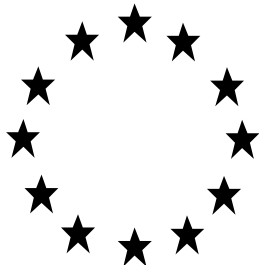
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



[RADIC R12]

Product type(s) [4]

[Active chlorine released from sodium hypochlorite as included in the Union list of approved active substances]

Case Number in R4BP: [BC-EX046178-11]

Evaluating Competent Authority: [BE]

Date: [22*/01/2021*]

Table of Contents

1 CONCLUSION

The Radic R12 is a SL formulation. The product is a clear and light yellow liquid with a relative density of 1.175 (at 20°C).The pH of the pure product is 13.72 and the pH of the 1% dilution is 12.02. No foam is formed after 1 and 12 min. A homogeneous solution is observed after 24 h. It has a surface tension 67.2mN/m at 20°C. The product is a Newtonian liquid.

Storage conditions should include restrictions ("Do not store at temperatures above 30°C", "Keep away from direct sunlight" and "Protect from frost").

The physical and chemical properties were adequately addressed, supporting a shelf-life of 6 months in HDPE packaging.

With regard to the physical and chemical hazards, the Radic R12 is classified as Corrosive to Metal – Category 1.

The provided titration method is adequately validated for the determination of the content of the active substances in the biocidal product Radic R12. For the determination of the relevant impurity, an IC method is also available.

According to the efficacy data/results submitted by the Applicant, the product RADIC R12, when used at +60°C during 15 min, is bactericidal & yeasticidal (up to 6 months if stored at +25°C in HPDE plastic cans) at 2.9% in food/feed industries (including meat and beverage industries) and in milking equipment by CIP (with circulation) procedures.

If the product is used according to use instructions and with the recommended RMM, the hazard quotients of the exposure scenarios are below 1. This means that no human health effects are expected for the professional use of the product.

Risk for consumers via residues in food: The estimated exposure is well below the exposure limit after rinsing step. No adverse health effects are expected from the indirect dietary exposure to chlorate because of the use of the product.

No unacceptable risk to the environment is expected from the use of Radic R12 as disinfectant for inner surfaces, neither for the STP or the aquatic compartment, nor for the terrestrial or groundwater compartment.

The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product Radic R12 was performed according to the Regulation (EU) 528-2012 and Regulation (EU) 2017-2100. Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product Radic R12.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Radic R12	Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Lema Chemie NV
	Address	Nijverheidsstraat 2, 2381 Weelde, Belgium
Authorisation number	BE2020-0040	
Date of the authorisation	22/01/2021	
Expiry date of the authorisation	22/01/2031	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Lema Chemie NV
Address of manufacturer	Nijverheidsstraat 2, 2381 Weelde, Belgium
Location of manufacturing sites	Nijverheidsstraat 2, 2381 Weelde, Belgium

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

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Nouryon Industrial Chemicals BV
Address of manufacturer	Velperweg 76 P.O. Box 60192 6800 SB Arnhem The Netherlands
Location of manufacturing sites	- Hauptstraße 47, 49479 Ibbenbüren, Germany - Elektrolysestraße 1, 06749 Bitterfeld-Wolfen, Germany - Welplaatweg 12, 3197 KS Botlek Rotterdam, The Netherlands - Oosterhorn 4, 9936 HD Farmsum, The Netherlands

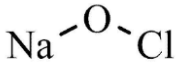
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Active substance	
ISO name	Active chlorine released from sodium hypochlorite
Remarks	As per the CAR: In water sodium hypochlorite (NaClO) hydrolyzes to hypochlorous acid (HClO) according to: $NaClO + H_2O \leftrightarrows Na^+ + HClO + OH^-$ Furthermore, hypochlorous acid participates in the following equilibrium with chlorine (Cl2): $HClO + H_3O^+ + Cl^- \leftrightarrows Cl_2 + 2H_2O$ The ratio of Cl_2/HClO/ClO^- is pH and temperature dependent. The pH-dependence is displayed in the following figure, where the percentage of the different species at the equilibrium is showed as a function of pH. Hypochlorous acid is predominant in the pH range 4 to 5.5, whereas the hypochlorite anion predominates at pH >10. Chlorine can be present at pH < 4 only.
Releaser	
IUPAC or EC name	Sodium hypochlorite
EC number	231-668-3
CAS number	7681-52-9
Index number in Annex VI of CLP	017-011-00-1
Minimum purity / content	Aqueous solution with an available (active) chlorine concentration ≤18% (w/w), in compliance with the EN 901:2013
Structural formula	

2.1.2.2 Candidate(s) for substitution

Sodium hypochlorite should not be considered a candidate for substitution since none of the conditions of Article 10 of the BPR are met.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w %)
Sodium hypochlorite	Sodium hypochlorite	Releaser	7681-52-9	231-668-3	29.583% **Pure sodium hypochlorite: 45 g/L or 3.82% (%)**
Active chlorine released from sodium hypochlorite	/	Active substance	/	/	**Pure active chlorine: 43g/L or 3.64 w/w**

The full composition of the biocidal product is provided in the confidential annex to the PAR.

2.1.2.4 Information on technical equivalence

The active substance is supplied from Akzo Nobel Industrial Chemicals BV, The Netherlands, which is a member of the Euro Chlor Sodium hypochlorite Biocide Registration Group and complies with the reference specification of sodium hypochlorite as set forward in the assessment report of sodium hypochlorite.

2.1.2.5 Information on the substance(s) of concern

Two substances of concern have been identified: potassium hydroxide and sodium metasilicate pentahydrate. Please see the confidential annex for further details.

One relevant impurity might be present in the product; sodium chlorate, which can be formed during storage. A dietary risk assessment for chlorate is included.

2.1.2.6 Type of formulation

SL – Soluble concentrate

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Metal Corrosion 1 Skin Corr. 1 Eye Damage 1 Aquatic Acute 1 Aquatic Chronic 2
Hazard statement	H290: May be corrosive to metals H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long-lasting effects.
Suppl. hazard statement	/
Specific concentration limits, M factor	M-factor acute: 10; M-factor chronic: 1
Labelling	
GHS pictogram	GHS05, GHS09
Signal words	Danger (Dgr)
Hazard statements	H290: May be corrosive to metals H314: Causes severe skin burns and eye damage. H410: Very toxic to aquatic life with long-lasting effects.
Suppl. hazard statement	/
Precautionary statements	P234 – Keep only in original packaging P390 - Absorb spillage to prevent material damage P260 - Do not breathe vapours P273 - Avoid release to the environment P280 - Wear protective gloves and eye protection P310 - Immediately call a POISON CENTER or doctor/physician P391 - Collect spillage P501 - Dispose of content/container in accordance with local/regional/national/international regulation P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water (or shower). P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
Note	1. Based on the extreme pH (>11.5), the biocidal product is automatically classified for metal corrosion, skin corrosion and eye damage. 2. H318 is not mentioned on the label because H314 is assigned.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Disinfection of inner surfaces by CIP

Product Type	4 – Food and feed area disinfectants
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Bacteria, Yeasts
Field of use	Indoor Disinfection of inner surfaces in food industry (including meat and beverage industries) and milking equipment by cleaning-in-place (CIP). Dilute manually or with automated dosing system.
Application method(s)	CIP: cleaning-in-place (with circulation)
Application rate(s) and frequency	On hard non-porous surfaces Thoroughly rinse (with fresh water) the surfaces before disinfection. For an effect on bacteria and yeasts : 2.9% RADIC R12 in a 15 min contact time at +60°C.
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section

2.1.4.2 Use-specific instructions for use

Please refer to general instructions of use

2.1.4.3 Use-specific risk mitigation measures

Please refer to general section under 2.1.5

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

Please refer to general section under 2.1.5

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

Please refer to general section under 2.1.5

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

Please refer to general section under 2.1.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Before treatment: rinse with 1 volume fresh water. Prepare a 2.9% dilution of Radic R12. Apply during 15 minutes at 60°C. Dosing can be done automatically or manually. After treatment: rinse with 4 volumes of cold fresh water.

2.1.5.2 Risk mitigation measures

General: - Labelling - Instructions for use - Rinsing recommended after use - Washing hands after use - Washing hands/face/eyes after accidental exposure PPE: - during manual mixing and loading: wearing of protective gloves (EN 374), goggles (EN 166) and clothing - during automated mixing and loading: wearing of protective gloves (EN 374), goggles (EN 166), clothing and respiratory protective equipment APF 10

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

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water (or shower). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. IF INHALED: Remove person to fresh air and keep comfortable breathing. In case of breathing difficulties seek immediate medical attention.

2.1.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

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

Store in original container Store in dry, cool, well-ventilated area. Do not store near acids. Keep away from direct sunlight. Keep away from heat. Protect from frost Store below 30°C Shelf life: 6 months

2.1.6 Other information

/

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
(Jerry)can	5L, 10L, 25L	HDPE, not transparent for light	Cap, HDPE	Professional	Yes
(Jerry)can	70 kg, 140 kg, 240 kg, 255 kg, 1000 kg, 1200 kg	HDPE, not transparent for light	Cap, HDPE	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New data has been generated regarding the biocidal product. All new studies are included in the annex 3.1.
No studies have been done on the active substance or substances of concern.

2.1.8.2 Access to documentation

The applicant holds a Letter of Access to the dossier of the active substance (Active chlorine released from sodium hypochlorite). This LoA is included in IUCLID section 13.

The applicant received a LoA to the DBP Consortium Data concerning the disinfection by-products risk assessment and supporting data. This LoA is also included in IUCLID section 13.

2.2 Assessment of the biocidal product

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

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

See section 2.1.4 Authorised uses for a detailed use description of the biocidal product.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual	3.8% NaOCl Test product: Radic R12 Batch 190314	Liquid	A. Bonetti 2019 2019/53 AM
Colour at 20 °C and 101.3 kPa	visual	3.8% NaOCl Test product: Radic R12 Batch 190314	Clear and light yellow	A. Bonetti 2019 2019/53 AM
Odour at 20 °C and 101.3 kPa	/	3.8% NaOCl Test product: Radic R12 Batch 190314	Characteristic of sodium hypochlorite	SDS
Acidity / alkalinity	CIPAC MT 191	3.8% NaOCl Test product: Radic R12 Batch 190314	6.98% w/w NaOH equivalent assay	A. Bonetti 2019 2019/53 AM
pH	CIPAC MT 75.3	3.8% NaOCl Test product: Radic R12 Batch 190314	Neat (20°C): 13.72 Dilution 1% (20°C): 12.02	A. Bonetti 2019 2019/53 AM
Relative density / bulk density	OECD 109 or Method A.3	3.8% NaOCl Test product: Radic R12 Batch 190314	1.175 (20°C)	A. Bonetti 2019 2019/53 AM
Storage stability test – **accelerated storage**	Test waived – A long term storage test at ambient temperature has been performed. A statement will be added on the label "Store below 30°C"			
	e-CA remark: According to the Guidance on the BPR Vol I Parts A+B+C (May 2018) under these conditions an accelerated storage study is not required. The waiver is acceptable.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	GIFAP monograph 17	3.8% NaOCl Test product: Radic R12 Batch 190314	6 months at 25°C	A. Bonetti 2019 2019/53 AM
	STUV19AA0881-1GLP_MdP		<u>Active substance (Active chlorine content)</u> T0: 3.89% T3: 3.30% T6: 2.86% (26.47% degradation)	
	STUV19AA0884-1GLP_MdP		<u>Chlorate anions content</u> T0: 0.0401% T3: 0.2453% T6: 0.3816%	
	Visual		<u>Appearance</u> T0: Clear and light yellow liquid T3: No variation T6: No variation	
	Visual		<u>Appearance of the packaging</u> T0: Blue 5 liters plastic can (HDPE), closed by a black screw cap T3: No variation T6: No variation	
	CIPAC MT 191		<u>Alkalinity</u> T0: 6.98% w/w NaOH equivalent assay T3: 7.61% w/w NaOH equivalent assay T6: 7.46% w/w NaOH equivalent assay	
	CIPAC MT75.3		<u>pH</u> Neat (20°C): T0:13.72 T3:13.87 T6:14.06	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Dilution 1% (w/v) (20°C): T0: 12.02 T3: 12.19 T6: 12.15	
	OECD 109		<u>Relative density</u> T0: 1.175 T3:1.174 T6: 1.174	
	<u>e-CA remark</u>: The analytical methods for determination of the active substance and chlorate content are validated within the study and are the same as reported in section 2.2.4. (STUV19AA0881-1GLP and STUV19AA0884-1GLP). Results show degradation of 26.47% after 6 months. As more than 10% degradation of the active substance during storage was expected and observed, in line with the Guidance on the BPR Vol. II Part A (ECHA, May 2018), a degradation products assessment have been performed. The degradation of the active substance (NaOCl) into chlorate explains the variation in NaOCl wt% over the 3 timepoints. The amount of chlorate formed is driven by the reaction pathway for degradation of hypochlorite to chlorate: $3OCl^{-}$ ➔ ClO^{3}- + $2Cl^{-1}$ For each mol hypochlorite degraded, according to this pathway 0.33 mol of chlorate is formed. Taking into account the difference in molecular weight, this means that for each 1% of sodium hypochlorite degraded, 0.33 x 83.447/74.44 = 0.38% chlorate is formed. When looking closer at the measured concentrations of NaOCl and Chlorate (see table below), the chlorate formation explains the "loss" of NaOCl. At T=3M only 0.071 % w/w NaOCl is degraded via a different path. At T=6M only 0.17% w/w NaOCl is degraded via a different path.			

[1] Staffan Sandin, Rasmus K. B. Karlsson, and Ann Cornell (2015): "Catalyzed and Uncatalyzed Decomposition of Hypochlorite in Dilute Solutions". *Industrial Engineering Chemical Research*, volume 54, issue 15, pages 3767–3774

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td colspan="4">
<table>
<tr><th></th><th>T0</th><th>T3</th><th>T6</th></tr>
<tr><td>avCl % w/w</td><td>3,89</td><td>3,3</td><td>2,86</td></tr>
<tr><td>NaOCl % w/w</td><td>4,08</td><td>3,46</td><td>3,00</td></tr>
<tr><td>ClO_3 % w/w</td><td>0,0401</td><td>0,2453</td><td>0,3816</td></tr>
<tr><td>Total NaOCl % w/w degraded</td><td></td><td>0,62</td><td>1,08</td></tr>
<tr><td>Total % NaOCl degradation</td><td></td><td>15,2%</td><td>26,5%</td></tr>
<tr><td>ClO_3 % w/w formed during storage</td><td></td><td>0,2052</td><td>0,3415</td></tr>
<tr><td>NaOCl % w/w degraded via chlorate path</td><td></td><td>0,5490</td><td>0,9136</td></tr>
<tr><td>% NaOCl degradation via chlorate path</td><td></td><td>13,4%</td><td>22,4%</td></tr>
<tr><td>Remaining NaOCl % w/w degraded</td><td></td><td>0,071</td><td>0,17</td></tr>
<tr><td>Remaining % NaOCl degraded</td><td></td><td>1,7%</td><td>4,1%</td></tr>
</table>

Given the above well-known and well-described NaOCl degradation pathways and the measurements of Chlorate formation, it can be concluded that all degradation components have been identified.

Moreover, an efficacy assessment has been performed (2019/53AM). Based upon available efficacy test data according to EN1276 and EN1650 on a 6-months aged sample, a shelf-life of 6 months is currently claimed (see section 2.2.5 for more details).

e-CA considers the applicant’s explanation to be acceptable.

Shelf-life: 6 months
</td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td colspan="4">Test waived – “Protect from frost” will be added to the label</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td colspan="4">Test waived – “Keep away from direct sunlight” will be added to the label. All commercial packagings are non-transparent to light.</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity</td><td colspan="4">Temperature: Refer to storage stability testing
Humidity: Not relevant. The product is a liquid.</td></tr>
<tr><td>Effects on content of the active substance</td><td colspan="4">Refer to storage stability testing.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and technical characteristics of the biocidal product - **reactivity towards container material**	The product is corrosive to metals; however, since the product is stored in HPDE containers, this is not relevant for commercial packages.			
Wettability	Test waived - Not relevant for liquid formulations.			
Suspensibility, spontaneity and dispersion stability	Test waived - Not relevant for soluble concentrates.			
Wet sieve analysis and dry sieve test	Test waived – Not relevant for liquids			
Emulsifiability, re-emulsifiability and emulsion stability	Test waived – Not relevant since no emulsions are formed.			
Disintegration time	Test waived – Not relevant for liquids			
Particle size distribution, content of dust/fines, attrition, friability	Test waived – Not relevant for this product since it is a liquid, but it is not spray or aerosol. No droplets are formed with the application of the product.			
Persistent foaming	CIPAC 47.3	3.8% NaOCl Test product: Radic R12 Batch 200722	Foam volume <u>Dilution 2.9%:</u> After 1 min: 0 mL After 12 min: 0 mL <u>Dilution 0.58%:</u> After 1 min: 0 mL After 12 min: 0 mL	C. Belussi 2020 STULV20AA4100-1
Flowability/Pourability/Dustability	Test waived – Not relevant for liquids			
Burning rate — smoke generators	Test waived – Not relevant. Product is not a smoke generator.			
Burning completeness — smoke generators	Test waived – Not relevant. Product is not a smoke generator.			
Composition of smoke — smoke generators	Test waived – Not relevant. Product is not a smoke generator.			
Spraying pattern — aerosols	Test waived – Not relevant. Product is not a spray product.			
Physical compatibility	Not relevant. Product is not intended to be used in combination with other products.			
Chemical compatibility	Not relevant. Product is not intended to be used in combination with other products. The product is only mixed with water.			
Degree of dissolution and dilution stability	Degree of dissolution	Test waived - Test not applicable for this product since it is not a water soluble bag or tablet.		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Dilution stability CIPAC 41.1	3.8% NaOCl Test product: Radic R12 Batch 200722	2.9% dilution Homogeneous solution after 30 min and after 24 h	C. Belussi 2020 STULV20AA4100-1
Surface tension	OECD 115/ EC method A.5	3.8% NaOCl Test product: Radic R12 Batch 200722	Dilution 2.9% at 20°C: 67.2 mN/m	C. Belussi 2020 STULV20AA4100-1
Viscosity	OECD 114 Rotational viscosimeter	3.8% NaOCl Test product: Radic R12 batch 190206	<u>Viscosity at 20°C:</u> 2.6 mPa.s – Newtonian liquid <u>Viscosity at 40°C:</u> 1.7 mPa.s – Newtonian liquid	A. Bonetti 2019 STULV19AA0885-1

Conclusion on the physical, chemical and technical properties of the product

Radic R12 is a clear and light yellow liquid with a relative density of 1.175 (at 20°C).The pH of the pure product is 13.72 and the pH of the 1% dilution is 12.02. No foam is formed after 1 and 12 min. A homogeneous solution is observed after 24 h. It has a surface tension 67.2mN/m at 20°C. The product is a Newtonian liquid.

With regard to product stability, no accelerated storage data and low temperature data are available, which is addressed by storage condition restrictions ("Do not store at temperatures above 30°C", "Keep away from direct sunlight" and "Protect from frost").

Long term storage studies at ambient temperature are available (2019/53 AM). The active substance content decrease of 26.47% after 6 months. As more than 10% degradation of the active substance during storage was expected and observed, in line with the Guidance on the BPR Vol. II Part A (ECHA, May 2018), an efficacy assessment and an assessment of the degradation products have been performed.

The degradation product is identified as Chlorate. Chlorate concentrations are therefore monitored and increase during the stability testing (T0: 0.0401% and T06: 0.3816%).

Based upon available efficacy test data according to EN1276 and EN1650 on a 6-months aged sample, a shelf-life of 6 months is currently claimed.

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Shelf-life: 6 months

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE Evaluation
Explosives	Test waived – The study does not need to be conducted because none of the components of the biocidal product has explosive properties. CAR Active chlorine released from sodium hypochlorite, January 2017: New test for explosives according to the UN Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria needs to be provided (at the maximum available concentration of sodium hypochlorite in water), at the latest six months before the date of approval. A Letter of Access to the dossier of the active substance in added in section 13 of the IUCLID file.				The applicant refers to the CAR of the active substance for the explosive property. However, this property has been requested as post-authorisation requirements, and the evaluation is still ongoing. Since there is no evidence provided concerning the explosive property, and the harmonized classification mentions no physico-chemical associated hazards, we propose to not classify the product Radic R12 as explosive at this stage. We suggest to postpone the evaluation of this data to the renewal stage of the product Radic R12.
Flammable gases	Not relevant, product is a liquid				
Flammable aerosols	Not relevant, product is not an aerosol				
Oxidising gases	Not relevant, product is a liquid				
Gases under pressure	Not relevant, product is a liquid				
Flammable liquids	EEC A.9	3.8% NaOCl Test product: Radic R12 batch 190206	Flash point: 82.0°C Radic R12 is not flammable.	A. Mazzei 2019 1901244	Acceptable
Flammable solids	Not relevant, product is a liquid				
Self-reactive substances and mixtures	Test waived – The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties. Not self-reactive, product does not contain self-reactive substances.				Acceptable
Pyrophoric liquids	Test waived – The product is not pyrophoric: does not ignite spontaneously in contact with air at normal temperature.				Acceptable
Pyrophoric solids	Not relevant, product is a liquid				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE Evaluation
Self-heating substances and mixtures	Test waived – The study does not need to be conducted because the product is a liquid.				Acceptable
Substances and mixtures which in contact with water emit flammable gases	Test waived – The product contains water as the major ingredient; therefore testing is not necessary.				Acceptable
Oxidising liquids	Test waived – The study does not need to be conducted because none of the co-formulants of the biocidal product has oxidising properties. CAR Active chlorine released from sodium hypochlorite, January 2017: New test for oxidising liquids according to the UN Recommendation on the Transport of Dangerous Goods, Manual of Tests and Criteria needs to be provided (at the maximum available concentration of sodium hypochlorite in water), at the latest six months before the date of approval. A Letter of Access to the dossier of the active substance in added in section 13 of the IUCLID file.				**e-CA remark:** The applicant refers to the CAR of the active substance for the oxidising liquids. However, oxidising liquids have been requested as post-authorisation requirements, and the evaluation is still ongoing. Since there is no evidence provided concerning oxidising liquids, and the harmonized classification mentions no physico-chemical associated hazards, we propose to not classify the product Radic R12 as oxidising liquids at this stage. We suggest to postpone the evaluation of this data to the renewal stage of the product Radic R12.
Oxidising solids	Not relevant, product is a liquid				
Organic peroxides	Test waived – The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria. No organic peroxides present in the product.				Acceptable
Corrosive to metals	Test waived – Based on the extreme pH (>11.5) the product is automatically classified for metal corrosion; hence no testing is required for the product.				Acceptable Radic R12 is considered as Corrosive to metals:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	BE Evaluation
					H290: May be corrosive to metals
Auto-ignition temperatures of products (liquids and gases)	Test waived – The study does not need to be conducted because none of the co-formulants are auto-ignitable.				Acceptable
Relative self-ignition temperature for solids	Not relevant, product is a liquid				
Dust explosion hazard	Not relevant, product is a liquid				

Conclusion on the physical hazards and respective characteristics of the product
Radic R12 is considered to be corrosive to metals. Therefore, H290 (Metal corrosion 1) is assigned. Concerning explosive property and oxidising liquids, the applicant refers to the CAR of the substance active. However, they have been requested as post-authorisation requirements, and the evaluation is still ongoing. We suggest to postpone the evaluation of this data to the renewal stage of the product Radic R12. The product does not require classification for other physical hazards.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues										
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Precision**	**Reference**
					Range	Mean	RSD			
NaOCl (active substance)	Titration with sodium thiosulfate	2 fortifications per concentration level (30%, 100% and 150%)	r=0.9999 and R^2= 1 1.07 – 5.40%w/w with respect to the active chlorine, corresponding To 30 – 150% of the theoretical value of the analyte in the sample n = 5 concentration levels	Interference <3% → not relevant	99.58% – 100.57%	100.08%	0.4%	/	Assay 3.73% w/w with respect to the active chlorine RSD = 0.8% n=6	M.G. Guiso 2019 STULV19AA0881-1 GLP
Chlorate	Ion Chromatography (IC) with a conductivity detector	2 fortifications per concentration level (0.010% (LOQ), 100% and 400%)	r=1.000 and R^2=1.000 0.010 % (LOQ) – 0.249% w/w of analyte (chlorate) in the test sample	Interference <3% → not relevant	96.89% - 103.83%	99.66%	2.28%	LOQ = 0.010 % w/w	Assay = 0.0353% w/w RSD = 0.85% n=6 (No outlier found (Grubbs, Dixon))	M.G. Guiso 2019 STULV19AA0884-1 GLP

			n = 5 concentration levels							

Radic R12 contains potassium hydroxide and sodium metasilicate pentahydrate, which are substances of concern. As these co-formulant are considered to be stable and not increase on the manufacture or storage of the product, no analytical method is required.

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
NaOCl (active substance)	See above								
Chlorate	See above								

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
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, hypochlorous acid/hypochlorite anion would react rapidly with organic matter in soil, anyway. (CAR Active chlorine released from sodium hypochlorite; January 2017)									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residue definition: Cl_2/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 m3 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. Exposure to gaseous chlorine is not expected, but through accidental events (chlorine can be formed and released when the active chlorine equilibrium is shifted to low pHs by strong acids, e.g. by mixing hypochlorite-based solutions with acidic cleaning agents). In case of an accidental release of chlorine, two analytical methods[2] for the monitoring of chlorine in workplace air are available in the CAR, which allow the determination of chlorine in workplace air in the range 0.3-7.0 mg Cl_2/m^3. In principle, the range can be expanded. Though not validated, the two available methods are published methods, so they can still be concluded to be acceptable for the purpose (determination of chlorine in workplace air. (CAR Active chlorine released from sodium hypochlorite; January 2017)									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
CAR Active chlorine released from sodium hypochlorite; January 2017: Analytical method for residues in drinking water: Residue definition: HclO/ClO^- and relevant metabolite chlorate ClO_3^- The analytical methods for active chlorine (HclO/ClO—) as available in the original Euro Chlor dossier are not acceptable, since the validation is not in accordance with the Additional Guidance on TNsG on analytical methods. Therefore, a fully-validated analytical method for active chlorine residues in drinking water is requested. A fully validated									

[2] 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
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

analytical method is also requested for the relevant metabolite chlorate (ClO3—). Methods, which are necessary for monitoring purposes, should be submitted at the latest six months before the date of approval of the active substance.

Analytical method for residues in 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 (DT50surface water = 56 min at environmental temperature)

In the framework of this dossier, the requirement for a method in drinking water is covered by the letter of access to the active substance data.

e-CA remark:

The applicant refers to the CAR of the active substance for analytical method for residues in drinking water. However, this analytical method has been requested as post-authorisation requirements and the evaluation is still ongoing. We suggest to postpone the evaluation of this data to the renewal stage of the product Radic R12.

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
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 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. (CAR Active chlorine released from sodium hypochlorite; January 2017)									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
CAR Active chlorine released from sodium hypochlorite; January 2017: Residue definition: $HClO/ClO^-$ and relevant metabolite chlorate ClO_3^-									

Fully-validated analytical methods for residues of both active chlorine (HClO/ClO–) and the relevant metabolite chlorate (ClO_3^-) are requested for monitoring purposes in various matrices and for the estimation of human and animal exposure. Nevertheless, active chlorine degrades rapidly in contact with food matrices, hence the request for analytical methods for their residues in food/feeding stuff cannot be met, but for chlorate only. Methods should be submitted at the latest six months before the active substance approval.

In the framework of this dossier, the requirement for a method in food/feeding stuff is covered by the letter of access to the active substance data.

Conclusion on the methods for detection and identification of the product

The provided titration method is adequately validated for determination of the content of the active substances in the biocidal product Radic R12.

The provided IC method is adequately validated for determination of the content of the relevant impurity chlorate in the biocidal product Radic R12.

No analytical method is required for the SOCs.

Analytical methods for detection are available in the active substance dossier (January 2017). However, the analytical method for drinking water in the CAR has been requested as post-authorisation requirements and the evaluation is still ongoing. We would like to suggest to postpone the evaluation of this data to the renewal stage of the product.

2.2.5 Efficacy against target organisms

2.2.5.1 Function organisms to be controlled) and field of use (products/objects to be protected) of the product RADIC R12

Main Group 01: DISINFECTANTS
Product types : PT4 (Food & feed Area)

The product RADIC R12 contains 3.82% w/w% Sodium hypochlorite (CAS N° 7681-52-9) as active substance.

The product RADIC R12 is a liquid concentrate to be diluted with potable water and is intended to be used by professional users only.

The product RADIC R12 is intended to have bactericidal and yeasticidal activities and to be used for disinfection of inner surfaces in food industry and milking equipment by cleaning-in-place (CIP) with circulation. The disinfectant is present in a stock tank or reservoir and dosed automatically or manually. A typical CIP cycle could contain several steps, such as pre-rinsing, treatment with acid/cleaning solution, intermediate rinsing, treatment with disinfectant and a final rinsing and drying step.

The product RADIC R12 is intended to be used to protect food and feed from contamination with spoilage organisms and pathogenic organisms that may cause disease. The "organisms to be protected" are human beings and animals.

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

The effect of sodium hypochlorite is to kill target organisms or to prevent growth. Hypochlorite aqueous solution is an extremely efficient biocide for prions, viruses, bacteria, parasites and fungi.

The hypochlorite ion is in equilibrium with hypochlorous acid (HClO) and chlorine (sum: active chlorine or available chlorine) depending on the pH value: chlorine is available only below pH 4, in the neutral pH range hypochlorous acid is the predominant species, and at pH values higher than 10 the only species present is the hypochlorite ion.
Hypochlorite reacts actively by chlorination of nitrogen with compounds like amino acids.
The disinfecting efficiency of hypochlorite aqueous solution is dependent on the active chlorine concentration and decreases with an increase in pH.
It is irrelevant whether active chlorine is released from either chlorine gas, calcium hypochlorite or sodium hypochlorite, so efficacy data from different sources of active chlorine can be used.

The concentrations to obtain efficacy on target organisms vary depending on the type of microorganism and the type of use of the substance.
No unacceptable suffering is caused using sodium hypochlorite.

The chlorination and the oxidation reaction of hypochlorous acid are unspecific.
Hypochlorous acid reacts by chlorination of nitrogen within amino acids. This results in:

- A destructive permeability change in bacterial walls and leakage of cell contents
- Inactivation of enzymes essential to cell metabolism
- Destruction of virus capsids

At low concentrations in water (0.1 to 1 mg/L) hypochlorite is able to inhibit bacterial growth. In this case the proteins of the membrane are partly destroyed, and the bacteria are not able to multiply.

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

2.2.5.3 Efficacy data

Efficacy tests performed according to suspension standards have been submitted : Phase 2/Step 1 efficacy tests are mandatory for products intended to be used for CIP with circulation procedures.

As the biocidal product contains co-formulants, a screening of the co-formulants was done to determine if additional efficacy testing is required (as described in CA-Nov17-Doc.4.2).

A co-formulant is considered a known AS if it is:
- Included in the review programme / under review as a new active substance, irrespective of PT
- Included in the Union list or annex I of the BPR, irrespective of PT
- Was included in the notified active substances list 2032/2003/EC
- Related to a substance in the above three categories

One substance was identified: potassium hydroxide (CAS 1310-58-3).

Based on a literature search, a cut-off concentration of 0.1M or 0.56% was derived (see obsolete Manual of Decisions used under the BDP (98/8/EC)). The in-use concentration in a 3.4% dilution of the product is 0.2302% KOH, being well below the cut-off derived from literature. Therefore, it can be concluded that potassium hydroxide can be excluded as potential active substance. No additional efficacy testing is required.

According to the Guidance on the BPR, for CIP only phase 2 step 1 testing is required, with a contact time as claimed and at the temperature as claimed. Since CIP is done at high temperatures (60°C), Enterococcus faecium is the only test organism for claiming bactericidal activity. For yeasts, no temperature resistant strains are available, therefore the standard test organism is tested at the maximum temperature for which the test is validated, which is in this case Candida albicans at 40°C.
Since the was more than 10% degradation of the active substance during storage, the efficacy tests have been repeated on samples that have been stored during the shelf life (6 months). For the tests on aged product, the product concentrations have been adapted in order to obtain the same in-use NaOCl concentration in the final dilutions.

<table>
<tr><th colspan="5">Experimental data on the efficacy of the biocidal product against target organisms</th></tr>
<tr><td colspan="2">Field of use envisaged</td><td>PT4</td><td colspan="2">Disinfection of inner surfaces by CIP (with circulation) in food industry, meat industry, beverage industry, agriculture and milking equipment
B + L - Dirty Conditions - 15 min at +60°C</td></tr>
<tr><td colspan="5"></td></tr>
<tr><th>Test product</th><th>Function & Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results : effects</th><th>Reference & R.I.</th></tr>
<tr>
<td>RADIC R12
Batch N°190314</td>
<td>Bactericidal activity
Enterococcus faecium (heat resistant reference test organism for products tested at T°C above +40°C)

Yeasticidal activity
Candida albicans</td>
<td>EN 1276 (2010)
+ EN 1650 (2013)
Quantitative suspension efficacy tests

- Fresh product
- Product stored 6 months at +25°C (in HPDE plastic can)

• Temperature :
+60 ± 1°C (for bacteria)
+40 ± 1°C (for yeasts)
• Contact time :
15 min
• Concentrations tested :
From 0.0026% to 5.8%
• I.S. : 5 conditions tested
0.3g/L BSA
3g/L BSA
1% Milk
3g/L BSA + 3 mL/L RBC
1% Sucrose</td>
<td>
<table>
<tr><th colspan="5">Minimal Effective Concentration Radic R12 (%)</th></tr>
<tr><th></th><th colspan="2">E. faecium</th><th colspan="2">C. albicans</th></tr>
<tr><th></th><th>J_0</th><th>$J_{+6months}$</th><th>J_0</th><th>$J_{+6months}$</th></tr>
<tr><td>Soiling</td><td></td><td></td><td></td><td></td></tr>
<tr><td>BSA 0.3%</td><td>0.52</td><td>1.7</td><td>1.31</td><td>0.87</td></tr>
<tr><td>Milk</td><td>0.52</td><td>0.58</td><td>1.31</td><td>0.58</td></tr>
<tr><td>BSA/RBC</td><td>1.57</td><td>1.7</td><td>2.62</td><td>2.9</td></tr>
<tr><td>Sucrose</td><td>0.52</td><td>0.58</td><td>0.13</td><td>0.14</td></tr>
</table>
Since bactericidal & yeasticidal activities are basic requirements for PT4 inner surface disinfection by CIP, one single Use concentration/Contact Time will be validated for each soiling condition.

Therefore, the product RADIC R12, when used at +60°C during 15 min, is bactericidal & yeasticidal (up to 6 months if stored at +25°C in HPDE plastic cans) :
- At 1.7% for CIP procedures in General food/feed industries (excluding milk, meat and beverage industries)
- At 1.31% for CIP procedures in milk industries
- At 2.9% for CIP procedures in meat industries
- At 0.58% for CIP procedures in beverage industries.
</td>
<td>Doc. "Radic R12 _ shelf life and efficacy _ final report"</td>
</tr>
</table>

Conclusion on the efficacy of the product

According to the efficacy data/results submitted by the Applicant, the product ***RADIC R12***, when used at +60°C during 15 min, is bactericidal & yeasticidal (up to 6 months if stored at +25°C in HPDE plastic cans) at 2.9% in food/feed industries (including meat and beverage industries) and in milking equipment by CIP (with circulation) procedures.
The product could be granted.

2.2.5.4 Occurrence of resistance and resistance management

Although different species vary in their sensitivity to active chlorine, development of acquired resistance is not expected since its multiple molecular sites of attack on the surface and within the microbial cells. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003 and Submission to SCENIHR, February 2008)] as one of the biocides where acquired resistance is least likely to develop. For the same reasons cross-resistance is not to be expected, nor has it been observed. Despite its use for almost a century in purifying drinking water, where very low (sub ppm) concentrations are continuously maintained, the development of acquired resistance has not been observed.

Adaptation of organisms to hypochlorite can be determined by comparison of the Minimum Inhibitory Concentration (MIC) but this is not relevant in practice as the actual use concentrations are much higher and thus a sufficient margin of safety is provided.

2.2.5.5 Known limitations

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

Do not bring the product in contact with acids; may release toxic gas.
Do not store the product in metal containers (metal corrosive).

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

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No toxicological test data are available on the biocidal product Radic R12. For all endpoints, effects on human health are derived from information on the individual components, using CLP mixture rules for product classification.

Active substance effects and critical concentrations are described in the sodium hypochlorite assessment report (CAR)[3]. According to the CAR, adverse effects of the active substance in humans are limited to local effects at the site of first contact and primary health hazards are associated with potential exposure to skin and eyes. Potential systemic effects are secondary to its direct irritating reactivity.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product is classified as skin corrosive
Justification for the value/conclusion	The study does not need to be conducted due to the extreme pH (>11.5) of the product. The available information indicates that the product should be classified for skin corrosion.
Classification of the product according to CLP and DSD	Skin corrosion 1 H314

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product is classified as serious eye damage
Justification for the value/conclusion	The study does not need to be conducted due to the extreme pH (>11.5) of the product. The available information indicates that the product should be classified as serious eye damage.
Classification of the product according to CLP and DSD	Eye damage 1 H318

Respiratory tract irritation

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to respiratory tract irritation according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for respiratory tract irritation, the product is also not classified.

[3] Assessment report Active chlorine released from sodium hypochlorite, PT2, January 2017, eCA: Italy

Skin sensitization

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to skin sensitization according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for skin sensitization, the product is also not classified

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to respiratory sensitization according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for respiratory sensitization, the product is also not classified.

Acute toxicity

Acute toxicity by oral route

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to acute oral toxicity according to Regulation (EC) No 1272/2008 (CLP). Based on the CLP mixture rules the product is not classified.

Acute toxicity by inhalation

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to acute inhalation toxicity according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for acute inhalation toxicity, the product is also not classified.

Acute toxicity by dermal route

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to acute dermal toxicity according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for acute dermal toxicity, the product is also not classified.

Information on dermal absorption

Data waiving	
Information requirement	Not relevant
Justification	According to the NaOCl assessment report, dermal absorption is considered as not relevant because chlorine-related toxicity is based on local effects only (with secondary systemic effects at high doses). Information on dermal absorption from the product is not available.

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

All ingredients present in the product have been screened, and potential substances of concern (SoC) for human health have been identified, according to the Guidance on the BPR Volume III Human Health.

Identified potential SoCs are assigned to one of four possible product hazard classification bands (from A to D) of increasing evaluation and risk management requirements.

BAND A – This band includes SoCs which trigger products to be classified for moderate acute toxicity, including narcosis, and/or mild irritation.
BAND B - This band includes SoCs which trigger products to be classified for severe or very severe acute toxicity, corrosion and/or sensitisation. *For these SoCs only a qualitative risk assessment will be performed during risk characterisation.*
BAND C – This band includes SoCs which trigger products to be classified for repeated dose toxicity, lactation effects and/or carcinogenicity, mutagenicity (or reprotoxicity in the lowest category). *For these SoCs a semi-quantitative risk assessment will be performed.*

BAND D – This band includes SoCs which trigger products to be classified for carcinogenicity (Cat 1, 2), reproductive toxicity (Cat 1, 2) and mutagenicity. *As none of the ingredients present is assigned to Band D, this is not discussed further.*

In total, the product contains 2 SoC:

- Potassium hydroxide
- Sodium metasilicate pentahydrate

The information on the substances of concern is provided in the confidential annex. Both are band B SoC and therefore a qualitative risk assessment will be performed.

Available toxicological data relating to a mixture

There are no further toxicological test data available on the product.

Other

Assessment of endocrine disruptor properties
Please refer to section 2.2.9.

Assessment of disinfection by-products
The applicant received a LoA to the DBP Consortium Data concerning the disinfection by-products risk assessment. This LoA is included in IUCLID section 13.

2.2.6.2 Exposure assessment

The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity without prior metabolism. NaOCl does not become systemically available upon dermal contact, ingestion or inhalation. Any systemic effects are considered to be secondary to local irritation/corrosion. Consequently, only a local exposure and risk assessment is performed for all relevant routes of exposure (i.e. oral, dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

Dermal exposure: For the dermal route of exposure, a semi-quantitative (Tier-1) assessment, and if required (i.e. in case the dermal NOAEC is exceeded in Tier-1), a qualitative (Tier-2) assessment is performed.

Inhalation exposure: For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed. Inhalation exposure should cover exposure to both vapour and aerosols in the air, but in the current dossier, vapour exposure towards NaOCl would only be relevant at lower in-use pH values. At pH values above 10, the active substance is mainly present in aqueous solutions as hypochlorite anion, which is not volatile. At pH values range 4 to 5.5, hypochlorous acid is the predominant species, which is volatile. As the pH of the product is above 10, vapour exposure is not relevant. Also, the SoC are not considered volatile. Thus, for inhalation, only exposure to aerosols will be considered.

The local risk assessment performed for the active substance covers the risk for the SoC with a local effect.

Oral exposure: not relevant, no oral exposure is expected.

In the absence of clear systemic effects, the BPC TOX working group (WGIII-2016, 26 May 2016) concluded that oral, dermal and inhalation absorption values are not deemed necessary.

Due to the high reactivity of chlorine species, residue formation is assumed to be negligible for aqueous solutions of NaOCl (CAR sodium hypochlorite, 2017). The BPC APCP-WGII-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage. Thus, chlorate may represent a worst-case for NaOCl residues. Sodium chlorate has a low exposure limit for oral exposure (low ADI and ArfD) and can have systemic effects. Because the product is intended to be used in the food industry, exposure to chlorate residues via oral route is possible and will be addressed in a dietary quantitative risk assessment. The dermal and inhalation exposure risk is covered by the local risk assessment of the active substance.

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

Dermal and inhalation exposure of the worker occurs during mixing & loading, i.e. when the user dilutes the product with water and manually loads the product in the stock tank or, in case of automated dosing, when the user (de)connects the containers to the pumping system or (de)connects the transfer lines.

The application (cleaning in place) takes place in a closed system. Thus exposure of the worker is not relevant during application.

The post-application phase comprises several tasks. After the content of the containers is emptied into the stock tank, empty containers are screwed down, stored and finally disposed of. As only minor amounts remain in the containers, exposure to sodium hypochlorite from empty containers is negligible and thus considered not relevant.

Dermal and inhalation exposure can occur during maintenance of the processing circuit (contact to in-use dilution) and during maintenance of the pipeline/stock tank (contact to concentrated product).

Secondary exposure cannot be excluded for professional bystanders/non-users.

Exposure to chlorate residues via food and drinking water is possible (see dietary risk assessment).

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

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1	Mixing and loading – manual	Primary exposure The professional user dilutes the product with water according to use instructions and/or manually loads the product in the stock tank or another recipient.	Professionals
2	Mixing and loading – automated	Primary exposure The product is loaded and diluted into the system by automated pumping from the packaging. The user (de)connects the containers to the pumping system or (de)connects the transfer lines.	Professionals
3	Application – cleaning in place	No relevant exposure Application in closed system	-
4	Post-application	No relevant exposure Empty containers are stored and finally disposed of.	Professionals
5	Post-application	Primary exposure Maintenance of system	Professionals
6	Indirect exposure	Secondary exposure Bystanders/non users who are present during the use of the biocidal product	Professionals

Industrial exposure

Industrial use is not foreseen for the product.

Professional exposure

Scenario 1: Mixing and loading – manual

Dermal and inhalation exposure of the worker occurs during mixing & loading, i.e. when the user dilutes the product with water and manually loads the product in the stock tank.

Quantitative risk assessment – dermal route

According to the ECHA Guidance on Human Health Risk Assessment1: "for local dermal effects, semi-quantitative hazard and exposure information could be used to support the qualitative risk assessment and resulting decision-making. The NOAEC (or the LOAEC if a NOAEC cannot be established) identified from the available animal or human data should be expressed as a percentage concentration (%). This NOAEC should then be compared directly with the in-use concentration (%) of the active substance in the representative product in each scenario without applying assessment factors. This comparison is meant to provide only an approximation of the magnitude of the risks rather than a precise, quantitative measure of the risks involved".

Dermal exposure	**Tier 1: no PPE**
Active substance [avCl] – concentrate	3.64% w/w
$NOAEC_{dermal}$ [avCl]	1%
% $NOAEC_{dermal}$ – concentrate	364%

The local exposure to the concentrated biocidal product is upper than the $NOAEC_{dermal}$, so a local qualitative risk assessment should be performed as tier 2.

Quantitative risk assessment - Inhalation route

Inhalation exposure to aerosols is calculated by using the Mixing and loading model 7 from the Technical Notes for Guidance (TNsG 2002, p.142, following HEEG opinion 1, 2008).

Inhalation exposure	**Tier 1: no PPE**	**Tier 2: PPE**
Active substance [avCl] – concentrate	3.64% (w/w)	3.64% (w/w)
Indicative value - Mixing and loading model 7	0.94 mg/m^3	0.94 mg/m^3
Potential air concentration [avCl]	0.034 mg/m^3	0.034 mg/m^3
Penetration through RPE	100%	10% (half mask & filter)
Actual air concentration [avCl]	**0.034 mg/m^3**	**0.0034 mg/m^3**

Scenario 2: Mixing and loading – automated

Dermal and inhalation exposure of the worker occurs during mixing & loading, in case of automated dosing, when the user (de)connects the containers to the pumping system or (de)connects the transfer lines.

Quantitative risk assessment – dermal route

According to the ECHA Guidance on Human Health Risk Assessment1: "for local dermal effects, semi-quantitative hazard and exposure information could be used to support the qualitative risk assessment and resulting decision-making. The NOAEC (or the LOAEC if a NOAEC cannot be established) identified from the available animal or human data should be expressed as a percentage concentration (%). This NOAEC should then be compared directly

with the in-use concentration (%) of the active substance in the representative product in each scenario without applying assessment factors. This comparison is meant to provide only an approximation of the magnitude of the risks rather than a precise, quantitative measure of the risks involved".

Dermal exposure	**Tier 1: no PPE**
Active substance [avCl] – concentrate	3.64% w/w
$NOAEC_{dermal}$ [avCl]	1%
% $NOAEC_{dermal}$ – concentrate	364%

The local exposure to the concentrated biocidal product is upper than the NOAECdermal, so a local qualitative risk assessment should be performed.

Quantitative risk assessment - Inhalation route

Inhalation exposure to aerosols is calculated by using the Mixing and loading model 7 from the Technical Notes for Guidance (TNsG 2002, p.142, following HEEG opinion 1, 2008).

Inhalation exposure	**Tier 1: no PPE**	**Tier 2: PPE**
Active substance [avCl] – concentrate	3.64% (w/w)	3.64% (w/w)
Indicative value - Mixing and loading model 7	22 mg/m^3	22 mg/m^3
Potential air concentration [avCl]	0.801 mg/m^3	0.801 mg/m^3
Penetration through RPE	100%	10% (half mask & filter)
Actual air concentration [avCl]	**0.801 mg/m^3**	**0.0801 mg/m^3**

Scenario 3: Application – cleaning in place

The application (cleaning in place) takes place in a closed system. Thus exposure of the worker is not relevant during application.

Scenario 4: Post-application - Empty containers are stored and finally disposed of

After the content of the containers is emptied into the stock tank, empty containers are screwed down, stored and finally disposed of. As only minor amounts remain in the containers, exposure to sodium hypochlorite from empty containers is negligible and thus considered not relevant.

Scenario 5: Post-application - Maintenance of system

Dermal and inhalation exposure can occur during maintenance of the processing circuit (contact to in-use dilution) and during maintenance of the pipeline/stock tank (contact to concentrated product).

Quantitative risk assessment – dermal route

Dermal exposure	**Tier 1: no PPE**
Active substance [avCl] – concentrate	3.64% w/w
$NOAEC_{dermal}$ [avCl]	1%
% $NOAEC_{dermal}$ – concentrate	364%

The local exposure to the concentrated biocidal product is upper than the $NOAEC_{dermal}$, so a local qualitative risk assessment should be performed as tier 2.

Quantitative risk assessment - Inhalation route

Inhalation exposure to aerosols is calculated by using the Mixing and loading model 7: manual loading/pouring of liquids, from the Technical Notes for Guidance (TNsG 2002, p.142, following HEEG opinion 1, 2008).

Inhalation exposure	**Tier 1: no PPE**	**Tier 2: PPE**
Active substance [avCl] – concentrate	3.64% (w/w)	3.64% (w/w)
Indicative value - Mixing and loading model 7	0.94 mg/m^3	0.94 mg/m^3
Potential air concentration [avCl]	0.034 mg/m^3	0.034 mg/m^3
Penetration through RPE	100%	10% (half mask & filter)
Actual air concentration [avCl]	**0.034 mg/m^3**	**0.0034 mg/m^3**

Scenario 6: Secondary exposure - Bystanders/non users who are present during the use of the biocidal product

The secondary exposure of professional non-users or bystanders cannot be totally excluded during use of the product. However, dermal contact with treated surfaces or equipment is considered to be non-relevant. Due to the high reactivity of NaOCl, residues on surfaces degrade very rapidly.

Secondary inhalation exposure of bystanders or non-users during mixing and loading cannot be excluded but is assumed to be equal or lower than the exposure of the user. Therefore, it is indirectly covered by the existing worst-case use scenarios. For use scenarios which require the wearing of RPE, the same RPE must be used by bystanders near the application area.

Combined scenarios
Combined scenarios are not relevant for the product.

Non-professional exposure

Use by non-professionals is not foreseen.

Exposure of the general public

Exposure of the general public is not foreseen.

Monitoring data

Not available

Dietary exposure

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
1.	Professional use	PT4 - inner surfaces disinfection of milk or drinking water tank	Human consuming of milk or drinking water
2.	Professional use	PT4 - disinfection inner surfaces by CIP	Human consuming of foodstuff

Information of non-biocidal use of the active substance
Besides being used as a disinfectant, sodium hypochlorite containing products are also applied as cleaning and bleaching agents. Household bleaches currently on the market for cleaning or bleaching contain on average 3-8% NaOCl.

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Not relevant, no livestock exposure.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Scenario 1: PT4 inner surfaces disinfection of milk or drinking water tank

Description of Scenario 1

The product is used for disinfection of inner surfaces by "*Cleaning In Place*" (CIP) in the food industry (disinfection of closed machinery such as for example tanks…).

After 6 months storage at ambient temperature, the concentration of active chlorine has de-creased with 27% and 0.3816% chlorate is measured, 0.011% correspond to the concentration of chlorate after dilution (2.9% of product).

Exposure estimation is an adaptation of calculation method described in section 5 of the Guidance on the BPR: Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses. Although the guidance is intended to address non-professional uses only, it is used to address professional uses as well since no other guidance documents on this topic are available at the moment. Dietary exposure has to be estimated using the following calculation:

$$\text{Reference calculation} \rightarrow Exp_{cons} = R_{application} \times A_{container} \div V_{milk} \times TF \times I_{milk} \div bw$$

$$\text{Adaptation of calculation} \rightarrow Exp_{cons} = ((F_t \times A_{container} \times \rho_W \times []_{chlorate} \times TF \times I_{milk.}) \div V_{milk}) \div bw$$

For this use, no method example is described in the guidance. The exposure estimation of chlorate residue is described below, following a 'layer thickness approach'. In this approach, a general storage tank for milk or drinking water are considered.

Considering that 10% of the chlorate remains on surfaces after rinsing (rinsing step figures in the mode of use). Indeed, according to the CAR for PT3, assumption of 10% and even 1% residues of chlorate on rinsed surfaces is made due to the high solubility of chlorate in water (for sodium chlorate solubility is 960-1000 g/L).

After disinfection the tank is filled with milk or drinking water (tier 1).
After disinfection and rinsing the tank is filled with milk or drinking water (tier 2).

For more explanations about calculations see section "3.4 Residue behavior".

	Parameters	Value
Tier 1	$[]_{chlorate}$: weight fraction compound -Chlorate (after 6 months storage)	 0.011%
	ρ_W : Volumetric masse density	1000 kg/m³
	F_t : Assumption of film thickness	20 µm
	$A_{container}$: Inner surface area of container	14.887 m^2
	V_{milk} : Volume of milk in container	4200 L
	TF : Mass transfer efficiency factor	100 %
	I_{milk} :Daily milk and dairy product consumption -adult -toddler -infant	 1.5 l/d 1.5 l/d 1.5 l/d

	I_{water}: Daily water consumption - adult - toddler - infant	 2 L/d 1 L/d 0.75 L/d
	Body weight -adult -toddler -infant	 60 kg 10 kg 8 kg
Tier 2	Rinsing efficiency	90% (for non-porous surfaces)

Description of Scenario [2] PT4: Disinfection of surfaces by CIP

The product is used for disinfection of inner surfaces by "*Cleaning In Place*" (CIP) in the food industry (disinfection of closed machinery such as for example pipe work..).

After 6 months storage at ambient temperature, the concentration of active chlorine has de-creased with 27% and 0.3816% chlorate is measured, 0.011% correspond to the concentration of chlorate after dilution (2.9% of product).

No guidance is available at EU level to assess the dietary risk from the biocidal use to disinfect food contact surfaces in the industrial or professional sector. Therefore, the risk assessment was carried out using the "*Food Contact Sanitizing Solutions Model*" (FCSSM), for estimating indirect dietary exposure to components of sanitizing solutions used in commercial settings.

The FCSSM updates FDA models used to establish tolerance regulations for food contact surface sanitizers (FCSS) and provide greater specificity and transparency. This model incorporates food consumption data (in mg/kg-body weight/day) from the 2011-2012 cycles of the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The FCSSM also updates the factors and assumptions underlying the use scenario estimates but does not otherwise change the basic approach taken by FDA.

The FCSSM allows determination of both acute and chronic exposure estimates for Use Scenarios 2 and 3 .

- Use Scenario 2 : All food processing equipment and utensils, including dairy. This use scenario estimates dietary exposure in food processing areas, on food processing equipment, and on utensils based on the worst-case scenario of Clean-In-Place (CIP) uses of food contact sanitizing solutions.
- Use Scenario 3 : All food processing equipment and utensils, excluding dairy. This use scenario is identical to Use Scenario 2 except that main categories of dairy items were removed from the analysis.

The calculated exposures for the use scenario are compared to the chemical-specific population-adjusted dose (10% of ADI in our case, 0.0003 mg/kg bw/d) to determine whether the exposure and risk estimates are below the chemical-specific level of concern (i.e. < 100% ADI). The FCSSM is generic in nature in that it does not rely on chemical-specific residue data or chemical-specific assumptions.

Dietary exposure has to be estimated using the following calculation:

$$EDI\left(\frac{\mu g}{kg\ BW}/_{day}\right) = \left(\frac{\left(1\frac{mg}{cm^2}\right)\left(FCSS\ Use\ Conc.\left(\frac{\mu g}{1000\ mg}\right)\right)}{\frac{mass\ food\ (g)}{surface\ area\ (cm^2)}}\right)\left(Food\ Intake\left(\frac{g}{kg\ BW}/_{day}\right)\right) = FCSS\ Intake\left(\frac{\mu g}{kg\ BW}/_{day}\right)$$

The EDI's for each food group within an age category are summed to give the total estimated dietary consumption of residues of chemical (chlorate) for that age group.

General assumptions included in the FCSSM include:

- A food weight factor (FWF) is used to represent the weight of food per unit surface area of the equipment, with the surface area of typical CIP systems provided by the relevant industry groups.

- It is assumed, following FDA guidance, that 1 mg/cm² of product residue is present on the surfaces and that all residue (100%) transfers to the food being processed.
- Daily intake of each of the relevant individual food items was determined for each population subgroup. Summary consumption statistics for food categories and U.S. subpopulations were developed by risksciences.net and Sielken & Associates using the consumption data in NHANES (specific intake amounts for each population subgroup can be seen on the corresponding use scenario tabs in the Excel spreadsheet)
- The model assumes that an individual consumes every single item in the food category.
- Summary consumption statistics were developed for each available category within each subpopulation.

Considering that 10% of the chlorate remains on surfaces after rinsing (rinsing step figures in the mode of use). Indeed, according to the CAR for PT3, assumption of 10% and even 1% residues of chlorate on rinsed surfaces is made due to the high solubility of chlorate in water (for sodium chlorate solubility is 960-1000 g/L).

Tier 1: Without rinsing step after disinfection
Tier 2: With rinsing step after disinfection

For more explanations about the using model see user guide model FCSSM and excel spread section 3.2 "*Output tables from exposure assessment tools*" (Human Health).

	Parameters	Value
Tier 1	$[]_{chlorate}$: weight fraction compound -Chlorate	0.011%
	95th Percentile Consumption (g/kg BW/day)	See spreadsheet or user guide present in annex 3.2
	FWFactor (g/cm²)	See spreadsheet or user guide present in annex 3.2
	Product residue present on the after disinfection (mg/cm²)	1
Tier 2	Rinsing efficiency	90% (for non-porous surfaces)

Calculations of transfer into foods:

Scenario 1

Tier 1:

		milk	**water**
In-use concentration NaOCl	%	0,11	0,11
In-use concentration of chlorate	%	0,011	0,011
Surface area tank	m²	14,8871319	14,8871319
Layer thickness	m	0,00002	0,00002

Volume of product remaining on the wall	m^3	0,00030	0,00030
Volumetric masse density	g/m^3	1000000	1000000
Volume of tank	L	4200	4200
mass transfer efficiency		1	1
Daily consumption adult	L/d	1,5	2
Daily consumption toddler	L/d	1,5	1
Daily consumption infant	L/d	1,5	0,75
Body weight adult	kg	60	60
Body weight toddler	kg	10	10
Body weight infant	kg	8	8
Chronic exposure estimation adult	µg/kg/day	1,9E-01	2,60E-01
Chronic exposure estimation toddler	µg/kg/day	1,16E+00	7,80E-01
Chronic exposure estimation infant	µg/kg/day	1,46E+00	7,31E-01

The systemic exposure of toddlers and infants is upper than 10% of ADI for chlorate. Therefore a tier 2 is proposed considering rinsing step efficiency of 90%.

Tier 2:

		milk	**water**
In-use concentration NaOCl	%	0,11	0,11
In-use concentration of chlorate	%	0,011	0,011
remaining after rinsing	%	10	10
In-use concentration of chlorate after rinsing	%	0,0011	0,0011
Surface area tank	m^2	14,8871319	14,8871319
Layer thickness	m	0,00002	0,00002
Volume of product remaining on the wall	m^3	0,000297743	0,000297743
Volumetric masse density	g/m^3	1000000	1000000
Volume of tank	L	4200	4200
mass transfer efficiency		1	1
Daily adult	L/d	1,5	2
Daily consumption toddler	L/d	1,5	1
Daily consumption infant	L/d	1,5	0,75
Body weight adult	kg	60	60

Body weight toddler	kg	10	10
Body weight infant	kg	8	8
Chronic exposure estimation adult	µg/kg/day	1,9E-02	2,60E-02
Chronic exposure estimation toddler	µg/kg/day	1,16E-01	7,80E-02
Chronic exposure estimation infant	µg/kg/day	1,46E-01	7,31E-02

The systemic toddlers and infants exposure is lower than 10% of ADI for chlorate. Further investigation on MRL is not necessary then.

Scenario 2:

For more explanation about calculations please refer to the user guide model FCSSM and excel spread section 3.4 "*Residue behaviour*".

All food processing equipment and utensils, including dairy :
Tier 1 – without rinsing step :

Population	systemic exposure to chlorate µg/kg bw/day
Infants*	0.51
Toddlers**	0.44
Adults***	0.15

* Infants <1 year old

** Children 1-2 years old

*** Adults 20-49 years old

The systemic exposure of toddlers and infants is upper than 10% of ADI for chlorate. Therefore a tier 2 is proposed considering rinsing step efficiency of 90%.

Tier 2 – with rinsing step :

Population	systemic exposure to chlorate µg/kg bw/day
Infants*	0.051
Toddlers**	0.044
Adults***	0.015

* Infants <1 year old

** Children 1-2 years old

*** Adults 20-49 years old

The systemic toddlers and infants exposure is lower than 10% of ADI for chlorate. Further investigation on MRL is not necessary then.

All food processing equipment and utensils, excluding dairy :
Tier 1 – without rinsing step :

Population	systemic exposure to chlorate

	µg/kg bw/day
Infants*	0.25
Toddlers**	0.31
Adults***	0.12

* Infants <1 year old

** Children 1-2 years old

*** Adults 20-49 years old

The systemic exposure of toddlers is slightly upper than 10% of ADI for chlorate. Therefore a tier 2 is proposed considering rinsing step efficiency of 90%.

Tier 2 – with rinsing step :

Population	systemic exposure to chlorate µg/kg bw/day
Infants*	0.031
Toddlers**	0.025
Adults***	0.012

* Infants <1 year old

** Children 1-2 years old

*** Adults 20-49 years old

The systemic exposure of toddlers is lower than 10% of ADI for chlorate. Further investigation on MRL is not necessary then.

Conclusion

To estimate the dietary transfer of chlorate into food as a consequence of using the product for CIP disinfection in food industry, no reference scenario is available.

A 'layer thickness approach' and the FCSSM are used to estimate the amount of chlorate transferred and the worst-case chronic exposure to an adult, toddler and infant. The risks are acceptable considering 90% rinsing efficiency (<10 % of ADI value). Further investigation on MRL is not necessary then.

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

The product is not intended for non-professional use.

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

Not needed for this product.

Aggregated exposure

[Template structure to be further developed once the methodology has been developed.]

Summary of dietary exposure assessment

Scenarios and values to be used in risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/rinsing step**	**Estimated total uptake** (µg chlorate/kg/day)	
			milk	**water**
1. Transfer into food: PT4 - inner surfaces disinfection of milk or drinking water tank	General public – adult	1/no rinse	1,90E-01	2.60E-01
		2/with rinse	1,90E-02	2.60E-02
	General public – infant	1/no rinse	1,46E+00	7.80E-01
		2/with rinse	1,46E-01	7.80E-02
	General public – toddler	1/no rinse	1,16E+00	7.31E-01
		2/with rinse	1,16E-01	7.31E-02
			with dairy	**without dairy**
2. Transfer into food: PT4 - disinfection inner surfaces by CIP	General public – adult	1/no rinse	1,50E-01	1.20E-01
		2/with rinse	1,50E-02	1.20E-02
	General public – infant	1/no rinse	5,10E-01	2.50E-01
		2/with rinse	5,10E-02	2.50E-02
	General public – toddler	1/no rinse	4,40E-01	3.1E-01
		2/with rinse	4,40E-02	3.1E-02

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
NOAECoral	rat 90-d subchronic repeated dose oral (drinking water) study rat 104-wks chronic repeated dose oral (drinking water) study	0.1%	1	-	0.1% avCl
NOAECdermal	human (dermatitis patients) 48 h-patch test study	1%	1	-	1% avCl
AECinhalation (chlorine)	monkey 52-wks subchronic repeated dose inhalation study human volunteer single dose inhalation study (4-8 h) human volunteer repeated dose inhalation study (3 d, 6 h/d)	NOAEC 1.5 mg/m3	3.2 (intra-species toxicodynamic factor)	-	0.5 ppm avCl (1.5 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
ArfD	based on human 12-wks repeated dose oral (drinking water) clinical study according to EFSA CONTAM Panel (EFSA	Not applicable	Not applicable	Not applicable	36 µg chlorate/kg bw

	Journal 2015;13(6):4135				
ADI	based on the TDI for perchlorate (derived from human observations) according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135)	Not applicable	Not applicable	Not applicable	3 µg chlorate/kg bw

Maximum residue limits or equivalent
Not applicable

Risk for industrial users
No industrial use

Risk for professional users

Systemic effects
Not applicable

Combined scenarios
No combined scenarios

Local effects

Exposure scenario	**Substance**	**Tier/PPE***	**Exposure limit value** (mg/m3)	**Estimated inhalation exposure (mg/m$^{3)}$**	**Estimated exposure/ AEC (%)**	**Acceptable (yes/no)**
Scenario 1: mixing and loading – manual	avCl	1/no PPE	0.5	0.034	6.8	Yes
Scenario 2: mixing and loading – automated	avCl	1/no PPE	0.5	0.801	160.2	**No**
		2/RPE 10	0.5	0.0801	16.02	Yes
Scenario 5: Post-application – maintenance of system	avCl	1/no PPE	0.5	0.034	6.8	Yes

Dermal exposure: semi-qualitative risk characterization professional uses

Hazard			Exposure						
Hazard category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**
Scenario 1: Mixing and loading – manual **Scenario 2: Mixing and loading – automated**									
High	Skin corr. Cat 1 (H314)	-	4	Professional users	<u>Mixing and loading</u>: manual or automated <u>Post-application: maintenance</u> Repair of broken dosing system; contact to concentrate	Skin, eye	<u>Mixing & loading:</u> Few minutes a day <u>Post-application:</u> Maintenance as required	3.64% avCl (splashes, hand to eye transfer)	**Organisation** • Training for staff on good practice • Procedures and training for emergency decontamination and disposal • Good standard of personal hygiene **RMM** <u>Labelling:</u> • Labelling according to CLP <u>Formulation:</u> • Product formulation which reduces e.g. splashes <u>Trained personnel:</u> • Trained workers • Containment as appropriate • Good standard of general ventilation • Regular cleaning of equipment and work area • Avoidance of contact with contaminated tools and objects **PPE** <u>Hand protection:</u>

									Suitable chemical resistant safety gloves (EN 374). Eye protection: Safety goggles (EN 166) Body protection: Protective clothing and closed foot-wear. Body protection must be chosen based on level of activity and exposure.

Conclusion
To assure a safe use of the product for professional users, the following PPE have to be considered:

- during manual mixing and loading: wearing of protective gloves (EN 374), goggles (EN 166) and clothing
- during automated mixing and loading: wearing of protective gloves (EN 374), goggles (EN 166), clothing and respiratory protective equipment APF 10

If the product is used according to use instructions and with the recommended RMM, the hazard quotients of the exposure scenarios are below 1. This means that no human health effects are expected for the professional use of the product.

Risk for non-professional users
Not applicable

Risk for the general public
Not applicable

Risk for consumers via residues in food

Dietary exposure

Summary table: estimated dietary exposure										
Exposure scenario	**Substance**	**Exposed group**	**Oral exposure limit**	**Exposure limit value (µg/kg bw/day)**	**Estimated oral uptake**			**Estimated uptake/ exposure limit (%)**		**Acceptable?**
						Milk	**Water**	**Milk**	**Water**	
Scenario 1: PT4 - inner surfaces disinfection of milk or drinking water tank	Chlorate	Adults	10 % of ADI	0.3	Tier 1/no rinse	1,9E-01	2.60E-01	63	87	Yes
		Infant	10 % of ADI	0.3	Tier 1/no rinse	1,46E+00	7.80E-01	487	260	**No**
					Tier 2/with rinse	1,46E-01	7.80E-02	49	26	Yes
		Toddler	10 % of ADI	0.3	Tier 1/no rinse	1,16E+00	7.31E-01	387	244	**No**
					Tier 2/with rinse	1,16E-01	7.31E-02	39	24	Yes
						with dairy	**without dairy**	**with dairy**	**without dairy**	
Scenario 2: PT4 - diinfection inner surfaces by CIP	Chlorate	Adults	10 % of ADI	0.3	Tier 1/no rinse	1,50E-01	1.20E-01	50	40	Yes
		Infant	10 % of ADI	0.3	Tier 1/no rinse	5,10E-01	2.50E-01	170	-	**No**
					Tier 2/with rinse	5,10E-02	2.50E-02	17	8	Yes
		Toddler	10 % of ADI	0.3	Tier 1/no rinse	4,40E-01	3.10E-01	147	103	**No**
					Tier 2/with rinse	4,40E-02	3.10E-02	15	10	Yes

The estimated exposure is below to the exposure limit. No adverse health effects are expected from the indirect dietary exposure to chlorate because of the use of the product.

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

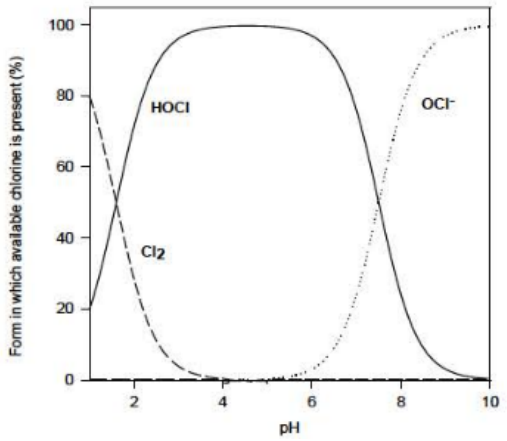
The combined exposure towards the active substance and the SoC was addressed in the sections above.

2.2.7 Risk assessment for animal health

No animals are directly or indirectly exposed by use of the product. A risk assessment for animal health is not required.

2.2.8 Risk assessment for the environment

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



The sum of these species [hypochlorite ion + hypochlorous acid + chlorine] is defined as active chlorine or available chlorine. For the chemical reactivity in aqueous solution with the same active chlorine concentrations and the same pH conditions, it is irrelevant whether active chlorine is generated from either chlorine gas, calcium hypochlorite or sodium hypochlorite. Therefore, all studies investigating hypochlorite aqueous solutions can be used for evaluation and assessment of active chlorine released from any of the three substances.

Concerning the concentration of hypochlorite solutions, two terms have to be distinguished: active chlorine and free available chlorine.
The active chlorine content of an oxidising chlorinating substance is related to the oxidising capacity of pure chlorine. 1 g of active chlorine is equivalent to 1.05 g of sodium hypochlorite or 0.74 g of HClO (please refer to Doc IIA of the CAR for more details).
Free available chlorine (FAC) is the sum of Cl2, HClO and ClO-. In practice, only HClO and ClO- are usually present because Cl2 is formed only at pH < 4. Both active and available chlorine are expressed as equivalent content of Cl2, based on the oxidising capacity as outlined before.

The product Radic R12 is a soluble concentrate containing 45 g/L of pure sodium hypochlorite (or 3.82 w/w%). None of the co-formulants is a substance of concern for the environment.

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

(1) On the assessment of the active substance :

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

The use of the product Radic R12, when used as described in the authorised uses section of this product assessment report, won't lead to a direct release to the surface water compartment (See "Fate and distribution in exposed environmental compartments" below). Therefore, a qualitative assessment for the active substance has been performed. See sections 2.2.8.2 and 2.2.8.3 for further details.

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

As indicated in the Assessment Report of Sodium Hypochlorite, an assessment of disinfection by-products (DBPs) should be done at product authorisation stage. The ENV-WG-I-2020 took the following conclusion : *"It was agreed that for the time being the information provided by the applicants in their dossiers on DBPs of all ongoing authorisation applications should be only summarized and no conclusion should be drawn referring to the current lack of guidance. In fact, all the participants agreed that the current 'guidance' covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment."*

See section 2.2.8.3 for further details.

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

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

See sections 2.2.8.2 to 2.2.8.3 for further details.

2.2.8.1 Effects assessment on the environment

In the CAR of sodium hypochlorite (IT, 2017) PNEC values are derived for the STP, fresh water, sediment and soil. All PNECs are expressed in terms of FAC. The atmosphere is not an environmental compartment of concern, and primary and secondary exposure are not considered relevant. The limit value for groundwater is 0.1 µg FAC/L.

No studies have been conducted on the product. Effects are based on data on the active substance. The applied endpoints are taken from the assessment report and summarised below.

PNEC	Lowest endpoint	AF	PNEC	Test/species
Free available chlorine (FAC)				
STP	NOEC: 41.1 mg/L	10	4.11 mg FAC/L	Respiration inhibition test
fresh water	NOEC: 2.1 µg/L	50	0.042 FAC µg/L	Algae
sediment	-	-	0.045 µg FAC/kg wwt	Equilibrium partioning from aquatic data using a theoretical K_{oc} of 13.22 L/kg. Calculated according to the Guidance part B, vol. IV; version 1 April 2015.
soil	-	-	0.015 µg FAC/kg wwt	
groundwater	Reference value for groundwater = 0.1 µg/L			
atmosphere	At environmental pH (6.5-8.5) half of the active chlorine is available as the unvolatile hypochlorite ion; half as hypochlorous acid with a Henry's law constant as 0.11 Pa m³/mol. Hence, the concentration in air will be very low and the air is not an environmental compartment of concern.			
birds	No data available for birds and mammals as primary and secondary poisoning is not considered relevant (see paragraph 2.8.2.2)			
mammals				

Substances of concern (SoC) for the environment were identified according to the BPR Guidance Vol IV, Environmental Parts B+C (2017). None of the co-formulants is a substance of concern for the environment.

Chlorate (relevant impurity):
During storage of the product, chlorate can be formed which is considered a relevant impurity.
No agreed endpoints for Sodium Chlorate are available at European level for biocides. Nevertheless, some data can be collected in the REACH registration dossier of the substance.
Toxicity to microorganisms is expected to be low (NOEC ≥ 1000 mg/L).
Short-term as well as long-term aquatic toxicity tests show that Sodium Chlorate is not very toxic to aquatic organisms and is less toxic than Active Chlorine (No EC50 or NOEC value under 10 mg/L was obtained for Sodium Chlorate).
No tests on sediment organisms were performed due to fast dissipation under anaerobic conditions, low toxicity to invertebrates, logKow of -2.9 (estimated value) and the high water solubility (approx. 700 g/l sodium chlorate).
For the soil compartment the lowest endpoint obtained is a NOEC = 333 mg/kg soil dw.

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

Sodium hypochlorite is classified Aquatic Acute 1 (H400) with an M-factor of 10 and Aquatic Chronic 1 (H410) with an M-factor of 1. Given the composition (3.82 % w/w sodium hypochlorite), the product Radic R12 is classified as:

- Acute aquatic hazard: Category Acute 1;
- Long-term aquatic hazard: Category Chronic 2.

Aquatic hazard information that could appear on the label
GHS Pictogram : GHS09 ***Signal Word:*** WARNING ***Hazard Statement:*** H410: Very toxic to aquatic life with long lasting effects ***Precautionary statement(s) :*** P273 : Avoid release to the environment P391 : Collect spillage. Hazardous to the aquatic environment P501 : Dispose of contents and container in accordance with local, regional, national, and international regulations

During storage of the product, chlorate can be formed (relevant impurity), which is classified as Aquatic Chronic 2 (H411). At the end of the maximum shelf life of 6 months, 0.3816% chlorate was measured in the long term storage stability test at ambient temperature. At that cocncentration, sodium chlorate does not contribute to the environmental classification of the product Radic R12.

Further Ecotoxicological studies

No further ecotoxicological studies have been conducted on active chlorine or the active chlorine releasing product supported in this document. No new data is available for the product Radic R12.

Data waiving	
Information requirement	Not relevant
Justification	There are valid data available on each of the components and synergistic effects between any of the components are not expected.

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

No new data is available for Radic R12.

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

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

No new data is available for Radic R12.

Data waiving	
Information requirement	Not relevant
Justification	Radic R12 is not in the form of bait or granules

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

No new data is available for Radic R12.

Data waiving	
Information requirement	Not relevant
Justification	Radic R12 is not in the form of bait or granules

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

No new data is available for Radic R12.

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

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

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

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

No new data is available for Radic R12.

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

Leaching behaviour (ADS)

Leaching tests are not available nor relevant for the use of product Radic R12 in PT4.

Testing for distribution and dissipation in soil (ADS)

No new data is available for Radic R12.

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

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

No new data is available for Radic R12.

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

Testing for distribution and dissipation in air (ADS)

No new data is available for Radic R12.

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

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

Not relevant. The product Radic R12 is not to be sprayed near to surface waters.

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

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

Not relevant. The product Radic R12 is not to be sprayed outside.

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

2.2.8.2 Exposure assessment

Radic R12 is a product containing sodium hypochlorite and is used for the disinfection of inner surfaces in food industry, meat industry, beverage industry, agriculture and milking equipment by cleaning-in-place (CIP). The product contains no substances of concern for the environment.

According to the efficacy data/results submitted by the Applicant, the product Radic R12, when used at +60°C during 15 min, is bactericidal & yeasticidal (up to 6 months if stored at +25°C in HPDE plastic cans) at 2.9% in food/feed industries (including meat and beverage industries) and in milking equipment by CIP (with circulation) procedures.

General information

Assessed PT	PT 4
Assessed scenarios	Scenario 1: Disinfection in food, drink and milk industries (FDM), assessment of entire plants (IHO, 2006) Scenario 2: Disinfection of milking parlour systems
ESD(s) used	Scenario 1 & 2: ESD for PT4: Emission scenarios for disinfectants used in food and feed areas (JRC, 2011)
Approach	Scenario 1 & 2: Qualitative approach following the ENV WG-I-2020 agreements
Distribution in the environment	Qualitative approach considering: - ENV WG-I-2020 agreements; - EUSES 2.2.0; - ECHA Guidance on the Biocidal Products Regulation, Volume IV Environment – Assessment and Evaluation (Parts B + C) (version 2.0, October 2017); - kinetic model of Vandepitte and Schowanek (ESD for PT5, Annex II).
Groundwater simulation	No simulations for leaching to groundwater using a higher tier model were performed
Confidential Annexes	No
Life cycle steps assessed	Scenario 1 & 2: Production: No Formulation: No Use: Yes Service life: No
Remarks	/

Emission estimation

Scenario 1: FDM-industry, assessment of entire plants (IHO, 2006)

This scenario considers a model food processing plant as local point source. The release of disinfectants from this local point source covers all disinfection processes which take place in the model plant.

Concerning the STP to which the waste water is released, two cases have been distinguished in the ESD:

- The waste water is released to an **on-site STP**. It's further assumed that the on-site treated waste water is directly released to surface water.
- The waste water is released to an **off-site STP**.

Although the emission estimation for the on-site STP case results in a calculated emission to the freshwater compartment (Ceffluent = Clocalwater), this has not to be considered as a direct release to surface water in the sense of the ENV WG-I-2020 agreements. Indeed, citing the ESD PT4 §2.1.3, it should be clear that no direct releases to surface water bodies take place for this scenario:

When disinfectants are applied by soaking, brushing or CIP, most of them end up in a sewage treatment plant.
[…]
Typically, untreated FDM waste water is high in both COD and BOD. Levels can be 10 – 100 times higher than in domestic waste water.
[…]
Due to the high load of organic substance in the waste water of FDMs, the waste water is usually pre-treated before release to the environment.
[…]
According to the Environment Agency of England and Wales, 2000, the main options for discharging waste water from an installation are:

- *to off-site STP without treatment;*
- *to off-site STP after partial treatment;*
- *to watercourse after full on-site STP;*
- *off-site re-use of certain waste water streams, e.g. as a feed stream in another industry, or for irrigation.*

Active chlorine released from sodium hypochlorite:

Considering the above argumentation and the ENV WG-I-2020 agreements, the releases of the product Radic R12 resulting from CIP in FDM-industry will be assessed qualitatively. No calculation of the emission to the environment is necessary. See section 2.2.8.3 below for further details on the qualitative assessment.

Chlorate (as relevant impurity):

Chlorate can be formed during storage of the product. At the end of the maximum shelf life of 6 months, 0.3816% chlorate was measured in the long term storage stability test at ambient temperature. Thus, emissions of chlorate are a small fraction compared to the emissions of active chlorine.

As agreed at WG ENV-I-2020, chlorate will be assessed qualitatively for all the environmental compartments. See section 2.2.8.3 below for further details on the qualitative assessment.

Scenario 2: Disinfection of milking parlour systems

In the ESD for PT4, it is assumed that the waste water from the milking parlour system is mainly released to the sewer system. No direct releases to surface water take place.

Active chlorine released from sodium hypochlorite:

Considering the ENV WG-I-2020 agreements, the releases of the product Radic R12 resulting from CIP in FDM-industry will be assessed qualitatively since no direct releases to surface water take place. See section 2.2.8.3 below for further details on the qualitative assessment.

Chlorate (as relevant impurity):

Chlorate can be formed during storage of the product. At the end of the maximum shelf life of 6 months, 0.3816% chlorate was measured in the long term storage stability test at ambient temperature. Thus, emissions of chlorate are a small fraction compared to the emissions of active chlorine.

As agreed at WG ENV-I-2020, chlorate will be assessed qualitatively for all the environmental compartments. See section 2.2.8.3 below for further details on the qualitative assessment.

Fate and distribution in exposed environmental compartments

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

The kinetic model of Vandepitte and Schowanek (sodium hypochlorite CAR, doc IIIA) shows that hypochlorite is eliminated during transport in the sewer within the first minutes. The $HClO/ClO^-$ (expressed as FAC) concentration drops quickly in the sewer, parallel to a sharp increase of the chloramine concentration, which can be explained by the high availability of ammonia in the sewer. Chloramine further reacts as an oxidant during additional transport in the sewer, the STP and in the river. The extensive degradation of chloramine in the activated sludge can be explained by the presence of reduced organic material. At environmental pH values (6.5-8.5) half of the active chlorine is present in the undissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion.

Based on the intended uses, the main emission pathway to the environment is expected to be the waste water. It is assumed that waste water is emitted to the surface water after treatment in either an on-site or an off-site (municipal) waste water treatment plant, leading to a undirect exposition to fresh water and fresh water sediments. The soil can also be exposed via indirect release through sludge application, leading to an emission to groundwater. Only the hypochlorous acid fraction is volatile and might enter the atmosphere due

to volatilisation from water and STP. However, the measured Henry's Law constant for hypochlorous acid of 0.11 Pa m^3 mol^{-1} indicates that concentration in air is very low. Consequently, air is not an environmental compartment of concern.

Identification of relevant receiving compartments based on the exposure pathway							
	Freshwater	**Freshwater sediment**	**STP**	**Air**	**Soil**	**Groundwater**	**Other**
Scenario 1: - on-site STP	+	N/R*	-	N/R	-	-	-
Scenario 1: - off-site STP	+	N/R*	++	N/R	+	+	-
Scenario 2	+	N/R*	++	N/R	+	+	-

++ compartment directly exposed; + compartment indirectly exposed; - compartment not exposed; N/R not relevant

* PNECsediment calculated from PNECaquatic using EPM.

Active chlorine released from sodium hypochlorite:

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	52.5	g/mol	Hypochlorous acid
Vapour pressure (at 25°C)	276	Pa	
Water solubility (at 25°C)	1E+05	mg/l	
Log Octanol/water partition coefficient	-0.87	Log 10	
Organic carbon/water partition coefficient (Koc)	13.22	L/kg	
Henry's Law Constant (at 20 °C)	0.11	Pa/m3/mol	Hypochlorous acid, measured
Biodegradability	Ready biodegradable		Sodium hypochlorite is an inorganic substance but is rapidly removed in presence of organic matter. The default value for readily degradable substances can be used for degradation in the STP (rate constant of 1 h^{-1}).
Total rate constant for degradation in bulk surface water	0.0389	d (at 12ºC)	DT50

Total rate constant for degradation in bulk sediment	0.0389	d (at 12ºC)	DT50
Rate constant for degradation in air	114.6	d	DT50
Total rate constant for degradation in bulk soil	6.48E-04	d (at 12°C)	DT50

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	0.033	Calculated for hypochlorous acid using EUSES 2.2.0 (incl. SimpleTreat 4.0)
Water	8.005	
Primary settler	0.119	
Surplus sludge	4.17E-03	
Degraded in STP	91.84	

The fate and distribution in the STP shows that the largest fraction of active chlorine is degraded while the non-degraded fraction is mainly distributed in the water phase.

It should however be noted that the degraded fraction is underestimated. The kinetic model of Vandepitte and Schowanek (please refer to the ESD for PT5 Annex II and to doc IIIA of the sodium hypochlorite CAR) shows that hypochlorite/hypochlorous acid is degraded during transport in the sewer within the first minutes. In accordance with the CAR for sodium hypochlorite, a DT50 value of 56 sec at 12°C is obtained for sodium hypochlorite in the sewer system. Considering a sewer residence time of 1 hour (proposed as default value in the ESD for PT5), this yields reductions of the active chlorine concentrations by a factor of approximately $1x10^{20}$.

Chlorate:
A valid ready biodegradability test is not available since Sodium Chlorate is inorganic and acts as an electron acceptor like molecular oxygen. Nevertheless, reduction of chlorate has been detected in terrestrial ecosystems, fresh water, marine environment, compost, and aquifers. These findings demonstrate the wide distribution of chlorate-reducing microorganisms and that chlorate is rapidly biodegradable.
Sodium Chlorate is not expected to degrade due to hydrolysis, and no data is available regarding photodegradation.

Sodium chlorate is highly soluble in water, is not expected to adsorb onto soil and does not evaporate. From these findings the environmental compartment in which sodium chlorate is expected to be present is water.

The high tendency of sodium chlorate to ionise and the very low log Kow (<-2.9) suggest that no significant bioaccumulation would occur.

Calculated PEC values

As indicated above, as the product is evaluated qualitatively, no calculation of the predicted environmental concentrations is necessary. See section 2.2.8.3 below for further details on the qualitative assessment.

Primary and secondary poisoning

Active chlorine released from sodium hypochlorite:
Primary poisoning is not expected for the intended uses.

Furthermore, active chlorine does not bio-accumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. Hence secondary poisoning is not of concern.

Chlorate:
Primary poisoning is not expected for the intended uses.

The high tendency of sodium chlorate to ionise and the very low log Kow (<-2.9) suggest that no significant bioaccumulation would occur. Hence secondary poisoning is not of concern.

2.2.8.3 **Risk characterisation**

As indicated above, the risk characterisation below is qualitative.

Atmosphere

Active chlorine released from sodium hypochlorite:
Hypochlorite might enter the atmosphere due to volatilisation from the STP. Exposure assessment in the CAR 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.

Chlorate:
Sodium chlorate is higly soluble in water (> 696 000 to < 736 000 mg/L at 20 °C ; pH 4.49 to 8.70) and its vapour pressure is low (< 3.5E-07 Pa at 20°C). Therefore the emission to air should be negligible and atmosphere is not a compartment of concern.

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

Sewage treatment plant (STP)

Active chlorine released from sodium hypochlorite:
The kinetic model of Vandepitte and Schowanek (please refer to the ESD for PT5, Annex II) shows that hypochlorite/hypochlorous acid is degraded during transport in the sewer within the first minutes. This rapid degradation is a result of the high reactivity of the active substance with organic matter and the high amount of organic matter in the sewer. In accordance with the CAR for sodium hypochlorite, a DT50 value of 56 sec at 12°C is obtained for sodium hypochlorite in the sewer system. Considering a sewer residence time of 1 hour

(proposed as default value in the ESD for PT5), this yields reductions of the active chlorine concentrations by a factor of approximately $1x10^{20}$. The concentrations of active chlorine to which microorganisms are exposed in the STP will thus be very low. Indeed, the concentration of hypochlorite in the environment modelled by Vandepitte and Schowanek is estimated to drop down to "zero" within the first minutes after release in the sewer.

Chlorate:
Given the low toxicity of sodium chlorate to microorganisms, the rapid biodegradation and the low emissions to the environment, no unacceptable risks are expected for the microorganisms of the STP.

Conclusion: No unacceptable risks are expected for the micro-organisms of the STP.

Aquatic compartment (incl. sediments)

Active chlorine released from sodium hypochlorite:
According to the reasoning followed for the STP, since the concentration entering the STP should already be close to zero, the concentration of active substance reaching the surface water compartment is expected to be even lower.

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

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

This reasoning is also valid for freshwater sediment organisms.

Chlorate:
Given the low toxicity of sodium chlorate to fresh water organisms, the rapid biodegradation, the low emissions to the environment (even negligible for sediment organisms due to the physchem properties of sodium chlorate) no unacceptable risks are expected for freshwater organisms.

Conclusion: No unacceptable risk for the organisms of the aquatic compartment is expected.

Terrestrial compartment

Active chlorine released from sodium hypochlorite:
Given the fact that the concentration of active substance in the STP sludge is assumed to be near-zero, the exposure of terrestrial compartment via sludge application is expected to be negligible. Additionally, the DT50 of the active substance in soil is equal to 56 seconds. Therefore, the terrestrial compartment is not considered to be of concern.

Chlorate:

Given the low toxicity of sodium chlorate to terrestrial organisms, the low emissions to the environment and the fact that sodium chlorate is mainly expected to be distributed to water (not in the STP sludge), no unacceptable risks are expected for terrestrial organisms due to sludge application on soil.

Conclusion: No unacceptable risk for the organisms of the terrestrial compartment is expected.

Groundwater

Active chlorine released from sodium hypochlorite:

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

Chlorate:

Given the low emissions to the environment, the fact that Sodium Chlorate is mainly expected to be distributed to water (not in the STP sludge) and its rapid degradation, no significant leaching to the groundwater compartment is expected.

Conclusion: The risks for the groundwater compartment are considered to be acceptable.

Primary and secondary poisoning

Primary and secondary poisoning are not considered relevant for the product Radic R12 (please refer to paragraph 2.2.8.2).

Mixture toxicity

The product Radic R12 contains only one active substance no substances of concern. Therefore, no mixture toxicity assessment should be performed.

Aggregated exposure (combined for relevant emmission sources)

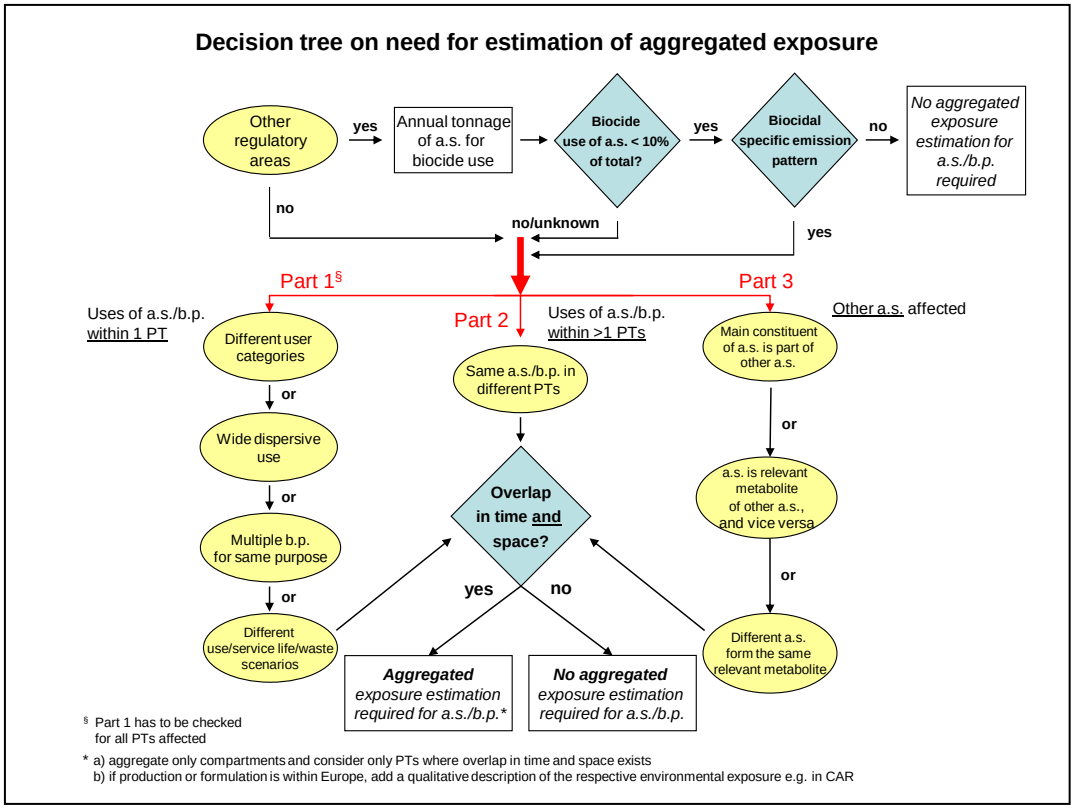


Figure 1: Decision tree on the need for estimation of aggregated exposure

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

Sodium Hypochlorite is used in other regulatory areas, the REACH dossier of the substance indicates that it is manufactured and/or imported in the European Economic Area in 1 000 000 - 10 000 000 tonnes per year.

The relevant compartment for an aggregate exposure assessment is the sewage treatment plant. 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 all three active substances should be considered to decide whether an aggregate exposure assessment is needed. However, this information is not available to the applicant.

Nevertheless, the qualitative assessment performed for the active substance shows a very rapid degradation of the substance, which prevents the accumulation of releases over time and space. Therefore, it's considered that no further aggregated exposure assessment is necessary.

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

Assessment of disinfection-by-products (DBPs)

As explained at the beginning of the environmental assessment section, the assessment of DPBs cannot be performed for the time being due to the lack of guidance and agreed parameters.

The applicant submitted the following information regarding the DBPs :

"At the time when the hypochlorite AR was written, it was indicated that it would be useful to perform an assessment on disinfection-by-products, but that given the absence of guidance, this should be done at product authorization. In the meantime, Guidance on the BPR: Volume V Disinfection By-Products v1.0 (2017) has become available, and thus DBPs were included in the environmental risk assessment here.
The applicant received a LoA to the DBP Consortium Data concerning the disinfection by-products risk assessment."

Contrary to what this text suggests, no DBPs were included in the environmental risk assessment. However, pending a usable guidance and agreed endpoints no such assessment is required.

Overall conclusion on the risk assessment for the environment of the product
The use of the product Radic R12 as disinfectant for inner surfaces in PT4 does not result in unacceptable risks for the environment.

2.2.9 Assessment of endocrine disrupting properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Radic R12:

Assessment of the ED properties of the active substances in Radic R12:

According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As active chlorine released from sodium hypochlorite is not part of the list[4] of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.
Therefore, BE eCA considers that there are no concerns regarding ED properties of active chlorine released from sodium hypochlorite.

Assessment of the ED properties of non-active substances (co-formulants) in Radic R12:

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

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

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product Radic R12.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

2.2.10 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life of biocidal product
Store in tightly closed containers. Store in dry, cool, well-ventilated area. Keep away from direct sunlight. Keep away from heat. Do not store near acids.

Recommended methods and precautions concerning handling and transport
Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes. Use only with adequate ventilation. Wash hands thoroughly after handling. Remove soiled or soaked clothing immediately.
Avoid mixing this product with acid or ammonia releases chlorine gas.

Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Formation of toxic gases is possible during heating or in case of fire.
Chlorine gas (Cl2)

Hazardous combustion products: Decomposition products may include the following materials:
Carbon oxides
nitrogen oxides (Nox)
Sulphur oxides
Oxides of phosphorus

Particulars of likely direct or indirect adverse effects
See product classification

First aid instructions, antidotes
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water (or shower).
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
IF INHALED: Remove person to fresh air and keep comfortable breathing. In case of breathing difficulties seek immediate medical advice.

Emergency measures to protect environment in case of accident
Confine and contain the spillage. Prevent any environmental discharge (sewers, rivers, ground). Dispose of contaminated material as waste according to section 13 of the SDS.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms
N/A

2.2.11 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

2.2.12 Comparative assessment

2.2.12.1 Screening phase

- Description of the assessement of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance.
- Consideration on whether the active substance(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but that benefit from derogation in accordance with Article 5(2) of the BPR.
- Conclusion of the screening phase: Stop comparative assessment / Tier IA / Tier IB / Tier II

2.2.12.2 Tier IA

- Description of biocidal products included in the comparison
- Main outcome of the comparison for:
    - risk for human health, animal health and the environment
    - significant economic or practical disadvantages
- Conclusion of Tier IA: Tier IB / Tier II

2.2.12.3 Tier IB

- Main outcome of the comparison for:
    - risk for human health, animal health and the environment
    - significant economic or practical disadvantages
- Conclusion of Tier IB: End of comparative assessment / Tier II

2.2.12.4 Tier II

- Description of non-chemical alternatives included in the comparison
- Main outcome of the comparison for:
    - risk for human health, animal health and the environment
    - efficacy
    - significant economic or practical disadvantages
- Conclusion of Tier II: stop comparative assessment/ End of comparative assessment

2.2.12.5 Overall conclusion

Final recommendation in terms of restriction(s) or prohibition of the biocidal product subject to comparative assessment.

3 ANNEXES

3.1 List of studies for the biocidal product

Title	Study number	Date	Laboratory	Autor
Shelf-life stability study at 25°C for 6 months on the test item "RADIC R12"	2019/53 AM	29/10/2019	Eurofins BioPharma Product Testing	A.Bonetti
Determination of surface tension, dilution stability and persistent foaming on the test item RADIC 12	STULV20AA 4100-1	31/07/2020	Eurofins BioPharma Product Testing	C. Belussi
Viscosity determination and persistent foaming tests on the test item "RADIC R12"	STULV19AA 0885-1 GLP	22/03/2019	Eurofins BioPharma Product Testing	A.Bonetti
Determination of the flash point and surface tension on the sample Radic R12	1901244	20/06/2019	Innovhub Stazioni sperimentali per l'industria Stazioni sperimentali per I combustibili	A.Mazzei
Validation of a titrimetric method for the quantification of active chlorine content in the test item "RADIC R12"	STULV19AA 0881-1 GLP	18/05/2019	Eurofins BioPharma Product Testing	M.G.Guiso
Validation of an IC method for the quantification of the chlorates content in the test item "RADIC R12"	STULV19AA 0884-1 GLP	07/07/2019	Eurofins BioPharma Product Testing	M.G.Guiso

3.2 Output tables from exposure assessment tools

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3.3 New information on the active substance

No new information is available. Data from NaOCl assessment reports are used in this dossier.

3.4 Residue behaviour

Due to the high reactivity of chlorine species, residues degrade very rapidly 'decomposition to physiological sodium and chloride). Hence residue formation is assumed to be negligible. Chlorate residues are relevant. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage. Thus, chlorate may represent a worst-case for NaOCl residues (regarding systemic effect).

Scenario [1]: PT4 - Inner surfaces disinfection of milk or drinking water tank


PT4_Disinfection of inner surfaces by Cl

Chlorate residues are assessed using following calculation.

Reference calculation → $Exp_{cons} = R_{application} \times A_{container} \div V_{milk} \times TF \times I_{milk} \div bw$

Adaptation of calculation → $Exp_{cons} = ((F_t \times A_{container} \times \rho_W \times []_{chlorate} \times TF \times I_{milk.}) \div V_{milk}) \div bw$

Parameters	Values	References
F_t: biocidal product (in-use solution) left after draining the container : Assumption of film thickness	Default: 20 µm	p317 Guidance on the BPR: Volume III (Parts B+C) PUBLIC: DRAFT Version 4.0 December 2017 5.6.4.2 Assessment of disinfectants used to treat water containers
[] $_{chlorate}$ (%)	Chlorate concentration after dilution: 0.011 % (tier 1) After rinsing step: 0.0011 % (tier 2)	Data provided by the applicant: Reasonable worst case: After 6 months storage at ambient temperature, the concentration of active chlorine has decreased with 27% and 0.3816% chlorate is measured. 0.011% correspond to the concentration of chlorate after dilution (2.9% of product).
Remaining after rinsing (%)	10 (tier 2)	Expert judgment: Chlorate, inorganic, n.o.s. is a white crystalline. It is soluble in water. Regarding the solubility of Sodium Chlorate, 1000 g/l water at 25 °C (PubChem). 10 % of rinsing factor according to the CAR of active substance PT3, Annex I.

ρ_W: Water	Volumetric masse density : 1 g/cm^3	We can assume in view of the high PT4 products dilution , the relative volumetric masse density of the diluted product is close to the volumetric masse density of water (1 g/cm^3).
Acontainer: inner surface area of container (m^2)	*Little exploitation :* To calculate the capacity of the bulk tank you require, you need to know how many milkings you need to store at peak. It is five milkings for every two day (E2D) collection and seven for every three day (E3D) collection. Other factors are the number of cows, now and in five years' time, and the yield per cow e.g. 30 litres/day at peak (6.5 gallons/day). Herd Size: 50 Bulk tank capacity for E2D: 50 x 30 x 2.5 = 3750 L Bulk tank capacity for E3D: 50 x 30 x 3.5 = 5250 L V= 4200 L (E2D) r = 72.5 cm V = πr^{2}h → h = V/ πr^2 = 254.345 cm A = 2πr^2 + 2 πrh = 148871.319 cm^2 = 14.887 m^2	Extrapolation based on : Structure of dairy herds, EU-14 DeLaval cooling tank DXCR
Vmilk: volume of milk in container (L)	V= 4200 L (E2D)	
TF: mass transfer efficiency factor (fraction of biocide residue transferred from inner container surface to water)	Default = 100 % = 1	P.40 Guidance on the BPR: Volume III (Parts B+C) PUBLIC: DRAFT Version 3.0 July 2017 Appendix 5-1: General default values and derivation of food contact areas 1.General default values for disinfectant and preserved cleaner, insecticides, drinking water disinfection and in-can preservatives in dishwashing detergents Table 44. General default values
Imilk: daily milk consumption (L/d) in France (95th percentile)	Adult = 1.5 l/d Infant = 1.5 l/d Toddler = 1.5 l/d	EMA food basket default value (MRL)
I_{water}: Daily water consumption	Adult: 2 L/d Toddler: 1 L/d Infant: 0.75 L/d	Default value

Body weight (kg)	Adult : 60 kg Toddler: 10 kg Infant: 8 kg	Recommendation 14 - Default human factor values for use in exposure assessments for bio-cidal products

Scenario [2] PT4: Disinfection of surfaces by CIP


fcssm-user-guide-version-1.pdf


FCSSMspreadsheet-CIPTier1xlsm


FCSSMspreadsheet-CIPTier2xlsm

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

All efficacy studies are described in section 2.2.5.5 and available in IUCLID and therefore not required to list here.

3.6 Confidential annex

See separate file "PAR_Radic R12_confidential annex

3.7 Other

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