avCl) is conceivable.

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).

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

In water, chlorine (Cl_2) disproportionates into hypochlorous acid (HClO) and hydrochloric acid (HCl). The ratio of Cl_2/HClO/ClO^- is pH and temperature dependent. At pH values > 10, the hypochlorite anion (ClO^-) is the predominant species and only exposure to aerosols of NaOCl (as avCl) is considered relevant. The minor fraction of volatile hypochlorous acid (HClO) is considered negligible. At pH<10, vapour of hypochlorous acid (HClO) should be taken into account for inhalation exposure.

According to measurements from the applicant, the industrial water that will be used in secondary applications (after disinfection and possible further treatment) has a pH around 8. At this pH, both hypochlorous acid and the hypochlorite anion are present in the water. Thus, inhalation exposure to vapour is relevant during the secondary usage of industrial water.

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

Strategy for the assessment of substance(s) of concern
No substances of concern are identified

Strategy for disinfectant by-products assessment
For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available, thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out. The current 'guidance' (Volume V, Guidance on Disinfection By-Products, 2017) covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.

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

Table 3.31 Summary table: main paths of human exposure

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

3.6.6.3 List of exposure scenarios

Table 3.32 Summary table: exposure scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group** (e.g. professionals, non-professionals, professional bystanders, non-professional bystanders/general public)
Primary exposure		
Scenario 1	***Disinfection of raw water***	
Task 1.1	*Mixing and loading - connecting chlorine gas cylinders to the automated dosing system*	Industrials
Task 1.2	*Application - automatic disinfection*	Industrials
Task 1.3	*Post-application – maintenance work*	Industrials
Task 1.4	*Post-application – handling of empty containers*	Industrials
Secondary exposure		
Scenario 2	***Exposure of the bystander***	Industrials
Scenario 3	***Application of industrial water by coarse spraying***	Industrials

3.6.6.4 Reference values to be used in risk characterisation

Table 3.33 Reference values to be used in risk characterisation

Reference	Study	NOAEL (LOAEL) or NOAEC (LOAEC)	AF	Correction for 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 (Chlorate)	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 (Chlorate)	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

3.6.6.5 Specific reference value for groundwater

No data

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

Scenario 1: Disinfection of raw water

Task 1.1: Mixing and loading - connecting chlorine gas cylinders to the automated dosing system

Table 3.34 Description and input parameters

Description of Task 1.1: Mixing and loading - connecting chlorine gas cylinders to the automated dosing system
According to the AR of active substance, for which a human health risk assessment has been conducted on a representative product identical to the product in the current application: 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 AR 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 Task 1.1

Summary table: estimated of local exposure from professional uses				
Scenario	**Tier/PPE**	**Local inhalation exposure** [mg avCl/m³]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Task 1.1	1/no PPE	0.498	n.r.	n.r.

Task 1.2: Application – automatic disinfection

No relevant exposure, the application takes place automatically in the water system. Therefore no contact with the concentrated and/or diluted product is expected.

Task 1.3: Post-application - maintenance work

Description of Task 1.3: Post-application – maintenance work
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 (AR 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 industrial users by dermal route.

Calculations for Task 1.3

Summary table: estimated of local exposure from professional uses				
Scenario	**Tier/PPE**	**Local inhalation exposure** [mg avCl/m³]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Task 1.3	1/no PPE	0.480	n.r.	n.r.

Task 1.4: Post-application – handling of empty containers

Empty containers are stored and restored to the distributor. The risk of exposure is therefore negligible and covered by the exposure during the maintenance work (task 1.3

Combined scenarios

Combined exposure is not relevant based on the absence of systemic effects after exposure towards chlorine gas.

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

Table 3.35 Summary table: estimated local exposure and risk characterisation for professional users

Summary table: estimated local exposure and risk characterisation for professional users						
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg avCl/m3]**	**Estimated total exposure [mg/m³]**	**Estimated exposure / AEC [%]** AECinhalation = 0.5 mg avCl/m³	**Acceptable (yes/no)**
Task 1.1	1/no PPE	n.r.	0.498	0.498	99.6%	YES
Task 1.2	1/no PPE	n.r.	No exposure			YES
Task 1.3	1/no PPE	n.r.	0.480	0.480	96%	YES
Task 1.4	1/no PPE	n.r.	Negligible			YES

Outcome of qualitative local risk assessment

Table 3.36 Outcome of qualitative local risk assessment

Hazard			Exposure information						Risk	
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMMs & PPE**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
Low	STOT SE 3	Although the product is also classified as skin/eye irritant, these routes of exposure are considered negligible due to the form in which the product is presented	**2**	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 mg avCl/m³)	**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	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few minutes per day for M&L) (↓) Low frequency

								Monitoring tool: • Local exhaust ventilation (according to the national legislation) • 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 mg avCl/m^3) 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 which 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.

3.6.6.7 Non-professional users

No exposure of the non-professional user is foreseen.

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

Scenario 2: Exposure of the professional bystander

Description and input parameters

Table 3.37 Description and input parameters

Description of Scenario 2: Exposure of the industrial bystander
The industrial bystander can be present during connecting or deconnecting of the chlorine gas cylinders or the maintenance work of the dosing system. Bystander will not be exposed greater than the user performing the task. (See primary exposure)

Scenario 3: Application of industrial water by coarse spraying

Description and input parameters

Table 3.38 Description and input parameters

Description of Scenario 3: Application of industrial water by coarse spraying
The industrial user can use the industrial water for cleaning or rinsing of containers terminals or ships. The user applies the water on hard surfaces using a compression sprayer (1-3 bar pressure). To assess inhalation exposure to aerosols during the spray application, the **Spraying model 1**, from BHHEM (p.281), is used. This model covers the mixing and loading and the application tasks. The exposure value from the model is as follow: • 104 mg/m^3 (inhalation) Exposure to vapour has been estimated using ART modelling. For dermal route exposure, a semi-qualitative local risk assessment is performed.

Input parameters for Scenario 3			
Inhalation exposure to aerosol			
	Parameters[1]	Value	Reference and justification[3]
Tier 1 (no PPE)	Max available chlorine	5 ppm or 0.0005% avCl	Max concentration used for disinfecting the industrial water
	Inhalation exposure value (mg/m^3)	104 mg/m^3	Spraying model 1
Inhalation exposure to vapour			
	Parameters[1]	Value	Reference and justification[3]
Tier 1 (no PPE)	Max available chlorine	5 ppm or 0.0005% avCl	Max concentration used for disinfecting the industrial water
	Duration	120 min	Headhoc Recommendation 6, default for compression spraying
	Process temperature	Room temperature	
	Vapour pressure	196 Pa	At 20°C
	Liquid mole fraction	See calculation below	Calculation
	Activity coefficient	1	
	Emission source	Near field	Primary emission source is located in the breathing zone of the worker (i.e. the volume of air within 1 meter in any direction of the worker's head)
	Activity class	Surface spraying of liquids	Hard surface compression spraying
	Situation	Moderate application rate (0.3-3 L/minute)	Headhoc Recommendation 3
	Spray direction	In any direction (including upwards)	
	Spray technique	Spraying with no or low compressed air use	1-3 bar
	Genral control measures	No localised controls	
	Process fully enclosed	No	
	Effective housekeeping practices in place	Yes	
	Work area	Indoors	

	Room size	Large workrooms only	
	Localized controls	No lozaliced controls	
	Ventilation rate	Only good natural ventilation	

[1] Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE.
[2] Only include the parameters changed with respect to the previous Tier. Tier 1 assessments should reflect the exposure for an unprotected person, normally only in higher tier assessments the use of PPE and/or RPE may be included as a refinement.
[3] Include the source of information (e.g. product information, recommendations, guidance documents, exposure models) and justification (where needed).

Calculations for Scenario 3

Exposure to aerosols has been calculated as follows:

Inhalation exposure value (104 mg/m³) x % avCl in-use dilution (0.0005%) = 0.00052 mg/m³

The percentage of HClO present at pH 8 has been calculated using the equation:

$$\mathrm{pH} = \mathrm{p}K_\mathrm{a} + \log_{10}\left(\frac{[\mathrm{A}^-]}{[\mathrm{HA}]}\right)$$

(pKa at 20°C = 7.582)

The percentage of HClO at pH 8 is 27.64%.

This percentage is used to calculate the in-use avCl concentration present as HClO (column 4). The liquid mole fractions of this percentage (column 5) were used as input in ART to calculate the exposure to vapour. The 90th percentile from the ART exposure predictions was considered.

% avCl in-use dilution	pH	% HClO at 20°C	% HClO in-use concentration	Liquid mole fraction HClO in-use
0.0005% (or 5 ppm)	8	27.64	0.0001382%	0.000000474

Note:
In order to assess whether the scenario 3 represents the worst-case secondary exposure for industrial users and covers, for instance, evaporation of HClO from a large container containing treated water, an extra exposure assessment was performed in ART. Where possible the same parameters as for scenario 3 were used, the activity class "Activities with open liquid surfaces or open reservoirs" was selected and a 480 min exposure duration was considered.
This assessment resulted in an exposure 10 times lower than the one during spraying.

Summary table: estimated exposure concentration for professional uses		
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m³)**
Scenario 3	**Exposure to aerosols**	
	1/ No PPE	0.00052
	Exposure to vapour	
	1/ No PPE	0.0019
	Exposure to aerosols + vapour	
	1/ No PPE	0.00242

In order to account for variations in HClO concentrations in relation to pH variations, the exposure to HClO vapour was also calculated considering a 50% HClO concentration and resulted in a 0.0035 mg/m³ exposure.

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

Table 3.39 Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

Summary table: estimated local exposure and risk characterisation for professional bystanders and non-professional bystanders/general public						
Exposure scenario	**Tier/PPE**	**Estimated dermal exposure [%]**	**Estimated inhalation exposure [mg/m³]**	**Estimated total exposure [mg/m³ or %]**	**Estimated exposure / AEC [%]** NOAECdermal = 1% AECinhalation = 0.5 mg/m³	**Acceptable (yes/no)**
Scenario 2	1/no PPE	SEE PRIMARY EXPOSURE				YES
Scenario 3	1/no PPE	n.r.	0.00242	0.00242 mg/m³	0.484	YES
		0.0005%	n.r.	0.0005%	0.05	YES

Outcome of qualitative local risk assessment

Since the dermal exposure doesn't exceed the NOAECdermal, further qualitative dermal risk assessment is not needed.

For the outcome of the qualitative local risk assessment of the industrial bystander mixing and loading or maintenance, reference is made to the primary exposure section.

Conclusion

For industrial bystanders present during connecting or disconnecting the product containers or during maintenance or repair of the gas pipe system, the same risk mitigation measures (RMMs) are mandatory as for the primary user:

- an alarm system (trigger value corresponding to the AEC: 0.5 mg avCl/m³) is in place which 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)

For other secondary exposure scenarios no risk mitigation measures need to be in place.

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

3.6.7 Monitoring data

No monitoring data available

3.6.8 Dietary risk assessment

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

3.6.8.1 Information of non-biocidal use of the active substance and residue definitions

Not relevant for this product.

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

A combined use with other active substances or biocidal products is not foreseen.

3.6.10 Overall conclusion on risk assessment for human health

Table 3.40 Overall conclusion on the risk assessment for human health from systemic and local exposure

Overall conclusion on the risk assessment for human health from systemic and local exposure			
Use number[1]	**Use description[2]**	**Conclusion[3]**	**Set of RMMs[3]**
Use #1	Disinfection of raw water from wells or rivers for the preparation of industrial water	acceptable with the following risk mitigation measure	For industrial users/bystanders during 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 which 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)

[1] Use numbers in accordance with the list of all uses indicated under section 2.2.
[2] Title of the specific use, as indicated in the SPC
[3] For the wording of the RMMs, refer to the "Frequently used sentences in the SPC and translations" available at https://echa.europa.eu/support/dossier-submission-tools/spc-editor. The conclusion and set RMMs should be in alignment with the overall conclusion under section 2.2

3.7 Risk assessment for animal health

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

3.7.1 Risk for companion animals

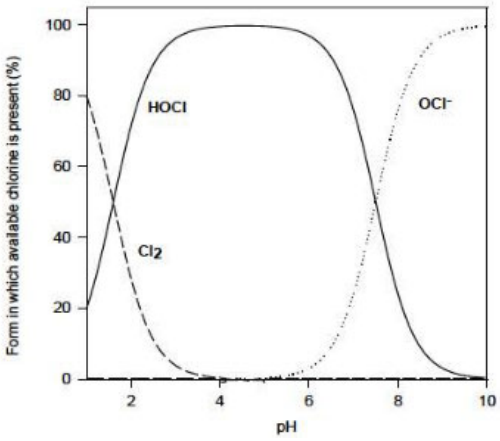
Risk assessment for companion animals is not relevant for the applied use.

3.7.2 Risk for livestock animals

Risk assessment for livestock animals is not relevant for the applied use.

3.8 Risk assessment for the environment

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



The sum of these species [hypochlorite ion + hypochlorous acid + chlorine] is defined as active chlorine or available chlorine (avCl). 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.

3.8.1 Available studies and endpoints applied in the environmental risk assessment

3.8.1.1 Endpoints for the active substance(s), metabolite(s) and transformation product(s)

No new endpoint studies have been submitted since the approval of the active substance. The risk assessment is entirely based on the list of endpoints as published in the AR of Chlorine (2017, rev. 2020) for which Italy was the rapporteur member state. The assessment report is available on the ECHA website.

The fate and behaviour of active chlorine in the environment is described in detail in the CAR of Chlorine (2017, CAR Doc. IIA). Active chlorine 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, active chlorine 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 (avCl) is converted to inorganic chloride. Oxidation is probably the predominant chemical reaction occurring in chlorine's disinfection processes. Furthermore, circumstances influencing the reactivity of active chlorine 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 (CAR of Chlorine, Doc. IIIA) shows that active chlorine is eliminated during transport in the sewer within the first minutes. The abundance of reaction partners allows a very quick reaction. 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.

The endpoints and the PNEC applied in the environmental risk assessment are summarised in the table below.

Table 3.41 Endpoints and PNEC values for the active substance(s) applied in the environmental risk assessment

Endpoints and PNEC values for the active substance applied in the environmental risk assessment			
	Value **Active substance**	**Unit**	**Remarks**
Fate and behaviour in the environment			
DT_{50} for biodegradation in surface water	56	min (at 12°C)	Worst case assumption, based on the kinetic model of Vandepitte and Schowanek (1997), assuming slower degradation due to lower content of Corg in surface water and sediment when compared to raw sewer.
Predicted no effect concentrations (PNEC)			
Sewage treatment plant	4.11	mg FAC*/L	Based on a NOEC** for respiration inhibition and an assessment factor of 10.
Surface water	0.042	µg FAC/L	Based on a multispecies microcosm study with a 7d NOEC and an assessment factor of 50.
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 BPR Guidance Vol. IV Parts B+C (2017).
Soil	0.015	µg FAC/kg wwt	
Bird	No data available for birds and mammals as primary and secondary poisoning is not considered relevant.		
Mammals			

* FAC: Free available chorine;
** endpoint is converted to standard soil

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

surface water. No PECs and PEC/PNEC ratios were consequently calculated for sediment.

No PNECs are available for the marine ecosystem. Because an additional dilution factor of 10 is applied to both PEC and PNEC, the risk ratios for the marine compartment are always equal to those for fresh water and fresh water sediment. Considering that the risk assessment for marine water is covered by the assessment for fresh water, PECs and PEC/PNEC ratios were not calculated for the marine ecosystem.

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

3.8.1.2 Endpoints for the product

No studies have been conducted on the product, as it is identical to the pure active substance. The exposure assessment and classification and labelling are based on the agreed endpoints for the active substance and available information for the non-active substance.

3.8.1.3 Substance(s) of concern

As the product in this dossier is pure active substance, no substances of concern regarding the environment were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume IV Environment (Parts B+C)). Consequently, only the active substance was addressed in the environmental risk assessment.

3.8.1.4 Screening for endocrine disruption relating to non-target organisms

Please refer to section 2.7.

3.8.2 Emission estimation

3.8.2.1 General information

Various phases in the life cycle of a product may cause emissions and environmental exposure. Significant release to the environment will occur during the application of products holding the biocide.

Based on TAB entry ENV-208 (October 2022), no groundwater assessment is needed for inorganic rapidly reacting substances such as active chlorine.

Based on TAB entry ENV-241 (October 2022), for products containing the active substance active chlorine released from chlorine and other active chlorine releasers that have relevant 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.

Release of active substance during the waste phase of the end-products is not assessed, as the product is only used for the disinfection of water. Hence an assessment of the waste phase of the end-product is not applicable.

Emission was calculated for the intended use based on the highest efficacious concentration, i.e. in-use concentration as specified in the SPC. Predicted Environmental Concentrations (PECs) were calculated according to the relevant exposure scenario documents (ESDs, release to the environment), the Guidance on the BPR: Volume IV Environment (Parts B+C) (distribution in the environment) and the Technical Agreements on Biocides (TAB, October

2022).

The table below summarises the risk assessment approach and indicates the receiving environmental compartments that have been identified as potentially exposed during the use of the product for the different applications. Compartments highlighted in bold are directly exposed.

Table 3.42 Environmental risk assessment

Environmental risk assessment				
Use number	**Scenario assessed**	**ESD applied**	**Maximum in-use concentration of the active substance**	**Receiving compartments[1]**
1	Disinfection of water for industrial processes	- 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 - Technical Agreements for Biocides (October 2022)	5 mg/L avCl	**STP** (quantitative) **Freshwater**[2] Freshwater sediment

[1] Only relevant receiving compartments based on the exposure pathway are listed and the compartment receiving the direct emissions is highlighted in bold.

[2] Freshwater can be either indirectly exposed via the STP, or directly when treated water is released to the surface water.

3.8.2.2 Emission estimation for the scenario(s)

Qualitative assessment:
As indicated above, as the product is evaluated qualitatively for release via STP, no calculation of the emission to the environment is necessary for the use *"Disinfection of raw water from wells or rivers for the preparation of industrial water – release via STP"* (TAB entry ENV-241, October 2022): 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."*

Quantitative assessment:
A quantitative assessment for the active substance has only been performed for the *"Disinfection of raw water from wells or rivers for the preparation of industrial water – direct release to surface water"* (TAB entry ENV-241, October 2022).

For the intended uses, emission scenarios are based on average consumption. Therefore, the 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.

Scenario 1- Disinfection of water for industrial use

After disinfection, treated water could be (partially) released to surface water (e.g. in case of cleaning of ships).

If chlorinated water is released directly to surface water, the exposure scenario is comparable to the one for the use "disinfection of waste water after the waste-water plant", which is assessed in the AR of Chlorine (PT2b- Disinfection of sewage/waste water in the effluent stream of the STP).

The in-use concentration for this use is 5 mg avCl/L. Although, as a worst-case, no degradation is considered, in reality a significant part of the chlorine added will already degrade between the application of chlorine and the release of the water after use.

Table 3.43 Input parameters for calculating the local emission

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: ***Disinfection of water for industrial use***			
Maximum concentration of disinfectant in treated water ($C_{(0)}$)	5	mg avCl/L	Highest in-use concentration
Reaction rate constant in surface water (k)	0.743	h^{-1}	The DT50 used is the $DT50_{surfacewater}$ = 56 min (AR of Chlorine)

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: ***Disinfection of water for industrial use***			
Residence time (contact time) (t)	0	h	Worst case
Dilution factor (at the point of complete mixing) (DIL)	10	[-]	BPR Guidance Vol. IV, Parts B+C (2017, chapter 2.3.7.3.1)

Calculations for Scenario

C(t) = Concentration at the release point to surface water [mg/L]

$$C(t) = C(0) \times e^{-kt} = C(0) \times e^{-\frac{ln(2)}{DT50}}$$

$Clocal_{water}$ = local concentration in surface water during emission period [mg/L]

$$Clocal_{water} = \frac{C(t)}{DIL}$$

Table 3.44 Resulting local emission to relevant environmental compartments

Resulting local emission to relevant environmental compartments		
Compartment	**local concentration in surface water during emission period ($Clocal_{water}$)[mg/L]**	**Remarks**
Freshwater[1]	0.5	

[1] Including sediment

3.8.3 Exposure calculation and risk characterisation

Table 3.45 Summary table of PNEC, PEC and PEC/PNEC values

Summary table of PNEC, PEC and PEC/PNEC values	
	Chlorine (FAC*)
PNEC values	
PNECstp (mg/L)	4.11
PNECwater (µg/L)	0.042
PNECsed (µg/kg wwt)	0.045
PNECsoil (µg/kg wwt)	0.015
SCENARIO 1 (direct release to surface water)	
PEC values	
PECstp (mg/L)	n.r.
PECwater (mg/L)	0.50
PECsed (mg/kg wwt)	n.r.
PECsoil (mg/kg wwt)	n.r.
PECgw (µg/L)	n.r.
PEC/PNEC values	
PEC/PNECstp	n.r.
PEC/PNECwater	**1.19 E+04**
PEC/PNECsed	n.r.
PEC/PNECsoil	n.r.

*FAC: free available chlorine; n.r.: not relevant

Atmosphere

The risk characterisation presented for the atmosphere is only qualitative.

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)

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 (CAR of Chlorine, 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 active chlorine released from 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

- 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.

This reasoning is also valid for freshwater sediment organisms.

- Direct release to surface water:

In case of direct release to surface water, the PEC/PNEC value for the aquatic compartment (including sediment) is 1.19 E+04. However, it should be noted that this is based on worst-case assumptions and does not take into account degradation between the disinfection and release of the water. It also considers a dilution factor of 10 in the surface water, which is an underestimation as only limited amounts of water will be released directly to surface water.

Conclusion: No unacceptable risk is expected for the use "disinfection of raw water from rivers or wells for the production of industrial water", in case of release via the STP. Direct release to surface water could, however, lead to unacceptable risk for the aquatic compartment.

Therefore, for this use, the following RMMs, which have been used in particular for other similar products and union authorisations, are proposed:

- *In case of direct release to surface water, reduce residual concentration of active chlorine by active carbon filtration or addition of reducing agents (e.g. ascorbic acid or sodium ascorbate) before discharging the treated water (or disinfected water) to the surface water. Alternatively, the water should be retained in a buffer after disinfection.*
- *Regular water quality assessment should be performed to ensure that the release of industrial effluents or discharge of ballast water in water bodies meets all required quality standards considering all relevant regulations.*

Terrestrial compartment

The risk characterisation presented for the terrestrial compartment is only qualitative (TAB ENV-241, October 2022). Since the concentration entering the STP should already be close to zero, the concentration of active substance reaching the soil compartment via sewage sluge application on agricultural soil is expected to be even lower. Due to the high reactivity with organic matter in sewer, STP and activated sludge, no active chlorine will reach the soil compartment.

Conclusion: Taking into account degradation of active chlorine in the sewer system, no

unacceptable risk is expected for soil.

Groundwater

The risk characterisation presented for the groundwater is only qualitative (TAB ENV-208, October 2022).

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 BPR Guidance Vol. IV, Parts B+C (2017), 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 active chlorine will reach the groundwater because active chlorine rapidly degrades in sewage sludge and soil.

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

Disinfection by-products (DBP) risk assessment

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available, thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out. The current 'guidance' (Volume V, Guidance on Disinfection By-Products, 2017) covering PT2, 11 and 12 is a strategy and not a concrete assessment method. Currently this guidance does not allow any harmonized DBP assessment.

3.8.4 Primary and secondary poisoning

3.8.4.1 Primary poisoning

Primary poisoning is not considered relevant for this active substance and PT.

3.8.4.2 Secondary poisoning

As the log K_{ow} for the active substance is <3 and the active substance is highly reactive, bioconcentration is not expected.

3.8.5 Mixture toxicity

Not relevant for this product as the product contains only one active substance and no co-formulants.

3.8.6 Aggregated exposure (combined for relevant emission sources)

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.

3.8.7 Overall conclusion on the risk assessment for the environment

Table 3.46 Overall conclusion on the risk assessment for the environment

Overall conclusion on the risk assessment for the environment			
Use number	**Use description**	**Conclusion**	**Set of RMMs**
1	Disinfection of raw water from wells or rivers for the preparation of industrial water	acceptable in case of release via the STP. acceptable in case of direct release with following risk mitigation measures:	• In case of direct release to surface water, reduce residual concentration of active chlorine by active carbon filtration or addition of reducing agents (e.g. ascorbic acid or sodium ascorbate) before discharging the treated water (or disinfected water) to the surface water. Alternatively, the water should be retained in a buffer after disinfection. • Regular water quality assessment should be performed to ensure the that the release of industrial effluents (or discharge of ballast water in water bodies) meets all required quality standards considering all relevant regulations.

3.9 Assessment of a combination of biocidal products

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

3.10 Comparative assessment

Not relevant. The Active substance is not a candidate for substitution.

4 Appendices

4.1 Calculations for exposure assessment

4.1.1 Human health

Scenario 3

ART REPORT

Spraying of treated water

Chemical details	
Chemical	HOCl
CAS No.	7790-92-3
Scenario details	
Number of activities	1
Total duration (mins)	120
Nonexposure period (mins)	0
Metadata	
ART version	1.5

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	196 Pa
Liquid mole fraction	4.7E-07
Activity coefficient	1
Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Moderate application rate (0.3 - 3 l/minute)
Spray direction	In any direction (including upwards)
Spray technique	Spraying with no or low compressed air use
Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes
Dispersion	
Work area	Indoors
Room size	Large workrooms only

Risk Management Measures

Localised controls	
Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Dispersion	
Ventilation rate	Only good natural ventilation

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.0019 mg/m³.

The inter-quartile confidence interval is 0.00095 mg/m³ to 0.0041 mg/m³.

4.1.2 Dietary assessment

Not relevant

4.1.3 Environment

None. Please refer to the relevant section for details on the scenarios.

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

No new information on the active substance is available.

4.3 List of studies for the biocidal product

Table 4.1 List of studies for the biocidal product

Author (s)	Year Report date	Reference No. *(Annex III requirement)* / IUCLID Section No.	IUCLID Document name	Title. Report No.	Type of publication	Source (where different from company) Study sponsor	GLP (Yes/No)	Data Protection Claimed (Yes/No)
H. Gabriel & A. Kampe	Mar 24, 2020	6.7 Efficacy data to support these claims	1_EN1276_bacteria_15°C_25min_3g/L BSA	Expert opinion Bactericidal Activity of Natriumhypochloridlsg . 5% in the quantitative suspension test according to DIN EN 1276:2019 (Phase 2, Step 1) L20/0110.1	study report	ARCHE CONSORTIA ON BEHALF OF CHLORINE CONSORTIUM	no	yes
C. Giarei	Mar 19, 2020	6.7 Efficacy data to support these claims	2_EN1276_algae_15°C_25min_20mg/L DOC	SUSPENSION TEST FOR THE EVALUATION OF ALGAECIDAL ACTIVITY IN DIRTY CONDITIONS ON "SODIUM HYPOCHLORITE SOLUTION 5%" STULV20AA0745-1	study report	ARCHE CONSORTIA ON BEHALF OF CHLORINE CONSORTIUM	no	yes
C. Giarei	Apr 17, 2020	6.7 Efficacy data to support these claims	3_EN1276_algae_15°C_25min_20mg/L DOC	SUSPENSION TEST FOR THE EVALUATION OF ALGAECIDAL ACTIVITY IN DIRTY CONDITIONS ON "SODIUM HYPOCHLORITE SOLUTION 5%" STULV20AA1294-1	study report	ARCHE CONSORTIA ON BEHALF OF CHLORINE CONSORTIUM	no	yes

A. De Bortoli	May 17, 2022	6.7 Efficacy data to support these claims	4_sim-use_bacteria(screening)_15°C_10&25min_natural soiling	Test Report STULV20AA4289-1 STULV20AA4289-1	study report	ARCHE CONSORTIA ON BEHALF OF THE CHLORINE CONSORTIUM	no	yes
C. Carloni	Oct 5, 2020	6.7 Efficacy data to support these claims	5_sim-use_bacteria_15°C_10&25min_natural soiling	Test report STULV20AA4360-1 STULV20AA4360-1	study report	ARCHE CONSORTIA ON BEHALF OF THE CHLORINE CONSORTIUM	no	yes
C. Giarei	Oct 26, 2020	6.7 Efficacy data to support these claims	6_sim-use_algae_15°C_10&25min_natural soiling	EVALUATION OF EFFICACY OF "SODIUM HYPOCHLORITE SOLUTION 5%" AGAINST ALGAE USING THREE DIFFERENT INDUSTRIAL WATERS (ASTM E645-18) STULV20AA4368-1	study report	ARCHE CONSORTIA ON BEHALF OF CHLORINE CONSORTIUM	no	yes

4.4 References

Reference to relevant guidance documents and legal texts have been made throughout this document in the specific sections.

4.5 Confidential information

Please refer to the separate document confidential annex of the PAR.