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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS

HYPO-CHLOR Product Family

Product type(s): 2

Active chlorine released from sodium hypochlorite

Case Number in R4BP: [BC-EF047438-44]

Evaluating Competent Authority: France

Date: March 2022

Table of Contents

CONCLUSION **4**

SUMMARY OF THE EVALUATION AND CONCLUSIONS OF THE RISK ASSESSMENT **4**

META 6
USES 6

PRESENTATION OF THE BIOCIDAL PRODUCT FAMILY INCLUDING CLASSIFICATION AND LABELLING **6**

DESCRIPTION OF USES PROPOSED TO BE AUTHORISED **6**

COMPARATIVE ASSESSMENT **7**

OVERALL CONCLUSION OF THE EVALUATION OF THE USES PROPOSED TO BE AUTHORISED **7**

1 ASSESSMENT REPORT **8**

PART I - FIRST INFORMATION LEVEL **8**

1.1 SUMMARY OF THE PRODUCT ASSESSMENT 8
1.1.1 Administrative information *8*
1.1.1.1 Identifier of the product / product family 8
1.1.1.2 Authorisation holder 8
1.1.1.3 Manufacturer(s) of the products of the family 8
1.1.1.4 Manufacturer(s) of the active substance(s) 8
1.1.2 Product (family) composition and formulation *10*
1.1.2.1 Identity of the active substance 10
1.1.2.2 Candidate(s) for substitution 10
1.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family 11
1.1.2.4 Information on technical equivalence 11
1.1.2.5 Information on the substance(s) of concern 12
2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product family 12
2.1.2.7 Type of formulation 12

PART II - SECOND INFORMATION LEVEL - META SPC 2A **12**

1.1.1 *Meta SPC 2A administrative information* *12*
1.1.1.1 Meta SPC identifier 12
1.1.1.2 Suffix to the authorisation number 12
1.1.1.3 Product type(s) 12
1.1.2 *Meta SPC 2A composition* *12*
1.1.2.1 Qualitative and quantitative information on the composition of the meta SPC 2A 12
1.1.2.2 Type(s) of formulation of the meta SPC 2A 13
AL – ready to use *13*
1.1.3 *Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2A* *13*
1.1.4 *Authorised use(s) of the META SPC 2A* *13*
1.1.4.1 Use description 13
1.1.5 *General directions for use of the meta SPC 2A* *15*
1.1.5.1 Instructions for use 15
1.1.5.2 Risk mitigation measures 15
1.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 15
1.1.5.4 Instructions for safe disposal of the product and its packaging 16
1.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 16
1.1.6 *Other information* *16*

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2A **16**

1.1.7 *Trade name(s), authorisation number and specific composition of each individual product* *16*

PART II - SECOND INFORMATION LEVEL - META SPC 2B **17**

1.1.8 *Meta SPC 2B administrative information* *17*
1.1.8.1 Meta SPC identifier 17
1.1.8.2 Suffix to the authorisation number 17
1.1.8.3 Product type(s) 17

1.1.9 *Meta SPC 2B composition* *17*
1.1.9.1 Qualitative and quantitative information on the composition of the meta SPC 2B 17
1.1.9.2 Type(s) of formulation of the meta SPC 2B 18
AL – ready to use *18*
1.1.10 *Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2B* *18*
1.1.11 *Authorised use(s) of the META SPC 2B* *19*
1.1.11.1 Use description 19
1.1.12 *General directions for use of the meta SPC 2B* *20*
1.1.12.1 Instructions for use 20
1.1.12.2 Risk mitigation measures 20
1.1.12.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 21
1.1.12.4 Instructions for safe disposal of the product and its packaging 21
1.1.12.5 Conditions of storage and shelf-life of the product under normal conditions of storage 21
1.1.13 *Other information* *21*

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2B 21

1.1.14 *Trade name(s), authorisation number and specific composition of each individual product* *21*
2.1.3 Packaging of the biocidal product *23*
2.1.4 Documentation *25*
2.1.4.6 Data submitted in relation to product application 25
2.1.4.7 Access to documentation 26
2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT FAMILY 27
2.2.2 Intended use(s) as applied for by the applicant *27*
2.2.3 Physical, chemical and technical properties *30*
2.2.4 Physical hazards and respective characteristics *61*
2.2.5 Methods for detection and identification *72*
2.2.6 Efficacy against target organisms *80*
2.2.6.6 Function and field of use 80
2.2.6.7 Organisms to be controlled and products, organisms or objects to be protected 80
2.2.6.8 Effects on target organisms, including unacceptable suffering 81
2.2.6.9 Mode of action, including time delay 81
2.2.6.10 Efficacy data 82
2.2.6.11 Occurrence of resistance and resistance management 96
2.2.6.12 Known limitations 96
2.2.6.13 Evaluation of the label claims 96
2.2.6.14 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 96
2.2.7 Risk assessment for human health *97*
2.2.7.6 Assessment of effects on Human Health 97
2.2.7.7 Exposure assessment 109
2.2.8 Risk assessment for animal health *144*
2.2.9 Risk assessment for the environment *144*
2.2.9.1 Effects assessment on the environment 145
2.2.9.2 Exposure assessment 150
2.2.9.3 Risk characterisation 157
2.2.10 Measures to protect man, animals and the environment *161*
2.2.11 Assessment of a combination of biocidal products *161*
2.2.12 Comparative assessment *161*

3 ANNEXES 161

3.2 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (FAMILY) 161
3.3 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS 170
3.4 NEW INFORMATION ON THE ACTIVE SUBSTANCE 170
3.5 RESIDUE BEHAVIOUR 170
3.6 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX) 171
3.7 CONFIDENTIAL ANNEX 171
[redacted] 171

CONCLUSION

SUMMARY OF THE EVALUATION AND CONCLUSIONS OF THE RISK ASSESSMENT

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family HYPO-CHLOR PRODUCT FAMILY.

General

France, as e-CA, received an application from Veltek Associates Inc Europe for union authorisation for the biocidal product family HYPO-CHLOR PRODUCT FAMILY.

The biocidal product family HYPO-CHLOR PRODUCT FAMILY containing 1.95 to 4.21% of sodium hypochlorite releasing from 0.25% to 0.5% of active chlorine is a product type 2 (PT2), intended to be used by professional users in industries for the disinfection of hard non–porous surfaces of manufacturing facilities (medical device, pharmaceutical, biopharmaceutical and diagnostic industries).

The biocidal product family HYPO-CHLOR PRODUCT FAMILY as submitted by the applicant was composed of two Meta SPC: products from Meta SPC 1 (HYPO-CHLOR 5.25%) are diluted in water before use and products from Meta SPC 2 (HYPO-CHLOR 0.25%; HYPO-CHLOR 0.25% NEUTRAL; HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL) are ready-to-use.

NOTE
After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs, Meta-SPC 2A and Meta-SPC 2B both containing ready to use products (HYPO-CHLOR 0.25% and HYPO-CHLOR 0.25% NEUTRAL for Meta-SPC 2A and HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL for Meta-SPC 2B).
These changes were considered in the efficacy and APCP sections but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions.

Physico-chemical properties and analytical methods

The physico-chemical properties of the biocidal product family HYPO-CHLOR PRODUCT FAMILY have been described and considered acceptable in the conditions of use detailed in the SPC.
The long term stability study is in progress for product in Meta SPC 2A and 2B and final results are required in post authorisation.
For Meta SPC 1, the sprayability properties after a long term storage is missing.

Shelf life of the Meta SPC 1: 6 months could not be stated at the WG as the content of active chlorine in the product decreased by more than 10% after storage and efficacy test data after storage were in progress during the WG and only available for the tested product post WG.

Shelf life of the Meta SPC 2A and 2B: 24 months

Meta SPC 1 and Meta SPC 2B are classified as corrosive to metals (H290).
Meta SPC 2A is not classified as corrosive to metals.

The analytical methods available are acceptable. In particular, the analytical method for the determination of hypochlorous acid, hypochlorite and chlorate active substance in

monitoring method in air monitoring is applicable to detect for all forms of active chlorine at the same time: chlorine, hypochlorous acid and sodium. Thus no data gap exist for the methods.

Efficacy

Efficacy of the HYPO-CHLOR Biocidal Product Family has been demonstrated against bacteria, yeast, fungi and bacterial spores, depending of the products, in the conditions of uses detailed in the SPC.

Substances of concern (SoCs)

None of the co-formulant included in the products was identified as substance of concern for human health and/or the environment.

Risk for Human Health

For the product of meta-SPC 1, the risk is acceptable considering the local effects of sodium hypochlorite with a respiratory protective equipment (min APF 4) providing that the user wears gloves, protection coverall and face shield for mixing and loading task for all modes of application, and wears a respiratory protective equipment (min APF 4) during application and rinsing with compression sprayer (1-3 bars).

For the products of meta-SPC 2 (2A and 2B), the risk is acceptable considering the local effects of sodium hypochlorite providing that the user wears a respiratory protective equipment (min APF 4) during application and rinsing with compression sprayer (1-3 bars).

For bystanders (worker), the following RMM should be added "It shall be ensured that the bystanders are not present in the treatment area during disinfection process by compression sprayer (1-3 bars). If it is necessary to be present, they have to wear same RPE and PPE as the user."

Risk for consumer under indirect exposure via food

Considering the intended uses of HYPOCHLOR PRODUCT FAMILY, residues in food or feed are not expected. Thus, the risk for consumer is considered acceptable.

Risk for the environment

The risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance NaOCl and chlorate formed during storage leading to negligible emissions to the environment.

The risks linked to chlorate formed during storage are acceptable for all uses considering a semi-qualitative assessment for groundwater and surface water intended for drinking water.

Overall conclusion

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family HYPOCHLOR PRODUCT FAMILY is reported in the table below, for each use.

Meta	Uses	Doses	Conditions of use	Conclusions
1	Disinfection of hard non-porous inanimate surfaces, materials and equipment.	Dilution : 5 to 10% v/v Contact time : 6 to 40 minutes	Industrial Users Indoor	**Not acceptable:** no shelf life could be set
2A*	Disinfection of hard non-porous inanimate surfaces, materials and equipment.	Ready to use Contact time : 8 to 40 minutes	Industrial Users Indoor	**Acceptable With RMM****
2B*	Disinfection of hard non-porous inanimate surfaces, materials and equipment.	Ready to use Contact time : 8 to 40 minutes	Industrial Users Indoor	**Acceptable With RMM****

*NB: the applicant submitted a BPF composed of 2 meta-SPCs: Meta-SPC 1 and Meta-SPC 2. After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs we decided to name Meta-SPC 2A and Meta-SPC 2B. When referring to both, we would talk about Meta-SPC 2.
** Please refer to the SPC for details.

Post authorisation data:
The long term stability study for Meta SPC 2 (A and B) are required as post authorisation data within 6 months.

PRESENTATION OF THE BIOCIDAL PRODUCT FAMILY INCLUDING CLASSIFICATION AND LABELLING

The description of the biocidal products and of the structure of the biocidal product family are available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 are available in the SPC.

DESCRIPTION OF USES PROPOSED TO BE AUTHORISED

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised is available in the SPC.

COMPARATIVE ASSESSMENT

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

OVERALL CONCLUSION OF THE EVALUATION OF THE USES PROPOSED TO BE AUTHORISED

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate uses, storage and transportation of the biocidal products.

For the proposed authorised uses, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the HYPO-CHLOR Biocidal Product Family is sufficiently effective;
2. the HYPO-CHLOR Biocidal Product Family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
    - the fate and distribution of the biocidal product family in the environment,
    - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
    - the impact of the biocidal product family on non-target organisms,
    - the impact of the biocidal product family on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

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

None of the co-formulants contained in the products of the HYPOCHLOR BIOCIDAL PRODUCT FAMILY are regulatory identified as endocrine disruptors or have significant ED properties.

1 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

1.1 Summary of the product assessment

1.1.1 Administrative information

1.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
HYPO-CHLOR® Product Family	France

1.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Veltek Associates, Inc. Europe
	Address	Branch Office Europe Rozengaard 1940 8212DT Lelystad Netherlands
Pre-submission phase started on	31/05/2018	
Pre-submission phase concluded on	04/07/2018	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

1.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Veltek Associates, Inc.,
Address of manufacturer	15 Lee Blvd. Malvern PA19355 USA
Location of manufacturing sites	15 Lee Blvd. Malvern PA19355 USA

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

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Univar USA Inc.
Address of manufacturer	532 East Emaus Street, Middleton Pennsylvania 17057

[1] Please fill in here the identifying product name from R4BP 3.

	USA
Location of manufacturing sites	[redacted]

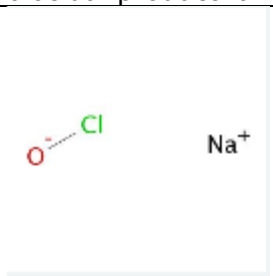
1.1.2 Product (family) composition and formulation

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 ☒

1.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Sodium hypochlorite
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 (sodium hypochlorite, solution ... % Cl active)
Minimum purity / content	Aqueous solution with an available (active) chlorine concentration 11.91% w/w, in compliance with the EN 901:2013 (Aqueous solution with an available / active chlorine concentration ≤18% w/w) One relevant impurity is present in the technical material: sodium chlorate (≤5.4% of the active chlorine, equiv. to 0,012 – 0,27 % w/w in the biocidal product family)
Structural formula	

1.1.2.2 Candidate(s) for substitution

Not relevant.

1.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Active chlorine released from sodium hypochlorite (expressed as equivalent Cl_2)	/	Active substance	/	/	*0.25*	*0.50*
Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w NaOCl)	Sodium hypochlorite	non active substance	7681-52-9	231-668-3	1.95	4.21

Note that no technical material (TC) exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. The technical active substance is defined as an aqueous solution of sodium hypochlorite with a max content of available chlorine set at 180 g/kg. For this dossier, the technical active substance is defined as an aqueous solution of sodium hypochlorite with a claimed purity of 125g/kg (12,5%w/w).

The concentration of active chlorine released from sodium hypochlorite has been calculated according to the active substance data from the CAR. In summary, the sodium hypochlorite content has been divided by the conversion factor of 1.05 in order to obtain the concentration of active chlorine released from sodium hypochlorite.

An overview of the structure of the HYPO-CHLOR BPF with composition information has been included in the confidential annex. The family contains 3 Meta SPC*. All products within the product family are based on sodium hypochlorite.

The contents of active substance and relevant impurities are in agreement with reference specifications as the source has been considered technically equivalent by ECHA (Decision n° TAP-D-1404753-23-00/F).

* NB: the applicant submitted a BPF composed of 2 meta-SPCs: Meta-SPC 1 and Meta-SPC 2. After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs we decided to name Meta-SPC 2A and Meta-SPC 2B. When referring to both, we would talk about Meta-SPC 2.

1.1.2.4 Information on technical equivalence

[redacted]

The applicant sources the active substance from Univar USA Inc. Decision number TAP-D-1404753-23-00/F confirms that the alternative source of active chlorine released from sodium hypochlorite is considered technically equivalent compared to the reference source.

1.1.2.5 Information on the substance(s) of concern

None of the co-formulant included in the products was identified as substance of concern for human health and/or the environment.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product family

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

None of the formulants contained in the product HYPO-CHLOR product family was identified as endocrine disruptors or have significant ED properties.

Please refer to the confidential annex for more details.

2.1.2.7 Type of formulation

AL (Ready to use)

PART II - SECOND INFORMATION LEVEL - META SPC 2A

1.1.1 Meta SPC 2A administrative information

1.1.1.1 Meta SPC identifier

Identification	META SPC 2A

1.1.1.2 Suffix to the authorisation number

1.1.1.3 Product type(s)

Product type(s)	2

1.1.2 Meta SPC 2A composition

1.1.2.1 Qualitative and quantitative information on the composition of the meta SPC 2A

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2)	/	Active substance	/	/	0.25	0.25

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w NaOCl)	Sodium hypochlorite	non active substance	7681-52-9	231-668-3	1.95	2.0

Note that no TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. For this dossier, the technical active substance is an aqueous solution of sodium hypochlorite with a claimed purity of 12,5% w/w.

1.1.2.2 Type(s) of formulation of the meta SPC 2A

AL – ready to use

1.1.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2A

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

Classification	
Hazard category	Aquatic chronic cat. 3
Hazard statement	H412 - Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	
Hazard statements	H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements	P234: Keep only in original packaging. P273: Avoid release to the environment P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/… container with a resistant inner liner. P501: Dispose of contents and container according to the local regulation.
Note	

1.1.4 Authorised use(s) of the META SPC 2A

1.1.4.1 Use description

Table 1. Use # 1 – Disinfectant, bactericidal, fungicidal, and sporicidal use - Meta SPC 2A

Product Type	PT 2

Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Yeasts, Fungi, Bacterial spores
Field of use	Indoors. For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs and not for use in healthcare area) Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries, without mechanical action. Only clean room for buffered products
Application method(s)	Mop, cloth, wipe, immersion or spraying (compression sprayer 1-3 bars or trigger spray). Only trigger spray for buffered products
Application rate(s) and frequency	Ready to use Apply as necessary Contact time: - Bactericidal, yeasticidal and fungicidal treatment: 8 minutes - Sporicidal treatment: 40 minutes Room temperature Clean conditions
Category(ies) of users	Industrial users
Pack sizes and packaging material	HDPE bottle 100 mL to 10L (In some packaging sizes the triggers are supplied but not attached to the bottle) HDPE SimpleMix bottle 473 mL and 3.79L with a smaller LDPE bottle inside HDPE drum 200 L

1.1.4.1.1 Use-specific instructions for use

- Do not use more than 35 mL/m².

1.1.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

1.1.5 General directions for use of the meta SPC 2A

1.1.5.1 Instructions for use

- Comply with the instructions for use.
- Use the product within a maximum of 24h after adding the buffer solution (only for HYPO-CHLOR® Neutral 0.25%) in order to ensure efficacious use.
- Inform the registration holder if the treatment is ineffective.
- Clean carefully the surfaces before application of the product.
- Apply only on non-porous surfaces.
- For mop/cloth/wipe applications, apply (spray/pour) the product onto the surface to be disinfected and then use a cloth/mop/wipe in order to have a uniform distribution of the product on the surface.
- Make sure to wet surfaces completely with the product. Allow to take effect for the required contact time.
- After contact time, rinse surfaces. Allow surface to air dry or wipe dry.
- The use for the disinfection of instruments and materials which is covered by the medical devices Regulation is not concerned by this authorisation.
- Products should not be used in conjunction with acids or ammonia.
- For trigger spray (buffered products), apply only on small surfaces

1.1.5.2 Risk mitigation measures

- Wear respiratory protection: min APF 4 for application and rinsing with compression sprayer (1-3 bars).
- It shall be ensured that the bystanders are not present in the treatment area during disinfection process by compression sprayer (1-3 bars). If it is necessary to be present, they have to wear same RPE and PPE as the user.
- Ventilation rate has to be min 20/h for buffered products (only for HYPO-CHLOR® Neutral 0.25%)
- Avoid all unnecessary exposure.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock

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

- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- Keep the container or label available.

1.1.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf life: 24 months.
- Protect from direct sunlight.
- Protect from frost.
- Do not store above 30°C.

1.1.6 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2A

1.1.7 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**HYPO-CHLOR 0.25%**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Active chlorine released from sodium hypochlorite (expressed as equivalent Cl_2)	/	Active substance	/	/	*0.25*
Sodium hypochlorite (technical solution with	Sodium hypochlorite	non active substance	7681-52-9	231-668-3	2.0

minimum purity of 14.5% w/w NaOCl)					

Trade name(s)	**HYPO-CHLOR NEUTRAL 0.25%**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2)	/	Active substance	/	/	0.25
Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w NaOCl)	Sodium hypochlorite	non active substance	7681-52-9	231-668-3	1.95

PART II - SECOND INFORMATION LEVEL - META SPC 2B

1.1.8 Meta SPC 2B administrative information

1.1.8.1 Meta SPC identifier

Identification	META SPC 2B

1.1.8.2 Suffix to the authorisation number

1.1.8.3 Product type(s)

Product type(s)	2

1.1.9 Meta SPC 2B composition

1.1.9.1 Qualitative and quantitative information on the composition of the meta SPC 2B

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2)	/	Active substance	/	/	0.47	0.50
Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w NaOCl)	Sodium hypochlorite	non active substance	7681-52-9	231-668-3	3.92	4.21

Note that no TC exists for sodium hypochlorite according to the CAR and reference specifications set at EU level. For this dossier, the technical active substance is an aqueous solution of sodium hypochlorite with a claimed purity of 12,5% w/w.

1.1.9.2 Type(s) of formulation of the meta SPC 2B

AL – ready to use

1.1.10 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2B

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

Classification	
Hazard category	Met. Corr. 1 Aquatic chronic cat. 3
Hazard statement	H290 - May be corrosive to metals H412 - Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	
Hazard statements	H290 - May be corrosive to metals H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements	P234: Keep only in original packaging. P273: Avoid release to the environment P390: Absorb spillage to prevent material damage. P406: Store in a corrosive resistant/… container with a resistant inner liner. P501: Dispose of contents and container according to the local regulation.
Note	

1.1.11 Authorised use(s) of the META SPC 2B

1.1.11.1 Use description

Table 2. Use # 1 – Disinfectant, bactericidal, fungicidal and sporicidal use - Meta SPC 2B

Product Type	PT 2
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, Yeasts, Fungi, Bacterial spores
Field of use	Indoors. For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs and not for use in healthcare area) Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries, without mechanical action. Only clean room for buffered products
Application method(s)	Mop, cloth, wipe, immersion or spraying (compression sprayer 1-3bars or trigger spray). Only trigger spray for buffered products
Application rate(s) and frequency	Ready to use Apply as necessary Contact time: - Bactericidal, yeasticidal and fungicidal treatment: 8 minutes - Sporicidal treatment: 40 minutes Room temperature Clean conditions
Category(ies) of users	Industrial users
Pack sizes and packaging material	HDPE bottle 100 mL to 10L (In some packaging sizes the triggers are supplied but not attached to the bottle) HDPE SimpleMix bottle 473 mL and 3.79L with a smaller LDPE bottle inside HDPE drum 200 L

1.1.11.1.1 Use-specific instructions for use

- Do not use more than 35 mL/m².

1.1.11.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

1.1.12 General directions for use of the meta SPC 2B

1.1.12.1 Instructions for use

- Comply with the instructions for use.
- Use the product within a maximum of 24h after adding the buffer solution (only for HYPO-CHLOR® Neutral 0.52%) in order to ensure efficacious use.
- Inform the registration holder if the treatment is ineffective.
- Clean carefully the surfaces before application of the product.
- Apply only on non-porous surfaces.
- For mop/cloth/wipe applications, apply (spray/pour) the product onto the surface to be disinfected and then use a cloth/mop/wipe in order to have a uniform distribution of the product on the surface.
- Make sure to wet surfaces completely with the product. Allow to take effect for the required contact time.
- After contact time, rinse surfaces. Allow surface to air dry or wipe dry.
- The use for the disinfection of instruments and materials which is covered by the medical devices Regulation is not concerned by this authorisation.
- Products should not be used in conjunction with acids or ammonia.
- For trigger spray (buffered products), apply only on small surfaces

1.1.12.2 Risk mitigation measures

- Wear respiratory protection: min APF 4 for application and rinsing with compression sprayer (1-3 bars).
- It shall be ensured that the bystanders are not present in the treatment area during disinfection process by compression sprayer (1-3 bars). If it is necessary to be present, they have to wear same RPE and PPE as the user.
- Ventilation rate has to be min 20/h for buffered products (only for HYPO-CHLOR® Neutral 0.52%)
- Avoid all unnecessary exposure.

- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock

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

- IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
- IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- Keep the container or label available.

1.1.12.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf life: 24 months.
- Protect from direct sunlight.
- Protect from frost.
- Do not store above 30°C.

1.1.13 Other information

-

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2B

1.1.14 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	**HYPO-CHLOR 0,52 %**
Authorisation number	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2)	/	Active substance	/	/	0.50
Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w NaOCl)	Sodium hypochlorite	non active substance	7681-52-9	231-668-3	4.21

Trade name(s)	HYPO-CHLOR NEUTRAL 0,52 %				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Active chlorine released from sodium hypochlorite (expressed as equivalent Cl2)	/	Active substance	/	/	0.47
Sodium hypochlorite (technical solution with minimum purity of 14.5% w/w NaOCl)	Sodium hypochlorite	non active substance	7681-52-9	231-668-3	3.92

2.1.3 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)
Non – Sterile Bottles	100 ml to 10L	HDPE	The bottle cap is polypropylene, the induction seal is polypropylene. In some packaging sizes the polyethylene triggers are supplied but not attached to the bottle. The bottles are sold in cardboard boxes.	Industrial	Yes
Sterile bottles	100 ml to 10L	HDPE	The bottle cap is polypropylene, the induction seal is polypropylene. In some packaging sizes the polyethylene triggers are supplied but not attached to the bottle. The bottles are surrounded by two to four sealed low density polyethylene bags in cardboard boxes.	Industrial	Yes
Sterile Drum	200L Drum	HDPE	High Density polyethylene. Blow molded, closed head. Molded integral top ring. Double bagged and shrink wrapped to secure it. For secure dispensing after opening, the 200L drum has a 5 centimetre top-mounted polypropylene screw cap (NPS threads) having a one-way directional dip tube attached to a length of 3/8 inch (0.95 cm) Santoprene® 73A FDA	Industrial	Yes

			rubber tubing to connect to a peristaltic non-product contact dispensing pump of the customer's choice – not supplied. The pump and tubing remain attached and ready for dispensing during the entire use period. There are no fittings for adding material back into the drum.		
SimpleMix, Sterile	3.79L bottle containing smaller LDPE bottle with buffer solution	Polyethylene bottles	High density polyethylene bottles with polypropylene caps. The main bottle contains a smaller bottle made of LDPE inside. The composition and volume of the smaller bottle is reported in the confidential annex. The smaller bottle contains simple mechanism to release its contents to mix it with the main product at the time of use. Each bottle is surrounded by two to 4 sealed low density polyethylene bags. They are sold in cardboard boxes.	Industrial	Yes
SimpleMix, Non sterile	3.79L bottle containing smaller LDPE bottle with buffer solution	Polyethylene bottles	High density polyethylene bottles with polypropylene caps. The main bottle contains a smaller bottle made of LDPE inside. The composition and volume of the smaller bottle is reported in the confidential annex. The smaller bottle contains simple mechanism to release its contents to mix it with the main product at the time of	Industrial	Yes

			use. They are sold in cardboard boxes.		
SimpleMix, Sterile	473 ml spray bottle containing smaller LDPP bottle with buffer solution	Polyethylene bottles	High density polyethylene bottles with polypropylene caps. Polyethylene trigger sprayers are attached. The main bottle contains a smaller bottle made of LDPE inside. The smaller bottle contains simple mechanism to release its contents to mix it with the main product at the time of use. Each bottle is surrounded by two to four sealed low density polyethylene bags. They are sold in cardboard boxes.	Industrial	Yes
SimpleMix, Non sterile	473 ml spray bottle containing smaller LDPP bottle with buffer solution	Polyethylene bottles	High density polyethylene bottles with polypropylene caps. Polyethylene trigger sprayers are attached. The main bottle contains a smaller bottle made of LDPE inside. The smaller bottle contains simple mechanism to release its contents to mix it with the main product at the time of use. They are sold in cardboard boxes.	Industrial	Yes

2.1.4 Documentation

2.1.4.6 Data submitted in relation to product application

Physico-chemical properties:
Physico-chemical properties studies and analytical methods were provided on several products of the family.

Efficacy:
Studies performed with products of the HYPO-CHLOR Product Family were submitted for the demonstration of the efficacy. Please refer to the list of references.

Risk for consumer under indirect exposure via food:

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected. Considering the intended uses no data is required.

2.1.4.7 Access to documentation

The applicant is a member of the EURO CHLOR Consortia for active chlorine from sodium hypochlorite and has full access to the data available on the active substance.

2.2 Assessment of the biocidal product family

NOTE
The applicant submitted a BPF composed of 2 meta-SPCs: Meta-SPC 1 and Meta-SPC 2. After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs, Meta-SPC 2A and Meta-SPC 2B both containing ready to use products (HYPO-CHLOR 0.25% and HYPO-CHLOR 0.25% NEUTRAL for Meta-SPC 2A and HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL for Meta-SPC 2B). However, the evaluation was held on the initial BPF composition.

Hence, these changes were considered in the efficacy and APCP sections but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions.When the splitting was of no consequence for the evaluation, the evaluation refers to Meta-SPC 2 (meaning both Meta-SPC 2A and 2B).

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

Table 1. Intended use # 1 – Disinfectant, fungicidal, virucidal and sporicidal use-Meta SPC 1

Product Type	PT 2
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bacteria, Yeast, Fungi, Bacterial spores, Virus
Field of use	Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries. For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Indoors.
Application method(s)	Mop, cloth, wipe, immersion or mechanical spray device
Application rate(s) and frequency	35 mL/m² - Dilute the product to 1/10 in water or 100 mL/Liter (10% v/v) dilution or dilute dilute the product to 1/20 in water or 50 mL/Liter (5 % v/v). Apply as necessary. Contact time 6-40 minutes temperature 20°C
Category(ies) of users	Industrial users
Pack sizes and packaging material	HDPE bottle 100 ml to 10L

	Non-sterile bottles; the bottle cap is polypropylene, the induction seal is polypropylene The bottles are sold in cardboard boxes. Sterile; the bottle cap is polypropylene, the induction seal is polypropylene. The bottles are surrounded by two to four sealed low density polyethylene bags in cardboard boxes. HDPE drum 200 L.
Pack sizes and packaging material	

Table 4. Intended use # 2– Disinfectant, fungicidal, virucidal and sporicidal use- Meta SPC2

Product Type	PT 2
Where relevant, an exact description of the authorised use	For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Bacteria, Yeast, Fungi, Bacterial spores, Virus
Field of use	Indoor Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries. For the disinfection of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs.
Application method(s)	Mop, cloth, wipe, immersion or mechanical spray device
Application rate(s) and frequency	35 mL/m² Apply as necessary Contact time: 3 to 40 min Temperature: 20°C
Category(ies) of users	Industrial users
Pack sizes and packaging material	HDPE bottle 100 ml to 10L Non-sterile bottles; the bottle cap is polypropylene, the induction seal is polypropylene. In some packaging sizes the triggers are supplied but not attached to the bottle. The bottles are sold in cardboard boxes. Sterile; the bottle cap is polypropylene, the induction seal is polypropylene. In some packaging sizes the triggers are supplied but not attached to the bottle. The bottles are surrounded by two to four sealed low density polyethylene bags in cardboard boxes.

	HDPE SimpleMix bottle and 3.79L Non-sterile bottles; high density polyethylene bottles with polypropylene caps. The main bottle contains a smaller bottle made of LDPE inside. The smaller bottle contains simple mechanism to release its contents to mix it with the main product at the time of use. They are sold in cardboard boxes. Sterile; high density polyethylene bottles with polypropylene caps. The main bottle contains a smaller bottle made of LDPE inside. The smaller bottle contains simple mechanism to release its contents to mix it with the main product at the time of use. Each bottle is surrounded by two to 4 sealed low density polyethylene bags. They are sold in cardboard boxes. High Density polyethylene. Blow moulded, closed head. Moulded integral top ring. Double bagged and shrink wrapped to secure it. For secure dispensing after opening, the 200L drum has a 5 centimetre top-mounted polypropylene screw cap (NPS threads) having a one-way directional dip tube attached to a length of 3/8 inch (0.95 cm) Santoprene® 73A FDA rubber tubing to connect to a peristaltic non-product contact dispensing pump of the customer's choice – not supplied. The pump and tubing remain attached and ready for dispensing during the entire use period. There are no fittings for adding material back into the drum. HDPE drum 200 L

2.2.3 Physical, chemical and technical properties

NOTE
The applicant submitted a BPF composed of 2 meta-SPCs: Meta-SPC 1 and Meta-SPC 2.
After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs, Meta-SPC 2A and Meta-SPC 2B both containing ready to use products (HYPO-CHLOR 0.25% and HYPO-CHLOR 0.25% NEUTRAL for Meta-SPC 2A and HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL for Meta-SPC 2B). However, the evaluation was held on the initial BPF composition.

Hence, these changes were considered in the efficacy and APCP sections but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions.When the splitting was of no consequence for the evaluation, the evaluation refers to Meta-SPC 2 (meaning both Meta-SPC 2A and 2B).

Meta SPC 1:
This Meta SPC contains 1 product: HYPO-CHLOR® 5.25%. This product has been tested.
Use concentrations: 5% v/v to 10% v/v (equiv. 0,25% to 0,5% active chlorine)

Property	Guideline and Method	Content of active substance in biocidal product (% w/w) Batch number	Results	eCA assessment	Reference
Physical state, colour, odour at 20 °C and 101.3 kPa	Visual	5.25% w/w Lot: 19-SHC-910355	Pale yellow liquid	Acceptable	[redacted]
Acidity / alkalinity	CIPAC MT 75.3 CIPAC MT 191	5.25% w/w Lot: 19-SHC-910355	pH (neat): 11.5 pH (1% w/v): 10.1 Alkalinity as % NaOH: 2.2%	Acceptable	
Relative density / bulk density	EPA OPPTS 830.7300	5.25% w/w	1.0028 g/mL at 20 ºC	Acceptable	

	OECD 109, EC A.3	5.25% w/w Lot: 19-SHC-910355	1.097 g/mL at 20 ºC (density) 1.097 (D_4^{20}; relative density)	Acceptable	
Storage stability test – **accelerated storage**	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4	5.25% w/w Lot: 19-SHC-910355	30 °C for 18 weeks in commercial packaging: Test item appearance: Before storage – Clear, pale yellow liquid After storage – No change. Container appearance: Before storage – 16 oz., double bagged, white, HDPE bottle, free from leakage, cracking, panelling, pitting, deformation, degradation, seepage and ballooning. After storage – No change. Weight change: Ca. -0.09% vs. T0. pH (neat): Before storage – 11.5 After storage – 11.5 pH (1% w/v): Before storage – 10.1 pH (1% v/v): After storage – 10.3 Alkalinity as % NaOH: Before storage – 2.2% After storage – 1.6%	The degradation of the active content is >10%. The biocidal product is not stable after accelerated storage. The product should not be stored above 30°C. It should also be noted that the chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after storage. Please refer to conclusion below and human health section regarding conclusion on that content.	

			Sodium hypochlorite content: Before storage – 5.65% After storage – 4.16% (-26,4%) Chlorate content: Before storage – 0.50% After storage – 1.07% (+114%) Dilution stability (1:10, highest in-use conc.): Before storage – Stable, no separation or sediment observed After storage – Stable, no separation or sediment observed		
Storage stability test – **long term storage at ambient temperature**	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	5.25% w/w Lot: 19-SHC-910355	A long-term storage stability study (18 months at room temperature in commercial packaging) has been provided. T0, T4, T6, T12, T15 and T18 months results are available: <u>Test item appearance</u>: T0, T4, T6, T12, T15, T18: Clear, pale yellow liquid – no change between any time intervals <u>Container appearance</u>: T0, T4, T6, T12, T15, T18: 16 oz., double bagged, white, HDPE bottle, free from leakage, cracking, panelling, pitting, deformation, degradation, seepage and ballooning – no change between any time intervals <u>Weight difference</u>: no significant change between T0 and T18 (maximum loss = 0.28 g) <u>pH (unmixed) (neat):</u> T0 : 11.5 T4: 11.5	The degradation of the active content is >10% after 6 months of storage. Section 4.2.1.1 of the Technical Agreements for Biocides APCP v2.0, states that in cases where active substance degradation is >10 % this generally requires efficacy data which were not available to APCP at the time of discussion therefore no shelf-life could be set for this meta SPC.”	[redacted]

			T6: 11.6 T12 : 12.0 T15 : 12.0 T18 : 11.8 <u>pH (1% w/v dilution):</u> T0 : 10.1 T4 :10.3 T6 : 10.3 T12 : 10.2 T15 : 10.1 T18 : 10.3 <u>Alkalinity as % NaOH</u>: T0: 2.2% T4 : 2.1% T6 : 1.9% T12 : 1.7 % T15 : 1.6 % T18 : 1.6 % <u>Sodium hypochlorite content</u>: T0 : 5.65% T4: 4.92% (-12.9 % difference from T0) T6: 4.96% (-12.2 % difference from T0 T12: 4.34% (-23.2 % difference from T0) T15: 4.24% (-24.9 % difference from T0) T18: 4.00% (-29.2 % difference from T0) <u>Chlorate content</u>: T0 : 0.50% T4 : 0.71% T6 : 0.80% T12 : 1.01%	Chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after storage. Please refer to conclusion below and human health section regarding conclusion on that content. In addition, the sprayability properties after a long term storage have not been tested.	

			T15 : 1.05% T18 : 1.12% <u>Sodium chlorate content</u>: T0: 0.64% T6 : 1.02% T12 : 1.29 % T15 : 1.34 % T18 : 1.43 % <u>Sodium chlorate/available chlorine</u>: T0: 11.85% T6 : 21.6% T12 : 31.2% T15 : 33.1% T18 : 37.5% <u>Dilution stability (1:10, highest in-use conc</u>.): T0: Stable after standing period. T4, T6, T12, T15, T18: Stable, no separation or sediment observed.		
Satisfactory operation of trigger sprayers	CIPAC MT 187, ISO 13320:2009	5.25% w/w Lot: 20-SHC-012121	<u>Spray type: trigger spray</u> <u>Before storage:</u> Average discharge rate = 0.61 g/act (n=3) Spray pattern: Ca. spherical, ovality ratio = 0.57 Observation of blockages: None <u>After 2 weeks at 54 °C storage:</u> Average discharge rate = 0.78 g/act (n=3) Spray pattern: Ca. spherical, ovality ratio = 0.72 Observation of blockages: None	Acceptable Sprays caracteristics have been assessed after accelerated storage and are considered acceptable. However, they should also be tested after long term storage and are	[redacted]

				required in post-authorisation.	
Storage stability test – **low temperature stability test for liquids**			Product label states "*Keep from frost*". Therefore, testing is not required.	Acceptable	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Current USP/NF General Chapter <671> Containers – Performance Testing (Spectral Transmission only)	5.25% w/w Lot: 18-SHC-808927	A spectral transmission study has been performed on the commercial packaging. Results: The maximum spectral transmission was ≤10% within the range 290-450 nm	According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. An adequate mitigation measure "protect from direct sunlight" should be added on the label.	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	waiver		Effects of temperature will be assessed as part of the accelerated storage stability study. The assessment of effects of humidity is considered not required due to the high water content of the formulation.	As the product is not stable after the accelerated storage (18 weeks at 30°C), the product should not be stored above 30°C.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity**	waiver		Accelerated and ambient temperature storage stability studies will assess this property of the product.	Acceptable	

towards container material					
Wettability	waiver		Not applicable to formulation type SL	Not relevant	
Suspensibility, spontaneity and dispersion stability	waiver		Not applicable to formulation type SL	Not relevant	
Wet sieve analysis and dry sieve test	waiver		Not applicable to formulation type SL	Not relevant	
Emulsifiability, re-emulsifiability and emulsion stability	waiver		Not applicable to formulation type SL	Not relevant	
Disintegration time	waiver		Not applicable to formulation type SL	Not relevant	
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187, ISO 13320:2009	HYPO-CHLOR® 5.25%, Lot: 20-SHC-012121	<u>Spray type: trigger spray</u> The median particle size (D50) was 164.85 µm at 0-week storage and 189.36 µm after 2 weeks storage at 54°C. 3.16 % of particles have a diameter <50 µm at 0-week storage and 4.74 % of particles have a diameter <50 µm after 2 weeks storage at 54 °C.	Acceptable The particle size distribution has been assessed after the accelerated storage. It should also be tested after long term storage and is required in post-authorisation.	[redacted]
Persistent foaming	CIPAC MT 47.2	5.25% w/w Lot: 18-SHC-809230	Product & WFI (water for injection) 50%: 3 mL of foam produced immediately after perturbation, which fully dissipated after 9 seconds. Product & tap water 50%: 12 mL of foam produced immediately after perturbation, which fully dissipated after 19 seconds.	Acceptable	[redacted]
Flowability/Pourability/Dustability	waiver		Not applicable to formulation type SL	Not relevant	
Burning rate —	waiver		Not applicable to formulation type SL	Not relevant	

smoke generators					
Burning completeness — smoke generators	waiver		Not applicable to formulation type SL	Not relevant	
Composition of smoke — smoke generators	waiver		Not applicable to formulation type SL	Not relevant	
Spraying pattern — aerosols	waiver		Not applicable to formulation type SL	Not relevant	
Physical compatibility	waiver		Not applicable as the product is not intended to be used in combination with other biocidal products	Not relevant	
Chemical compatibility	waiver		Incompatible with acids, ammonia and metals	According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. A mention EUH031 "contact with acids liberates toxic gas" is proposed by the applicant for the product. The product should not be used in conjunction with acids or ammonia.	
Degree of dissolution and dilution stability	CIPAC MT 41	5.25% w/w Lot: 19-SHC-910355	At 10% v/v The solution remained stable	Acceptable	[redacted]
Surface tension	EC A.5	5.25% w/w Lot: 19-SHC-910355	63.4 mN/m (neat)	Acceptable	

Viscosity	EPA OPPTS 830.7100 (ASTM D445/D446)	5.25% w/w Lot: 165333A	1.238 mm^2/s at 20 ºC 0.815 mm^2/s at 40 ºC	Acceptable	[redacted]

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

The product HYPO-CHLOR 5.25% is a soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements. The product is a pale-yellow liquid with a pH of 11.5 (neat) or 10.1 (1% w/v) and alkalinity of 2.2.
After accelerated storage (30 ° C / 18 weeks), no significant changes were observed in terms of appearance (formulation and packaging), product weight, pH (neat, 1%), alkalinity and dilution stability. However, hypochlorite content decreased by 26% vs. T0 . The product should not be stored above 30°C.

Results of the ambient storage stability study show that the product is not stable after 6 months at ambient temperature as the degradation of the active substance is higher than 10%. No shelf life can be set for this meta SPC as no efficacy data were available after storage.

It should be noted that the chlorate content is higher than the maximum content set in the regulation after storage.
The source of active substance is a recognised source, thus, the content of chlorate just after manufacturing of the AS have to be in compliance with reference specification: chlorate is < 5.4 %.

It is well-known that sodium hypochlorite is an unstable substance that degrades rapidly, mainly in chlorate. Considering the instability of the active substance and its fast degradation in chlorate, FR considers that it is not appropriate and not relevant to check the specification of the relevant impurity chlorate in products in the context of identity of substance. It is however important to determine this relevant impurity after storage for toxicological and ecotoxicological impact on risk assessment.

To be in agreement with reference specification, the quantification of chlorate should have been performed just after the manufacturing of the AS, which it is not possible as the shelf life study is performed on the formulated products. As the samples of the products should be sent to the GLP laboratory for analyse, degradation of the sodium hypochlorite in the products cannot be technically avoided. In consequence, at T0 of the shelf-life study analysis, the content of chlorate could be already above the reference specification of the AS. For this dossier, the initial times (T0) of the shelf life study correspond to several weeks after the formulation of the product which explains that the content of chlorate is higher than the one reported in the reference specifications set at EU level.

Please refer to human health section regarding conclusion on chlorate content on risk assessement.

The active substance will decompose in the presence of sunlight/UV. Therefore, the product should be kept protected from light.

No low storage stability has been provided, the product label states "Keep from frost".
The product should not be used in conjunction with acids or ammonia.
The sprayability properties after a long term storage are missing.

Shelf life: 6 months

Meta SPC 2A and 2B:

Meta SPC 2A contains 2 products (HYPO-CHLOR® 0.25% and HYPO-CHLOR® Neutral 0.25%).
Meta SPC 2B contains 2 products (HYPO-CHLOR® 0.52% and HYPO-CHLOR® Neutral 0.52%).

These meta-SPC were initially assessed as one Meta SPC (Meta SPC 2) however, due to hazard property issues, it was decided to devide this meta-SPC in two-meta SPCs. Nevertheless, their compositions are sufficiently similar to assess the physical chemical properties in one part here.
HYPO-CHLOR® Neutral 0.52%, considered as the worst-case formulation based on the composition (due to the highest active substance content and highest contents of co-formulants), has been tested for stability. Cross reading is acceptable for all products within Meta SPC 2 (2A and 2B).
Some packaging consist of two compartments. In the main compartment, the biocidal product can be found, and the small compartment contains the buffer solution. The smaller bottle is located within a separate section of the main bottle with a simple mechanism to release its contents to mix it with the main product at the time of use. The composition of the smaller bottle is reported in the confidential annex. The volume of product in each compartment is reported below:

Product	Part A: Main Compartment (sodium hypochlorite) Fill Volume	Part B: Secondary (smaller) Bottle (Buffer solution) Fill Volume
HYPO-CHLOR Neutral 0.25%	473 mL	11.6-12.1 mL
HYPO-CHLOR Neutral 0.25%	3.79 L	94-95 mL
HYPO-CHLOR Neutral 0.52%	473 mL	19-20 mL
HYPO-CHLOR Neutral 0.52%	3.79 L	151-152 mL

In the following table, some properties have been assessed before or/and after mixing. Before and after mixing refers to whether the buffer component of the product has been activated (after mixing) or not (before mixing).

Property	Guideline and Method	Content of active substance in biocidal product (% w/w) Batch number	Results	eCA assessment	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 16-SHC-607736	After mixing: Liquid with no signs of clumping nor phase separation	Acceptable	[redacted]
		HYPO-CHLOR® Neutral 0.25%, 0.25% w/w active chlorine, Lot: 17-SV-708644	After mixing: Liquid with no signs of clumping nor phase separation	Acceptable	
	Visual	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 19-SHC-910377	Before mixing: Liquid	Acceptable	
	Visual	HYPO-CHLOR® 0.52%	Read across to L. Ansah-Johnson, 2019c	Acceptable	
	Visual	HYPO-CHLOR® 0.25%	Read across to L. Ansah-Johnson, 2019c The physical state would be the same, based on composition differences between the 0.52% and 0.25% formulations.	Acceptable	

Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6302	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 16-SHC-607736	After mixing: Colour <1 on the Lovibond colour scale	Acceptable
		HYPO-CHLOR® Neutral 0.25%, 0.25% w/w active chlorine, Lot: 17-SV-708644	After mixing: Colour <1 on the Lovibond colour scale	Acceptable
	Visual	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 19-SHC-910377	Before mixing: Pale-yellow	Acceptable
	Visual	HYPO-CHLOR® 0.52%	Read across to L. Ansah-Johnson, 2019c	Acceptable
	Visual	HYPO-CHLOR® 0.25%	Read across to L. Ansah-Johnson, 2019c The colour would not be significantly different, based on composition differences between the 0.52% and 0.25% formulations.	Acceptable
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830.6304	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 16-SHC-607736	Slight chlorine odour	Acceptable

		HYPO-CHLOR® Neutral 0.25%, 0.25% w/w active chlorine, Lot: 17-SV-708644	Chlorine odour	Acceptable
			The endpoint is no longer required	
Acidity / alkalinity	EPA OPPTS 830.7000	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 16-SHC-607736	pH After mixing: 7.63 at 25 ºC (neat formulation)	Acceptable
		HYPO-CHLOR® Neutral 0.25%, 0.25% w/w active chlorine, Lot: 17-SV-708644	pH After mixing: 7.71 at 25 ºC (neat formulation)	Acceptable
	CIPAC MT 75.3 CIPAC MT 191	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 19-SHC-910377	pH (neat, 23.7 °C, before mixing): 10.6 pH (1% w/v, 23.3 °C, before mixing): 9.0 pH (1% w/v, 23.6 °C, after mixing): 7.7 Alkalinity (before mixing): 0.236	Acceptable
	CIPAC MT 75.3	HYPO-CHLOR® 0.52%	Read across to L. Ansah-Johnson, 2019c (before mixing)	Acceptable

	CIPAC MT 191	HYPO-CHLOR® 0.25%	Read across to L. Ansah-Johnson, 2019c (before mixing) The pH would not be significantly different, based on composition differences between the 0.52% and 0.25% formulations. The pH value would be slightly more neutral.	Acceptable
Relative density / bulk density	EPA OPPTS 830.7300	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 16-SHC-607736	After mixing: 1.0205 g/mL at 20 ºC	Acceptable
		HYPO-CHLOR® Neutral 0.25%, 0.25% w/w active chlorine, Lot: 17-SV-708644	After mixing: 1.0098 g/mL at 20 ºC	Acceptable

Storage stability test – **accelerated storage**	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 19-SHC-910377	30 °C, 18 weeks in commercial packaging: All tests were carried out on the test substance as received (i.e. un-mixed), with the exception of pH (1% dilution), which was determined on the mixed and un-mixed formulations; dilution stability was also determined on a 1:10 ratio; and sprayability was performed on the mixed formulation. <u>Test item appearance (before mixing):</u> Before storage – Clear, pale yellow liquid. After storage – No change. <u>Container appearance</u>: Before storage – 16 oz., white, HDPE spray bottles with 0.64 oz. bottles attached, free from leakage, cracking, panelling, pitting, deformation, degradation, seepage and ballooning. After storage – No change. <u>Weight change</u>: Ca. -0.20% vs. T0. <u>pH (neat, before mixing):</u> Before storage – 10.6 After storage – 10.4 <u>pH (1%, before mixing):</u> Before storage (1% w/v) – 9.0 After storage (1% v/v) – 9.1 <u>pH (neat, after mixing):</u> Before storage –	Acceptable The product HYPO-CHLOR Neutral 0,52% is considered stable after 18 weeks at 30°C. However, it should be noted that the chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after storage. Please refer to conclusion below and human health section regarding conclusion on that content. Moreover, the MMAD is missing after storage. A shelf life of 24 months can be granted for products of meta SPC 2.	[redacted]

			After storage – 7,8 <u>pH (1%, after mixing):</u> Before storage (1% w/v) – 7.7 After storage (1% v/v) – 7.5 <u>Alkalinity (% NaOH) (before mixing):</u> Before storage – 0.236 After storage – 0.232 <u>Sodium hypochlorite content (before mixing</u>): Before storage – 0.59% After storage – No change. <u>Chlorate content (before mixing):</u> Before storage – 0.042% After storage – 0.044% <u>Sodium chlorate content</u>: Before storage – 0.054% After storage – 0.056% <u>Sodium chlorate/available chlorine</u>: Before storage – 9.53% After storage – 9.99% <u>Dilution stability (before mixing, 1:10 dilution):</u> Before storage – Stable after standing period. After storage – Stable after standing period. <u>Dilution stability (after mixing, 1:10 dilution):</u> Before storage – Stable after standing period. After storage – Stable after standing period. <u>Sprayability (n=10) (after mixing):</u>	The products should not be stored above 30°C.	

			Before storage – No clogging or blockage observed, spray rate = ca. 0.92 g/spray After 22 weeks storage – No clogging or blockage observed, spray rate = ca. 0.90 g/spray , spray pattern : each pull was a large cone shaped mist. The MMAD should also have been performed after storage, as some products are supplied with trigger sprayer attached to the bottles.		
	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	HYPO-CHLOR® 0.52%	Read across to L. Ansah-Johnson, 2019c	Acceptable The product HYPO-CHLOR 0,52% is considered stable after 18 weeks at 30°C.	[redacted]
	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	HYPO-CHLOR® 0.25%, Neutral 0.25%	Read across to L. Ansah-Johnson, 2019c The 0.52% formulation is considered more 'worst-case', based on the compositions.	Acceptable The products HYPO-CHLOR 0,25% and HYPO-CHLOR neutra 0,25% are considered stable after 18 weeks at 30°C.	[redacted]

Storage stability test – **long term storage at ambient temperature**	EPA OPPTS 830.6317; EPA OPPTS 830.6320; visual; VEL-2010-05	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 16-SHC-607736	Stability study: storage for 24 months at ambient temperature in HDPE container. At each time point, one bottle was tested for sodium hypochlorite (un-mixed) and one bottle was activated (the content of the 2 compartment were mixed), held 23 hours then tested for sodium hypochlorite content. Test item appearance. T0: liquid sample with no phase separation and no clumping. T24: no change. Container appearance. T0: no evidence of corrosion on the lids, liners, seams or sides of the container. T24: no change. Sodium hypochlorite content (pre-mixing). T0: 0.57%. T18: 0.53% (7% loss on T0) T24: 0.57%. Sodium hypochlorite content (post-mixing & after 23 hr). T0: 0.33%. T18: 0.34% (3.0% gain on T0). T24 : 0.30% pH and density of the bottle containing the buffer solution : pH T0: 7.08, T24: 6.90 density: T0: 1.28 T24: 1.27	Only the AS content and the test item / container appearance have been assessed. All other properties are missing. In consequence, this study is considered as supporting information as another complete study is available. Besides, as the AS content decreases quickly after mixing with buffer, the product label should state: "Use the product within a maximum of 24h after adding the buffer solution."	[redacted]

	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 19-SHC-910377	A long-term storage stability study is in progress. Results after 4 months, 6 and 12 months storage are available. Container : simpleMix 16 oz/ 473mL aseptic mixing system Initial weight: ca. 754.87 g <u>Test item appearance before mixing:</u> T0: Clear, pale yellow liquid T4: Clear, pale yellow liquid T6: Clear, pale yellow liquid T12: Clear, pale yellow liquid <u>Container appearance before mixing</u> : T0: 16 oz., white, HDPE spray bottles with 0.64 oz. bottles attached, free from leakage, cracking, panelling, pitting, deformation, degradation, seepage and ballooning T4: no change T6: no change T12: no change <u>pH (neat) before mixing</u>: T0: 10.6 T4: 10.6 T6: 10.3 T12 : 10.3 <u>pH(neat) after mixing</u>: T0: NA T4: 7.7 T6: 7.4 T12: 7.7 <u>pH (1% w/v dilution) before mixing</u>: T0: 9.0	Results after 12 months storage are acceptable. A shelf life of 24 months can be granted based on the accelerated stability study results. The final report of the long-term storage study is expected on March 2021 and is required in post authorisation. Moreover, the chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after storage. Please refer to conclusion below and human health section regarding conclusion on that content.	[redacted]

			T4: 9.1 T6: 8.7 T12 : 9.2 pH (1% w/v dilution) after mixing: T0: 7.7 T4: 7.6 T6: 7.4 T12 : 7.9 Alkalinity before mixing (% NaOH) : T0: 0.236 T4: 0.252 T6: 0.227 T12 : 0.2 Sodium hypochlorite content before mixing: T0: 0.59% T4: 0.57% T6: 0.58% T12: 0.57% Available chlorine content: T0: 0.56% T4: 0.54% T6: 0.55% T12: 0.54% Chlorate content before mixing: T0: 0.042% T4: 0.041% T6: 0.043% T12: 0.046% Sodium chlorate content: T0: 0.054%		

			T4: 0.052% T6: 0.055% T12: 0.059% <u>Sodium chlorate/available chlorine</u>: T0: 9.5% T4: 9.6% T6: 9.9% T12: 10.9% <u>Dilution stability before mixing (1 :10 dilution)</u>: T0: stable T4: stable T6: stable T12 : stable <u>Dilution stability after mixing (1:10 dilution)</u>: T0: stable T4: stable T6: stable T12 : stable <u>Sprayability after mixing</u>: T0: No clogging or blockage observed, spray rate = ca. 0.92 g/spray T6: No clogging or blockage observed, spray rate = ca. 0.63 g/spray – cone shape spray pattern for some trials T12: No clogging or blockage observed, spray rate = ca. 0.95 g/spray - cone shaped spray After 6 months of storage, a significant decrease of the amount of product released / spray was observed for some trials (results		

repoted below).

Trial	Difference (g)
1[2]	-[3]
2[1]	0.94
3[1]	0.96
4[1]	0.96
5[1]	0.98
6[1]	0.85
7[4]	0.48
8[2]	0.14
9[2]	0.30
10[2]	0.32
11[2]	0.45

Trigger was observed to be sticking for trials 7 to 11; solution was strickling and no spray pattern was observed for these trials.
However, after 12 months of storage the he amount of product released / spray was similar for the 10 trials:

			<table><tr><th>Trial</th><th>Difference (g)</th></tr><tr><td>1</td><td>-[1]</td></tr><tr><td>2</td><td>0.95</td></tr><tr><td>3</td><td>0.93</td></tr><tr><td>4</td><td>0.94</td></tr><tr><td>5</td><td>0.97</td></tr><tr><td>6</td><td>0.95</td></tr><tr><td>7</td><td>0.96</td></tr><tr><td>8</td><td>0.96</td></tr><tr><td>9</td><td>0.95</td></tr><tr><td>10</td><td>0.96</td></tr><tr><td>11</td><td>0.95</td></tr></table> Therefore, eCA considers that the spray device can be considered stable. This should be confirmed with the spayability results after 24 months of storage. The MMAD results are reported in the section on particle size distribution.		

	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	HYPO-CHLOR® 0.52%	Read across to L. Ansah-Johnson, 2019c and d.	A shelf life of 24 months can be granted based on the accelerated stability study results.	[redacted]
	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	HYPO-CHLOR® Neutral 0.25%	Read across to L. Ansah-Johnson, 2019c and d. The 0.52% formulation is considered the 'worst-case', based on the compositions.	A shelf life of 24 months can be granted based on the accelerated stability study results. The product label should state: "Use the product within a maximum of 24h after adding the buffer solution."	[redacted]

	OPPTS 830.6317 OPPTS 830.6320 CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41 SANCO/3030/99 rev.4 Validated analytical methods in section 2.2.5	HYPO-CHLOR® 0.25%	Read across to L. Ansah-Johnson, 2019c The 0.52% formulation is considered the 'worst-case', based on the compositions.	A shelf life of 24 months can be granted bsed on the accelerated stability study results. [redacted]
Satisfactory operation of trigger sprayers	In-house method	HYPO-CHLOR® Neutral 0.52%, Lot: 19-SHC-910912	Before storage: Discharge rate: 0,87g/act Spray pattern (n = 3): Ca. spherical, ovality ratio = 0.75-0.77 Observation of blockages: None After storage at 54°C for 2 weeks: Discharge rate 1.007g/act Spray pattern (n = 2): Ca. spherical, ovality ratio = 0.77-0.53. diameters:128.08 mm and 136.14 mm Observation of blockages: None <u>After 12 months at ambient temperature storage</u> Discharge rate = 0.98 g/act Spray pattern (n = 2): Ca. spherical, ovality ratio = 0.75-0.85. Diameters: 91.54 to 120.82 mm Observation of blockages: None	Acceptable [redacted]

		HYPO-CHLOR® Neutral 0.25%, Lot: 19-SHC-910264	Before storage: Discharge rate:0,85g/act Spray pattern (n = 3): Ca. spherical, ovality ratio = 0.77-0.84 Observation of blockages: None After storage at 54°C for 2 weeks: Discharge rate 0.98g/act Spray pattern (n = 2): Ca. spherical, ovality ratio = 0.75-0.68. diameters:108.45 mm and 137.39 mm Observation of blockages: None After 12 months at ambient temperature storage Discharge rate = 0.98 g/act Spray pattern (n = 2): Ca. spherical, ovality ratio = 0.66 – 0.75. diameters: 110.72 to 117.56 mm Observation of blockages: None	Acceptable	
Storage stability test – **low temperature stability test for liquids**			All formulations: Product label will state "*Keep from frost*". Therefore, testing is not required.	Acceptable	

Effects on content of the active substance and technical characteristics of the biocidal product - **light**	waiver		All formulations: This endpoint is waived as the containers are opaque.	According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. An adequate mitigation measure "protect from direct sunlight" should be added on the label.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	waiver		All formulations: Effects of temperature will be assessed as part of the accelerated storage stability study. The assessment of effects of humidity is considered not required due to the high water content of the formulation.	Acceptable	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	waiver		All formulations: Accelerated and ambient temperature storage stability studies will assess this property of the product.	Acceptable	
Wettability			Not applicable to formulation type AL		
Suspensibility, spontaneity and dispersion stability			Not applicable to formulation type AL		

Wet sieve analysis and dry sieve test			Not applicable to formulation type AL		
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable to formulation type AL		
Disintegration time			Not applicable to formulation type AL		
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 187, ISO 13320:2009	HYPO-CHLOR® Neutral 0.52%, Lot: 19-SHC-910912	The median particle size (D50) for the samples range from 94.88µm to 119.74µm and an overall group average of 104.83µm +/- 13.15µm. Ca. 16.22% (n = 3) of particles have a diameter <50 µm. After storage at 54°C for 2 weeks the median particle size (D50) for the sample ranged from 92.95 to 173.74 µm and an overall group average of 133.00 µm +/- 57.62µm. Ca. 12.84% (n = 2) of particles have a diameter <50 µm. After storage at room temperature for 12 months the median particle size (D50) for the sample ranged from 124.40 to 131.76 µm and an overall group average of 128.08 µm +/- 5.20 µm. Ca. 10.34 % (n = 2) of particles have a diameter <50 µm.	Acceptable	[redacted]

		HYPO-CHLOR® Neutral 0.25%, Lot: 19-SHC-910264	The median particle size (D50) for the samples range from 83.49µm to 106.44µm and an overall group average of 94.52µm +/- 11.50µm. Ca. 18.19% (n = 3) of particles have a diameter <50 µm. After storage at 54°C for 2 weeks the median particle size (D50) for the sample ranged from 84.44 to 95.91 µm and an overall group average of 90.18 µm +/- 8.11 µm. Ca. 18.33 % (n = 2) of particles have a diameter <50 µm. After storage at room temperature for 12 months the median particle size (D50) for the sample ranged from 87.36 to 88.44 µm and an overall group average of 88.10 µm +/- 1.05 µm. Ca. 17.74 % (n = 2) of particles have a diameter <50 µm.	Acceptable	
Persistent foaming			Not applicable to formulation type AL		
Flowability/Pourability/Dustability			Not applicable to formulation type AL		
Burning rate — smoke generators			Not applicable to formulation type AL		
Burning completeness — smoke generators			Not applicable to formulation type AL		
Composition of smoke — smoke generators			Not applicable to formulation type AL		

Spraying pattern — aerosols			Not applicable to formulation type AL		
Physical compatibility	Waiver		All formulations: Not applicable as the products are not intended to be used in combination with other biocidal products	Acceptable	
Chemical compatibility	waiver		Incompatible with acids, ammonia and metals	Acceptable Products should not be used in conjunction with acids or ammonia.	
Degree of dissolution and dilution stability			Not applicable to formulation type AL		
Surface tension	OECD 115, EC A.5	HYPO-CHLOR® Neutral 0.52% Lot: 19-SHC-910377	Before mixing: 69.56 mN/m (neat) After mixing: 68.36 mN/m (neat)	Acceptable	[redacted]
	OECD 115, EC A.5	HYPO-CHLOR® 0.52%	Read across to C. Wo, 2019c (before mixing)	Acceptable	[redacted]
	OECD 115, EC A.5	HYPO-CHLOR® 0.25%, Neutral 0.25%	Read across to C. Wo, 2019c The 0.52% formulation is considered the 'worst-case', based on the compositions.	Acceptable	[redacted]

Viscosity	ASTM D445/D446 EPA OPPTS 830.7100	HYPO-CHLOR® 0.52%, 0.52% w/w active chlorine, Lot: 10-SHC-001236	1.022 mm^2/s at 20 ºC 0.671 mm^2/s at 40 ºC	Acceptable
	EPA OPPTS 830.7100	HYPO-CHLOR® Neutral 0.25%, 0.25% w/w active chlorine, Lot: 17-SV-708644	After mixing: 1.001 mm^2/s at 26 ºC	Acceptable
	ASTM D445/D446 EPA OPPTS 830.7100	HYPO-CHLOR® 0.52% Neutral	Read across to C. Wo, 2011a (for before mixing)	Acceptable
	ASTM D445/D446 EPA OPPTS 830.7100	HYPO-CHLOR® 0.25%	Read across to C. Wo, 2011a The 0.52% formulation is considered more 'worst-case', based on the compositions.	Acceptable

Conclusion on the physical, chemical and technical properties of the product
Products of meta SPC 2A and 2B are AL (ready to use) formulations. All studies have been performed in accordance with the current requirements. The products are pale-yellow liquids with a chlorine odour. The product HYPO-CHLOR® Neutral 0.52%, considered as the worst-case formulation based on the composition, has been tested for stability. Cross reading is acceptable for the other 3 products of these Meta SPC. The product is stable after storage at 30 °C for 18 weeks and 12 months at ambient temperature.

It should be noted that the chlorate content exceeds the limit set in regulation before and after storage.
The source of active substance is an approvedsource, thus, the content of chlorate just after manufacturing of the AS is in compliance with reference specification: chlorate is < 5.4 %.
It is well-known that sodium hypochlorite is an unstable substance that degrades rapidly, mainly in chlorate. Considering the instability of the active substance and its fast degradation in chlorate, FR considers that it is not appropriate and not relevant to check the specification of the relevant impurity chlorate in products.
To be in agreement with reference specification, the quantification of chlorate should have been performed just after the manufacturing of the AS, which it is not possible as the shelf life study is performed on the formulated products. As the samples of the products should be sent to the GLP laboratory for analyse, degradation of the sodium hypochlorite in the products cannot be technically avoided. In consequence, at T0 of the shelf-life study analysis, the content of chlorate could be already above the reference specification of the AS. For this dossier, the initial times (T0) of the shelf life study correspond to several weeks after the formulation of the product which explains that the content of chlorate is higher than the one reported in the reference specifications set at EU level.
Please refer to human health section regarding conclusion on chlorate content on risk assessement.

Final results of the long-term ambient stability study are required in post authorisation.
A spectral transmission study showed the packaging is close to opaque. However, the solutions will decompose in the presence of sunlight/UV. Therefore, the products should be kept protected from light.
No low storage stability has been provided, the products label states “Keep from frost”.
The products should not be stored above 30°C.
Products should not be used in conjunction with acids or ammonia.
The product should be used within a maximum of 24h after adding the buffer solution (only for HYPO-CHLOR® Neutral 0.52% and HYPO-CHLOR® Neutral 0.25%).
Shelf life: 24 months

2.2.4 Physical hazards and respective characteristics

The physical hazard properties have been tested on the the biocidal product HYPO-CHLOR 5.25 (5.25% active chlorine) product in order to cover the Meta SPC 1, 2 A and B for most of the physical hazard properties. Only the corrosive tests have been performed on different biocidal products for the Meta SPC 1, 2A and 2B separetly.

Property	Guideline and Method	Content of active substance in biocidal product (% w/w) Batch number	Results	Reference	eCA assessment
Explosives	A sodium hypochlorite aqueous solution with an active chlorine concentration of 15.9% w/w was considered for explosive properties. Read across to the active substance data set is applicable.				According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaClO (16.7%) are not explosive. Based on the composition of the products, cross reading is acceptable since data from the CAR are a worst case.
Flammable gases	Not applicable to liquid formulations				Not relevant as the product is a liquid
Flammable aerosols	Not applicable to liquid formulations				Not relevant as the product is not an aerosol
Oxidising gases	Not applicable to liquid formulations				Not relevant as the product is a liquid
Gases under pressure	Not applicable to liquid formulations				Not relevant as the product is not a gas under pressure
Flammable liquids	EPA OPPTS 830.6315	HYPO-CHLOR® Neutral 0.52%, 0.52% w/w active chlorine, Lot: 16-SHC-607736	No flash point observed below 93 ºC	A. Pitt, 2017, Report No. A22909	Acceptable
		HYPO-CHLOR® Neutral 0.25%,	No flash point observed below 93 ºC	K. Helmberger, 2017,	Acceptable

Property	Guideline and Method	Content of active substance in biocidal product (% w/w) Batch number	Results	Reference	eCA assessment
		0.25% w/w active chlorine, Lot: 17-SV-708644		Report No. A24466	
	Due to the high water content of the formulations, lack of flammable components and existing negative results on the other liquid formulations, the products will not exhibit a flash point below boiling at ca. 100 °C, and will not meet the criteria for classification as a flammable liquid under EU CLP/ GHS.				Acceptable Other products are dilutions of the active substance therefore read across to the active substance data set is applicable. Sodium hypochlorite solutions are not known to spontaneously ignite when exposed to air or to emit flammable gases.
Flammable solids	Not applicable to liquid formulations				Not relevant as the product is a liquid
Self-reactive substances and mixtures	According to the Guidance on the application of the CLP criteria, "substances and mixtures must be considered for classification in hazard class self-reactive property unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG, Manual of Tests and Criteria". Based on the composition, no constituent contain the chemical group listed in these tables, we can expect that the products of the family do not have self-reactive properties.				Agree, however, this has been confirmed with a DSC test. See below.

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Content of active substance in biocidal product (% w/w) Batch number</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td>ASTM E 537-20 TA-Q2000 DSC</td><td>HYPO-CHLOR 5.25%</td><td>DSC results:
<table><tr><th>Headspace</th><th>Ramp Rate, β (°C/min)</th><th>Onset Temperature T_o (°C)</th><th>Extrapolated Onset Temperature, T_s (°C)</th><th>Peak Temperature, T_p (°C)</th><th>Reaction Type</th><th>Heat of Reaction, $-\Delta H_R$ (J/g)</th></tr><tr><td>Air</td><td>2.0</td><td>50.1</td><td>84.7</td><td>124.8</td><td>Exothermic</td><td>48.8</td></tr></table></td><td>[redacted]</td><td>DSC tests confirm the non-classification in this hazard class as heat of decomposition is lower than 300 J/g.</td></tr>
<tr><td>Pyrophoric liquids</td><td colspan="3">Not applicable because the product is known to be stable in air</td><td>Acceptable</td></tr>
<tr><td>Pyrophoric solids</td><td colspan="3">Not applicable to liquid formulations</td><td>Not relevant as the product is a liquid</td></tr>
<tr><td>Self-heating substances and mixtures</td><td colspan="3">Not applicable to liquids.</td><td>Not relevant due to the physical state of the product family.</td></tr>
<tr><td>Substances and mixtures which in contact with water emit flammable gases</td><td colspan="3">Not applicable due to the high-water content of the formulation</td><td>Acceptable</td></tr>
<tr><td>Oxidising liquids</td><td colspan="3">The products are dilutions of the active substance therefore read across to the active substance data set is applicable.</td><td>According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaClO (25.3%) are not considered as oxidizing liquid.</td></tr>
</table>

Property	Guideline and Method	Content of active substance in biocidal product (% w/w) Batch number	Results	Reference	eCA assessment
					Cross reading is acceptable since data from the CAR are a worst case.
Oxidising solids	Not applicable to liquid formulations				Not relevant as the product is a liquid
Organic peroxides	Not applicable because no organic peroxide functional groups are present within components of the formulation.				Acceptable
Corrosive to metals	Test C1, UN-MTC	HYPO-CHLOR® Neutral 0.25%, 0.25% w/w active chlorine, Lot: 18-SHC-808992 and 18-SHC-808991 This product is representative of meta SPC 2A products.	Steel metal coupons were exposed for a period of 1 week at 55°C under 3 conditions (gas phase, half submerged and liquid phase). Results are presented below (2 replicate for each coupon location) Coupon Location / %Mass Lost Gas Phase: 0.5; 0.4 Half Submerged: 7.2; 6.4 Liquid Phase: 7.8; 7.2 Control: 0.0 Localized corrosion was not observed but uniform corrosion attack occurred on all surfaces. As the percent mass lost from all coupons after seven days was less than or equal to 13.5% (max. 7,8%), the	[redacted]	Acceptable The product HYPO-CHLOR® Neutral 0.25% is not classified as Corrosive to Metals (H290). Meta SPC 2A is not classified as Corrosive to Metals

Property	Guideline and Method	Content of active substance in biocidal product (% w/w) Batch number	Results	Reference	eCA assessment
			test item does not meet the criteria as corrosive to metals for steel, as described in UN Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria, Sixth Revised Editions, Section 37, Test C.1. Aluminium metal coupons were exposed for a period of 1 week at 55°C under 3 conditions (gas phase, half submerged and liquid phase). Results are presented below (2 replicate for each coupon location) Coupon Location / %Mass Lost Gas Phase: 0.2, 0.2 Half Submerged: 1.0, 1.0 Liquid Phase: 1.1, 1.2 Control: 0.0 Localized corrosion was not reported but minor uniform corrosion attack occurred on all surfaces. As the percent mass lost from all coupons after seven days was less than or equal to 13.5% (max. 1,2%), the test item does not meet the criteria as corrosive to metals for aluminium, as described in UN Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria, Sixth Revised Editions, Section 37, Test C.1.		

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Content of active substance in biocidal product (% w/w) Batch number</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td>Test C1, UN-MTC</td><td>Hypo-Chlor 0.52 %
SHC-16Z-0.52
Lot 21-SHC-114159

This product is representative of meta SPC 2B products.</td><td>Steel and aluminium metal plates were exposed for a period of 1 week at 55°C under 3 conditions (above the formulation, dipped into the formulation and immersed in the formulation).

Steel plates dimensions: 20mm*50mm*3mm
Aluminium plates dimensions: 20mm*50mm*2mm

Results of uniform corrosion are presented below:
<table>
<tr><th></th><th colspan="4">DNA6374/1-3 for Aluminium, DNA6374/4-6 for Steel</th></tr>
<tr><th></th><th>Pre Test Weight (g)</th><th>Post Test Weight (g)</th><th>Difference in Storage (g)</th><th>Percentage Mass Loss (% w/w)</th></tr>
<tr><td>Steel (Exposed above the formulation)</td><td>22.87718</td><td>22.83850</td><td>-0.03868</td><td>-0.16908</td></tr>
<tr><td>Steel (Half dipped into the formulation)</td><td>22.84211</td><td>20.05705</td><td>-2.78506</td><td>-12.1927</td></tr>
<tr><td>Steel (Completely immersed in the formulation)</td><td>22.80963</td><td>21.68487</td><td>-1.12476</td><td>-4.93108</td></tr>
<tr><td>Aluminium (Exposed above the formulation)</td><td>5.18664</td><td>5.19057</td><td>+0.00393</td><td>+0.075772</td></tr>
<tr><td>Aluminium (Half dipped into the formulation)</td><td>5.39688</td><td>5.42269</td><td>+0.02581</td><td>+0.478239</td></tr>
<tr><td>Aluminium (Completely immersed in the formulation)</td><td>5.46778</td><td>5.52888</td><td>+0.0611</td><td>+1.117455</td></tr>
</table>
As the thickness of the steel plates is 3mm (instead of 2mm), the maximum acceptable mass loss for steel has been recalculated by eCA considering the</td><td>[redacted]</td><td>Acceptable

The products HYPO-CHLOR® 0.52% is classified as Corrosive to Metals (H290).

Meta SPC 2B is classified as Corrosive to Metals (H290).</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Content of active substance in biocidal product (% w/w) Batch number</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>difference in thickness. Taking into account the volume of the plates and the maximum mass loss of 13.5% for a plate of 2mm, the maximum mass loss for a plate with a thickness of 3mm is 20.25%.
The maximum weight losses observed (12.2%w/w for steel and 1.1% for aluminium) are below the acceptable limits (13.5% for aluminium and 20.25% for steel).

For localized corrosion, the plates were measured using a micrometer before and after the exposure period. Results are reported below:
<table><tr><th>Description</th><th>Pre-Storage Depth DNA6374/1-6</th><th>Post Storage Depth DNA6374/1-6</th><th>Difference in Storage (mm)</th></tr><tr><td>Steel (exposed above the Formulation)</td><td>Uniform 2.95 mm</td><td>3.02 mm to 3.12 mm</td><td>+0.07 mm to +0.17 mm</td></tr><tr><td>Steel (half dipped into the Formulation)</td><td>Uniform 2.96 mm</td><td>2.75 mm to 2.85 mm</td><td>-0.21 mm to -0.11 mm</td></tr><tr><td>Steel (completely immersed in the formulation)</td><td>Uniform 2.95 mm</td><td>2.82 mm to 2.88 mm</td><td>-0.13 mm to -0.07 mm</td></tr><tr><td>Aluminium (exposed above the formulation)</td><td>Uniform 1.99 mm</td><td>Uniform 2.01 mm</td><td>+0.02 mm</td></tr><tr><td>Aluminium (half dipped into the formulation)</td><td>Uniform 2.00 mm</td><td>2.01 mm to 2.06 mm</td><td>+0.01 mm to +0.06 mm</td></tr><tr><td>Aluminium (completely immersed in the formulation)</td><td>Uniform 2.01 mm</td><td>Uniform 2.07 mm</td><td>+0.06 mm</td></tr></table>A maximum intrusion depth of 0.21mm (210µm) was observed for steel. This is higher than the acceptable limit of 0.12 mm (120µm after 7 days of exposure).

Therefore, the test item is classified as corrosive to metals.</td><td></td><td></td></tr>
<tr><td></td><td>Test C1, UN-MTC</td><td>Hypo-Chlor 5.25 %
SHC-16Z-5.25</td><td>Steel and aluminium metal plates were exposed for a period of 1 week at 55°C under 3 conditions (above the formulation, dipped into the formulation and immersed in the formulation).</td><td>[redacted]</td><td>Acceptable

The products HYPO-CHLOR®</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Content of active substance in biocidal product (% w/w) Batch number</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td>Lot 21-SHC-113944</td><td>Steel plates dimensions: 20mm*50mm*3mm
Aluminium plates dimensions: 20mm*50mm*2mm

Results of uniform corrosion are presented below:
<table><tr><td></td><td colspan="4">DNA6373/1-3 for Aluminium, DNA6373/4-6 for Steel</td></tr><tr><td></td><td>Pre Test Weight (g)</td><td>Post Test Weight (g)</td><td>Difference in Storage (g)</td><td>Percentage Mass Loss (% w/w)</td></tr><tr><td>Steel (Exposed above the formulation)</td><td>22.86054</td><td>22.84835</td><td>-0.01219</td><td>-0.05332</td></tr><tr><td>Steel (Half dipped into the formulation)</td><td>22.88947</td><td>20.30527</td><td>-2.58420</td><td>-11.28991</td></tr><tr><td>Steel (Completely immersed in the formulation)</td><td>22.89653</td><td>19.52031</td><td>-3.37622</td><td>-14.74555</td></tr><tr><td>Aluminium (Exposed above the formulation)</td><td>5.36319</td><td>5.36911</td><td>0.00592</td><td>0.11038</td></tr><tr><td>Aluminium (Half dipped into the formulation)</td><td>5.38980</td><td>5.31356</td><td>-0.07624</td><td>-1.41452</td></tr><tr><td>Aluminium (Completely immersed in the formulation)</td><td>5.40430</td><td>5.23329</td><td>-0.17101</td><td>-3.16433</td></tr></table>The maximum weight losses observed (14.74%w/w for steel and 3.16%w/w for aluminium) are below the acceptable limits (13.5% for aluminium and 20.25% for steel). The maximum acceptable mass loss for steel has been recalculated considering the difference in thickness.</td><td></td><td>5.25% is classified as Corrosive to Metals (H290).

Therefore, Meta SPC 1 is classified as Corrosive to Metals (H290).</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Content of active substance in biocidal product (% w/w) Batch number</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>For localized corrosion, the plates were measured using a micrometer before and after the exposure period. Results are reported below:
<table>
<tr><th>Description</th><th>Pre-Storage Depth DNA6373/1-6</th><th>Post Storage Depth DNA6373/1-6</th><th>Difference in Storage (mm)</th></tr>
<tr><td>Steel (exposed above the Formulation)</td><td>Uniform 2.96 mm</td><td>3.05 mm to 3.41 mm</td><td>+0.09 mm to +0.45 mm</td></tr>
<tr><td>Steel (half dipped into the Formulation)</td><td>Uniform 2.95 mm</td><td>3.15 mm to 3.96 mm</td><td>+0.20 mm to +1.01 mm</td></tr>
<tr><td>Steel (completely immersed in the formulation)</td><td>Uniform 2.96 mm</td><td>3.19 mm to 3.93 mm</td><td>+0.23 mm to +0.97 mm</td></tr>
<tr><td>Aluminium (exposed above the formulation)</td><td>Uniform 2.00 mm</td><td>Uniform 2.01 mm</td><td>+0.01 mm</td></tr>
<tr><td>Aluminium (half dipped into the formulation)</td><td>Uniform 2.01 mm</td><td>2.01 mm to 2.05 mm</td><td>+0.00 mm to +0.04 mm</td></tr>
<tr><td>Aluminium (completely immersed in the formulation)</td><td>Uniform 2.01 mm</td><td>Uniform 2.05 mm</td><td>+0.04 mm</td></tr>
</table>
A maximum intrusion depth of 1.01mm (1010µm) was observed for steel. This is higher than the acceptable limit of 0.12 mm (120µm after 7 days of exposure).

Therefore, the test item is classified as corrosive to metals.</td><td></td><td></td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td colspan="3">Due to the high water content of the formulations and lack of flammable components, the liquid formulations will boil below any auto-ignition temperature.</td><td></td><td>Acceptable</td></tr>
<tr><td>Relative self-ignition temperature for solids</td><td colspan="3">Not applicable to liquid formulations</td><td></td><td>Not relevant as the product is a liquid</td></tr>
<tr><td>Dust explosion hazard</td><td colspan="3">Not applicable to liquid formulations</td><td></td><td>Not relevant as the product is a liquid</td></tr>
</table>

Conclusion on the physical hazards and respective characteristics of the products in meta SPC 1 and 2B

The products of meta SPC 1 and 2B are classified as Corrosive to Metals (H290). The products are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties.

Conclusion on the physical hazards and respective characteristics of the products in meta SPC 2A
The products of meta SPC 2A are not classified as Corrosive to Metals (H290). The products are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties.

2.2.5 Methods for detection and identification

The product of meta SPC 1 and 2 products of meta SPC 2 (HYPO-CHLOR 0.52% now in Meta SPC 2B and HYPO-CHLOR 0.25% now in meta SPC 2A) are aqueous dilutions of sodium hypochlorite. For these products, read-across to active substance dossier can be made.
The only difference with the 2 remaining products of meta SPC 2 (HYPO-CHLOR Neutral 0.52% now in Meta SPC 2B and HYPO-CHLOR Neutral 0.25% now in Meta SPC 2A) is that the formulation in these products is diluted with a buffer solution immediately prior to use.
The applicant has access to the EU active substance data package. However, additional validated methods have been submitted in this dossier as reported below.

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**	**Reference**
					Range	Mean	RSD		
Meta 1									
Sodium hypochlorite *Product:* ***HYPO-CHLOR 5.25%***	Titration[a]	0.1928 g* / n=1 0.4147 g* / n=1 *fortification of blank solutions with 12% reference standard	0.5017-0.7463 g sample, n=6, r^2=1.000, y=14.651x+0.333	Placebo (i.e. without active substance) showed no interferences.	n/a	96	n/a *Precision analysis:* n=6 %RSD=0.62 %RSDr=2.07 (5.65% mean sodium hypochlorite content)	n/a	[redacted]
Sodium hypochlorite *Product:* ***HYPO-CHLOR 5.25%***	Read-across also to active substance dossier. A fully validated method for the determination of active chlorine in 1% w/w sodium hypochlorite aqueous solutions is available in the EU active substance dossier. Upon appropriate dilution, the method is applicable also to higher hypochlorite concentrations. Veltek Associates Inc. are part of the Euro-chlor consortium and have access to the EU active substance data package.								
Chlorate *Product:* ***HYPO-***	Ion chromatography[b]	0.066 mg chlorate (2.2% w/w	1-49.75 µg/mL, n=8, r^2 =	Chromatograms of blank/water, standard	n/a	95.5	n/a *Precision analysis:* n=5	Proposed by applicant: Address	[redacted]

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**	**Reference**
					Range	Mean	RSD		
CHLOR 5.25%		spike) / n=1 (duplicate) 0.132 mg chlorate (4.4% w/w spike) / n=1 (duplicate)	1.000, y=0.0837x–0.0389	and sample have been provided. No interference observed.			%RSD=0.78 %RSDr=2.97 (0.5% mean chlorate content)	ed in EU active substance dossier, which Veltek have access to. RMS: 5g/kg based on precision results (n=5)	[redacted]
Chlorate *Product:* ***HYPO-CHLOR 5.25%***	Read-across also to active substance dossier. A fully validated method for the determination of chlorate in 1% w/w sodium hypochlorite solutions is available in the EU active substance dossier. Upon appropriate dilution, the method is applicable also to higher sodium hypochlorite/chlorate concentrations. Veltek Associates Inc. are part of the Euro-chlor consortium and have access to the EU active substance data package.								
Meta 2									
Sodium hypochlorite *Product:* ***HYPO-CHLOR 0.52%***	Titration VEL-2010-05[a]	80%* / n=3 100% * / n=3 120% * / n=3 *of average determ	80-120% of average determined analyte concentration n=5 (from 0.32%	Placebo (i.e. without active substance) showed no interferences.	97 97 97	97 97 97	0 0 0 *Precision analysis:* n=6 %RSD=0.11 %RSDr=3.06 (0.4164	n/a	[redacted]

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**	**Reference**
					Range	Mean	RSD		
		mined analyte concentration (0.4164%)	to 0,48%), duplicate determinations r^2=1.00				% mean sodium hypochlorite content)		
Chlorate *Product:* ***HYPO-CHLOR 0.52%***	Read-across to HYPO-CHLOR Neutral 0.52% (Meta 2). Both HYPO-CHLOR Neutral 0.52% and HYPO-CHLOR 0.52% contain the same formulation, the only difference being that the formulation in HYPO-CHLOR Neutral 0.52% is diluted with a buffer solution immediately prior to use. Refer also to active substance dossier. A validated method for the determination of chlorate in 1% w/w sodium hypochlorite aqueous solutions is available in the active substance dossier. The method supports analysis in HYPO-CHLOR 5.25% (meta 1) and HYPO-CHLOR 0.25% (meta 2; see relevant sections), therefore is also considered appropriate for determination in HYPO-CHLOR 0.52%. Veltek Associates Inc. are part of the Euro-chlor consortium and have access to the EU active substance data package.								
Sodium hypochlorite *Product:* ***HYPO-CHLOR 0.25%***	Titration VEL-2010-05[a]	80%* / n=3 100%* / n=3 120%* / n=3 *of target analyte concentration	0.2358-0.3682% (80-120% of target analyte concentration) n=5, duplicate determinations r^2=1.00	Placebo (i.e. without active substance) showed no interferences. However, no chromatograms have been provided.	98-102 99 98-100	101 99 99	2.3 0 1.2 *Precision analysis:* n=6 %RSD=0 %RSDr=3.21 (0.30% mean sodium hypochlorite content)	n/a	[redacted]
Chlorate *Product:* ***HYPO-***	Read across to active substance dossier. A validated method for the determination of chlorate in 1% w/w sodium hypochlorite aqueous solutions is available in the active substance dossier. The analytical range of the method to determine chlorate content also covers								

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**	**Reference**
					Range	Mean	RSD		
CHLOR 0.25%	analysis in HYPO-CHLOR 0.25%. Veltek Associates Inc. are part of the Euro Chlor consortium and have access to the EU active substance data package.								
Sodium hypochlorite *Product:* ***HYPO-CHLOR Neutral 0.52%***	Titration[a]	0.1928 g* / n=1 0.4147 g* / n=1 *fortification of blank solutions with 12% reference standard	5.4914-6.7591 g sample, n=6, r^2=1.000, y=1.538 x+0.358	Placebo (i.e. without active substance) showed no interferences.	n/a	96	n/a *Precision analysis:* n=6 %RSD=0.34 %RSDr=2.90 (0.59% mean sodium hypochlorite content)	n/a	[redacted]
Chlorate *Product:* ***HYPO-CHLOR Neutral 0.52%***	Ion chromatography[b]	0.066 mg (2.2% w/w spike) / n=1 (duplicate) 0.132 mg (3.6% w/w spike) / n=1 (duplicate)	1-49.75 µg/mL, n=8, r^2=1.000, y=0.0815x–0.0309	Chromatograms of blank/water, standard and sample have been provided. No interference observed.	n/a	97.3	n/a *Precision analysis:* n=5 %RSD=1.16 %RSDr=4.32 (0.042% mean chlorate content)	Addressed in EU active substance dossier, which Veltek have access to. RMS: 0,42 g/kg based on precision results (n=5)	[redacted]

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**	**Reference**
					Range	Mean	RSD		
Sodium hypochlorite *Product:* ***HYPO-CHLOR Neutral 0.25%***	Read-across to HYPO-CHLOR 0.25% (Meta SPC 2 (A and B)). Both products contain the same formulation, the only difference being that the formulation in HYPO-CHLOR Neutral 0.25% is diluted with a buffer solution immediately prior to use.								
Chlorate *Product:* ***HYPO-CHLOR Neutral 0.25%***	Read-across to HYPO-CHLOR 0.25% (Meta SPC 2 (A and B)). Both products contain the same formulation, the only difference being that the formulation in HYPO-CHLOR Neutral 0.25% is diluted with a buffer solution immediately prior to use.								

[a]Titration:

Potassium iodide was dissolved in distilled or deionised water and solution added to a separate flask containing test substance. The mixture was swirled until homogenous. Sulfuric acid solution (conc. sulfuric acid: water 1:3 v/v) was added and the contents titrated immediately against 0.1N sodium thiosulfate until a pale-yellow solution was obtained. Starch indicator solution was added and titration continued until the blue-black colour just disappeared.

[b]Ion chromatography:

The test item was added to a 50 mL centrifuge tube and filled to volume with water. Aliquots were mixed with EDA solution (i.e. EDA mixed with water) in 50 mL centrifuge tubes and filled to volume with water. Samples were analysed by ion chromatography using a Dionex IonPac AS9-HC, 4 x 250 mm column.

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: $HClO/ClO^-$

Monitoring methods for the determination of active chlorine released from sodium hypochlorite in soil were discussed in the active substance assessment reports for use in PT 2 and were considered not necessary; active chlorine ($HClO/ClO^-$) reacts rapidly with organic matter.

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: $Cl_2/HClO/ClO^-$ Monitoring methods for the determination of active chlorine released from sodium hypochlorite in air were discussed in the active substance assessment reports for use in PT 2 and were considered not necessary. For PT 2, no spray applications are envisaged. Despite this, two analytical methods are available for monitoring chlorine in workplace air as a result of accidental release of chlorine. These are: • OSHA Method, Chlorine in Work place Atmosphere, 05.01.83; Smith and Cochran, Spectrophotometric determination of Free Chlorine in Air using Sulphamic acid/Tri-iodide procedure, Anal. Chem., 1986, 58, 1591. • 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 Colormetric method using DPD for routine control purposes 15.10.85 No validation data are available to validate these two methods, however they are published, so were considered fit for the purpose of monitoring chlorine at the workplace. These methods are based on the oxidative behaviour of chlorine to produce a marker then analysed. Therefore, these methods are applicable to detect for all forms of active chlorine at the same time: chlorine, hypochlorous acid and sodium hypochlorite.									

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		

Surface water

Residue definition: $HClO/ClO^-$

Monitoring methods for the determination of active chlorine released from sodium hypochlorite in surface water were discussed in the active substance assessment reports for use in PT 2 and were considered not necessary; active chlorine ($HClO/ClO^-$) reacts rapidly with organic matter.

Drinking water

Residue definition: $HClO/ClO^-$ and relevant metabolite chlorate ClO_3^-

Fully validated monitoring methods for determination of active chlorine and the relevant metabolite (sodium chlorate) were not available at active substance approval in PT 2, though were provided post-submission. Veltek Associates Inc. are part of the Euro Chlor consortium and have access to the EU active substance data package.

Analytical methods for animal and human body fluids and tissues

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: $HClO/ClO^-$

Monitoring methods for the determination of active chlorine released from sodium hypochlorite in body fluids and tissues were discussed in the active substance assessment reports for use in PT 2 and were considered not necessary; active chlorine ($HClO/ClO^-$) reacts rapidly with organic matter. Furthermore, due to corrosive properties, systemic toxicity would be secondary to local effects.

Despite this, two analytical methods for monitoring chlorine in the workplace air (see analytical methods for air above) are also meaningful for monitoring human exposure.

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		

Residues in food and feeding stuff are not expected from use in PT 2.

Conclusion on the methods for detection and identification of the product

In the EU dossier for sodium hypochlorite for PT 2, analytical methods are available for determination of hypochlorite and relevant impurity chlorate in aqueous sodium hypochlorite solutions that can be used to support several of the HYPO-CHLOR products.

Veltek Associates Inc. are part of the Euro-chlor consortium and have access to the EU active substance data package.

Validated analytical methods have also been provided specifically for determination of sodium hypochlorite in HYPO-CHLOR 5.25% (Meta SPC 1), HYPO-CHLOR 0.52%, HYPO-CHLOR 0.25% and HYPO-CHLOR Neutral 0.25% (Meta SPC 2); and for determination of chlorate in HYPO-CHLOR Neutral 0.52% (Meta SPC 2).

Monitoring methods for the determination of active chlorine released from sodium hypochlorite in soil, surface water, air, body fluids and tissues and in food or feed were discussed in the active substance assessment reports for PT 2 and considered not necessary. Fully validated monitoring methods for determination of active chlorine and sodium chlorate (the relevant metabolite) in drinking water were not available at active substance approval, though were provided post-submission. Veltek Associates Inc. are part of the Euro Chlor consortium and have access to the EU active substance data package.

2.2.6 Efficacy against target organisms

NOTE
The applicant submitted a BPF composed of 2 meta-SPCs: Meta-SPC 1 and Meta-SPC 2. After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs, Meta-SPC 2A and Meta-SPC 2B both containing ready to use products (HYPO-CHLOR 0.25% and HYPO-CHLOR 0.25% NEUTRAL for Meta-SPC 2A and HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL for Meta-SPC 2B). However, the evaluation was held on the initial BPF composition.

Hence, these changes were considered in the efficacy and APCP sections but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions.When the splitting was of no consequence for the evaluation, the evaluation refers to Meta-SPC 2 (meaning both Meta-SPC 2A and 2B).

2.2.6.6 Function and field of use

MG 01: Disinfectants
PT2: Disinfectants and algaecides not intended for direct application to humans or animals

Veltek's HYPO-CHLOR Biocidal Product Family is a family of PT 2 disinfectant products intended for industrial indoor use. The product family includes three Meta SPCs:

- Meta SPC 1: Concentrate PT2.
- Meta SPC 2 splits into Meta SPC 2A and Meta SPC 2B: Ready to use products PT2.

Veltek's HYPO-CHLOR Biocidal Product Family is based on the active substance active chlorine released from sodium hypochlorite (CAS 231-668-3) at a concentration initially ranging from 0.24% to 5.25% NaOCl or 0.23 to 5% active chlorine. After WG-VI-2021, the concentation is ranging from 0.25% to 5% active chlorine.

Veltek's HYPO-CHLOR Biocidal Product Family is formed of disinfectants intended to be used in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.

The products are used by industrial users, by mopping, wiping (with a wipe or a cloth), immersion or mechanical spraying without mechanical action.

It has to be noted that in the frame of application for marketing authorisation of HYPO-CHLOR Biocidal Product Family as a biocidal product family, the use for the disinfection of instruments and materials which is covered by the medical devices Regulation is not concerned.

2.2.6.7 Organisms to be controlled and products, organisms or objects to be protected

The biocidal product family is intended for general disinfection of hard non-porous inanimate surfaces, and materials and equipment, which are not used for direct contact with food or feeding stuffs.

Products family irreversibly inactivates vegetative bacteria, yeasts, moulds, bacterial spores and virus.

The product family is used for the purpose of the protection of human health.

2.2.6.8 Effects on target organisms, including unacceptable suffering

The products are able to produce a reduction in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity), of mould spores (fungicidal activity), of viable bacterial endospores (sporicidal activity) and of infectious virus particles (virucidal activity) of relevant test organisms under defined conditions.

2.2.6.9 Mode of action, including time delay

Chlorine released from sodium hypochlorite has an unspecific mode of action.

Microbial inactivation by chlorine can result from a number of factors: oxidation of sulfhydryl enzymes and amino acids; ring chlorination of amino acids; loss of intracellular contents; decreased uptake of nutrients; inhibition of protein synthesis; decreased oxygen uptake; oxidation of respiratory components; decreased adenosine triphosphate production; breaks in DNA; and depressed DNA synthesis. The actual microbiocidal mechanism of chlorine might involve a combination of these factors or the effect of chlorine on critical sites. There is no time delay to the toxic effect.

Contact times for the different activities claimed are determined in the efficacy tests (see table below).

2.2.6.10 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Meta-SPC 1							
Disinfectant	PT2	HYPO-CHLOR 5.25%	*Pseudomonas aeruginosa* ATCC 15422, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541, *Escherichia coli* ATCC 10536	EN 1276:2019 Suspension test Phase 2 step 1	Concentrations tested: 10.0%, 5.0% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 3 and 6 minutes. Test temperature: 20°C	Log R >5 at 5.0% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 3 minutes	6.7.3 HYPO-CHLOR 5.25% EN 1276:2019. J001198-1 RI=1
Disinfectant	PT2	HYPO-CHLOR 5.25%	*P. aeruginosa* ATCC 15422 *S. aureus* ATCC 6538 *E. hirae* ATCC 10541 *E. coli* ATCC 10536	EN 13697:2015 +A1:2019 Surface test without mechanical action Phase 2 step 2		Log R >4 at 5.0% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 6 minutes	6.7.4 HYPO-CHLOR 5.25% EN 13697:2015+A1:2019. J001198-3 RI=1
Disinfectant	PT2	HYPO-CHLOR 5.25%	*Candida albicans* NCPF 3179 *Aspergillus brasiliensis* ATCC 16404	EN 1650:2019 Suspension test Phase 2 step 1	Concentrations tested: 10.0%, 5% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 6 and 8 minutes.	Log R >4 at 5.0% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 6 minutes.	6.7.5 HYPO-CHLOR 5.25% EN 1650:2019. J001198-2 RI=1

Disinfectant	PT2	HYPO-CHLOR 5.25%	*C. albicans* ATCC 10231 *A. brasiliensis* ATCC 16404	EN 13697:2015 +A1:2019 Surface test without mechanical action Phase 2 step 2	Test temperature: 20°C	Log R >3 at : 5.0% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 8 minutes. 10% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 6 minutes for *A. brasiliensis* only. Results are not validated for yeasts for 6 min contact time (NC and NT are < 0,5Nc).	6.7.6 HYPO-CHLOR 5.25% EN 13697:2015+A1:2019. J001258 RI=1
Disinfectant	PT2	HYPO-CHLOR 5.25%	*Bacillus subtilis* ATCC 6633	EN 13704:2018 Suspension test Phase 2 step 1	Concentrations tested: 10%, 5% and 1% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 25 and 40 minutes. Test temperature: 20°C	Log R >3 At 10% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 25 minutes. At 5% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 40 minutes.	6.7.7 HYPO-CHLOR 5.25% EN 13704:2018. J001198-4 RI=1
Disinfectant	PT2	HYPO-CHLOR 5.25%	*Murine norovirus,* strain S99 Berlin *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Poliovirus* type 1, LSc-2ab	EN 14476:2013 +A2:2019 Suspension test Phase 2 step 1	Concentrations tested: 10%, 5% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 10 minutes Test temperature: 20°C	*Murine norovirus* Log R >4 at 10% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 10 minutes. *Adenovirus* and *Poliovirus*: Log R < 4 for all tested concentrations. Furthermore, test method is not validated for Adenovirus (difference between Product suppression control and Virus control > 0.5 log).	6.7.13 HYPO-CHLOR 5.25% EN 14776:2013+A2:2019. J001198-6 RI=1

Disinfectant	PT2	HYPO-CHLOR 5.25%	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Poliovirus* type 1, LSc-2ab	EN 14476:2013 +A2:2019 Suspension test Phase 2 step 1	Concentrations tested: 10%, 5% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 15 and 20 minutes Test temperature: 20°C	For both virus, test method is not validated for 15 min contact time (difference between Product suppression control and Virus control > 0.5 log). *Poliovirus* and *Adenovirus*: Log R >4 at 10% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 20 minutes.	6.7.13 HYPO-CHLOR 5.25% EN 14776:2013+A2:2019. J001307-4 RI=3
Disinfectant	PT2	HYPO-CHLOR 5.25%	*Murine norovirus,* strain S99 Berlin *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5	EN 16777:2018 Surface test Phase 2 step 2	Concentrations tested: 10%, 5% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 10 minutes Test temperature: 20°C	*Murine norovirus:* Log R >4 at 10% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 10 minutes. *Adenovirus*: Test method is not validated (difference between Product suppression control and Virus control > 0.5 log).	6.7.14 HYPO-CHLOR 5.25% EN 16777:2018. J001198-7 RI=1 (norovirus) RI=3 (Adenovirus)
Disinfectant	PT2	HYPO-CHLOR 5.25%	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5	EN 16777:2018 Surface test Phase 2 step 2	Concentrations tested: 10%, 5% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 15 minutes Test temperature: 20°C	Log R >4 at 10% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 15 minutes.	6.7.14 HYPO-CHLOR 5.25% EN 16777:2018. J001307-2 RI=1
Meta-SPC 2							

Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*S. aureus* ATCC 6538 *P. aeruginosa* ATCC 15442 *E. hirae* ATCC 10541 *E. coli* ATCC 10536	EN 1276:2019 Suspension test Phase 2 step 1 Deviations: The product was tested at a concentration of 97%, using the modified method stated in BS EN 13727 at contact times of 3 and 6 minutes. The product was prepared 23 hours before testing by addition of the associated buffer and all testing performed between 23 and 24 hours after preparation.	Concentrations tested: 97%, 50% and 0.1 (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 3 and 6 minutes. Test temperature: 20°C	Log R >5 at 50% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 3 minutes.	6.7.8 HYPO-CHLOR Neutral 0.52% EN 1276:2019. J001197-1 RI=1
Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*S. aureus* ATCC 6538 *P. aeruginosa* ATCC 15422 *E. hirae* ATCC 10541 *E. coli* ATCC 10536	EN 13697:2015 Surface test without mechanical action Phase 2 step 2 Deviation: The product was prepared 23 hours before testing by addition of the associated buffer and all testing performed between 23 and 24 hours after preparation.	Concentrations tested: 97%, 50% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 3 and 6 minutes. Test temperature: 20°C	Log R >4 at 50% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 6 minutes Test method is not validated for 3 min contact time as NT-Nc > 0.3 for *E.coli*.	6.7.9 HYPO-CHLOR Neutral 0.52% EN 13697:2015. J001197-3 RI=1 (RI=3 for *E.coli*)

Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*C. albicans* ATCC 10231 *A. brasiliensis* ATCC 16404	EN 1650:2019 Suspension test Phase 2 step 1 Deviations: The product was tested at a concentration of 97%, using the modified method stated in BS EN 13727 at contact times of 3 and 6 minutes. The product was prepared 23 hours before testing by addition of the associated buffer and all testing performed between 23 and 24 hours after preparation.	Concentrations tested: 97%, 50% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 3 and 6 minutes. Test temperature: 20°C	*C. albicans* Log R >4 at 50% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 3 minutes. *A. brasiliensis* Log R >4 at 97% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 3 minutes and at 50% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 6 minutes.	6.7.10 HYPO-CHLOR Neutral 0.52% EN 1650:2019. J001197-2 RI=2 (*A. brasiliensis*: N= 1.46e7 thus < 1,5e7)
Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*C. albicans* NCPF 3179 *A. brasiliensis* ATCC 16404	EN 13697:2015 +A1:2019 Surface test without mechanical action Phase 2 step 2 Deviation: The product was prepared 23 hours before testing by addition of the associated buffer and all testing performed between 23 and 24 hours after preparation.		Log R >3 at 50% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 3 minutes.	6.7.11 HYPO-CHLOR Neutral 0.52% EN 13697:2015. J001197-3 RI=1

Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*B. subtilis* ATCC 6633	EN 13704:2018 Suspension test Phase 2 step 1 Deviations: The product was tested at a concentration of 97%, using the modified method stated in BS EN 13727. The product was prepared 23 hours before testing by addition of the associated buffer and all testing performed between 23 and 24 hours after preparation.	Concentrations tested: 97%, 50% and 0.05% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 20 and 30 minutes. Test temperature: 20°C	Log R >3 at 97% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 20 minutes. Log R >3 at 50% under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 30 minutes.	6.7.12 HYPO-CHLOR Neutral 0.52% EN 13704:2018. J001197-4 RI=1
Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*Murine norovirus,* strain S99 Berlin *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Poliovirus* type 1, LSc-2ab	EN 14476:2013 +A2:2019 Suspension test Phase 2 step 1	Concentrations tested: Neat (80%), 50% and 0.1% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 10 minutes Test temperature: 20°C	*Murine norovirus/* Log R >4 when used neat under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 10 minutes. *Adenovirus* and *Poliovirus*: Log R < 4 for all tested concentrations. Furthermore, test method is not validated for Adenovirus (difference between Product suppression control and Virus control > 0.5 log).	6.7.15 HYPO-CHLOR Neutral 0.52% EN 14776:2013+A2:2019. J001197-6 RI=1

Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5	EN 14476:2013 +A2:2019 Suspension test The product was prepared 24 hours before testing by addition of the associated buffer Phase 2 step 1	Concentrations tested: Neat (80%), 50% and 0.1% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 10 minutes Test temperature: 20°C	Log R >4 when used neat under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 10 minutes. Test method is validated (Virus control = 7.83 log thus <8 but a 4 log reduction can be demonstrated).	6.7.15 HYPO-CHLOR Neutral 0.52% EN 14776:2013+A2:2019. J001197-6-adeno-retest RI=1
Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*Poliovirus* type 1, LSc-2ab	EN 14476:2013 +A2:2019 Suspension test Phase 2 step 1	Concentrations tested: Neat (80%), 50% and 0.1% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 10 minutes for all viruses and 15 and 20 minutes for Poliovirus Test temperature: 20°C	Log R>4 when used neat under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 20 minutes.	6.7.15 HYPO-CHLOR Neutral 0.52% EN 14776:2013+A2:2019. J001307-3 RI=2, because of a methodological deviation: Formaldehyde control at 30 min is not between-0,5 et – 2,5 but at -2.7.

Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*Murine norovirus,* strain S99 Berlin *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5	EN 16777:2018 Surface test Phase 2 step 2	Concentrations tested: Neat (80%), 50% and 0.1% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 10 minutes Test temperature: 20°C	*Murine norovirus*: Log R>4 neat under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 10 minutes. Test method is not validated for Adenovirus (difference between Product suppression control and Virus control > 0.5 log).	6.7.16 HYPO-CHLOR Neutral 0.52%EN 16777:2018. J001197-7 RI=1 (norovirus) RI=3 (Adenovirus)
Disinfectant	PT2	HYPO-CHLOR Neutral 0.52%	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5	EN 16777:2018 Surface test Phase 2 step 2	Concentrations tested: Neat (80%), 50% and 0.1% (v/v). Clean conditions (0.3 g/l bovine albumin). Contact time: 15 minutes Test temperature: 20°C	Log R>4 neat under clean soiling conditions (0.3 g/l bovine albumin) at 20°C, 15 minutes.	6.7.16 HYPO-CHLOR Neutral 0.52%EN 16777:2018. J001307-1 RI=1

Veltek's HYPO-CHLOR Biocidal Product Family is a family of PT 2 disinfectant products intended for industrial indoor use. The product family includes two Meta SPCs:

- Meta SPC 1: Concentrate PT2. HYPO-CHLOR 5.25%.
- Meta SPC 2: Ready to use products PT2. HYPO-CHLOR 0.25 %, HYPO-CHLOR 0.52%, HYPO-CHLOR Neutral 0.25 %, HYPO-CHLOR Neutral 0.52%.

Note: After WG-VI-2021, Meta SPC 2 was split in two changing the composition of the BPF (now including 3 meta-SPC):

- Meta SPC 1: Concentrate PT2. HYPO-CHLOR 5.25%.
- Meta SPC 2A: HYPO-CHLOR 0.25 %, HYPO-CHLOR Neutral 0.25 %.
- Meta SPC 2B: HYPO-CHLOR 0.52%, HYPO-CHLOR Neutral 0.52%

- **HYPO-CHLOR 5.25% (Meta-SPC 1), HYPO-CHLOR 0.52% and HYPO-CHLOR 0.25 % (Meta-SPC 2)**

The applicant has proposed to read across the efficacy data from the concentrate (HYPO-CHLOR 5.25%) to its two straight dilutions HYPO-CHLOR 0.52% (10% of HYPO-CHLOR 5.25%) and HYPO-CHLOR 0.25 % (approx. 5% of HYPO-CHLOR 5.25%).

Claim: *Bactericidal claim for disinfection of clean hard non-porous surfaces*, materials and equipment *by immersion, without mechanical action at 5 % (v/v) HYPO-CHLOR 5.25% or neat HYPO-CHLOR 0.52 % and HYPO-CHLOR 0.25 % with a contact time of 6 minutes at 20°C, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.*

Following tests have been submitted:

- EN 1276 to support bactericidal claims. The product HYPO-CHLOR 5.25% passed the test at 5 % (v/v) under clean conditions (0.3 g/l bovine albumin) at 3 minutes contact time and 20°C. See IUCLID 6.7.3 HYPO-CHLOR 5.25% EN 1276:2009.
- EN 13697 to support bactericidal claims. The product HYPO-CHLOR 5.25% passed the test at 5 % (v/v) under clean conditions (0.3 g/l bovine albumin) at 6 minutes contact time and at 20°C. See IUCLD 6.7.4 HYPO-CHLOR 5.25% EN 13697:2015.

The claim is validated for *HYPO-CHLOR 5.25% (meta-SPC 1) at* 5% (v/v)*, neat HYPO-CHLOR* 0.52% and neat HYPO-CHLOR 0.25 % (Meta-SPC 2), with a contact time of 6 min at 20°C under clean conditions.

Claim: *Yeasticidal and fungicidal claims for disinfection of clean hard surfaces, materials and equipment by immersion without mechanical action:*

- *at 10 % v/v HYPO-CHLOR 5.25% or neat HYPO-CHLOR 0.52% with a contact time of 6 minutes or*
- *at 5 % v/v HYPO-CHLOR 5.25% or neat HYPO-CHLOR 0.25 % with a contact time of 8 minutes at 20°C*

in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.

Following tests have been submitted:

- EN 1650 to support yeasticidal and fungicidal claims. The product HYPO-CHLOR 5.25% passed the test at 5 % (v/v) under clean conditions (0.3 g/l bovine albumin) at 6 minutes contact time and 20°C. See IUCLID 6.7.5 HYPO-CHLOR 5.25% EN 1650:2013.
- EN 13697 to support yeasticidal and fungicidal claims. The product HYPO-CHLOR 5.25% passed the test at 5 % (v/v) under clean conditions (0.3 g/l bovine albumin) at 8 minutes contact time and 20°C. See IUCLID 6.7.6 HYPO-CHLOR 5.25%. EN 13697:2015.

The claim is validated at 5 % (v/v) HYPO-CHLOR 5.25% (Meta-SPC 1), neat HYPO-CHLOR 0.52 % and neat HYPO-CHLOR 0.25 % (Meta-SPC 2) with a contact time of 8 minutes at 20°C, under clean conditions.

Claim: *Sporicidal claim for disinfection of clean hard surfaces, materials and equipment by immersion, without mechanical action at 10 % v/v HYPO-CHLOR 5.25% or neat HYPO-CHLOR 0.52% with a contact time of 25 minutes or 5 % v/v HYPO-CHLOR 5.25% or neat HYPO-CHLOR 0.25% with a contact time of 40 minutes at 20°C in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.*

Following tests have been submitted:

- EN 13704 to support efficacy against bacterial spores. The product HYPO-CHLOR 5.25% passed the test at 10 % (v/v) at 25 minutes contact time under clean conditions (0.3 g/l bovine albumin) and 20°C and at 5 % (v/v) at 40 minutes contact time under clean conditions (0.3 g/l bovine albumin) and 20°C. See IUCLID 6.7.7 HYPO-CHLOR 5.25% EN 13704:2018
- Currently there is not phase 2, step 2 test validated method for sporicidal claims. It is considered that a suspension test will be sufficient.

The claim is validated at 10 % v/v HYPO-CHLOR 5.25% (meta-SPC 1), neat HYPO-CHLOR 0.52% (Meta-SPC 2) with a contact time of 25 minutes or 5.00% HYPO-CHLOR 5.25% and neat HYPO-CHLOR 0.25 % (Meta-SPC 2) with a contact time of 40 minutes at 20°C under clean conditions.

Claim: *Virucidal claims for disinfection of clean hard surfaces, materials and equipment by immersion, without mechanical action at 10%* (v/v) *HYPO-CHLOR 5.25% or neat HYPO-CHLOR 0.52% with a contact time of 20 minutes at 20°C in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.*

Following tests have been submitted:

- EN 14476 to support efficacy against viruses. The product HYPO-CHLOR 5.25% passed the test at 10 % (v/v) at 20 minutes contact time under clean conditions (0.3 g/l bovine albumin) and 20°C. See IUCLID 6.7.13 HYPO-CHLOR 5.25% EN 14476:2013+A2:2019
- EN 16777 to support efficacy against viruses. The product HYPO-CHLOR 5.25% passed the test at 10 % (v/v) at 15 minutes contact time under clean conditions (0.3 g/l bovine albumin) and 20°C. See IUCLID 6.7.14 HYPO-CHLOR 5.25% EN 16777:2018.

The claim is validated for 10 % (v/v) HYPO-CHLOR 5.25% (meta-SPC1) or neat HYPO-CHLOR 0.52% (meta-SPC2) with a contact time of 20 minutes at 20°C under clean conditions.

- **HYPO-CHLOR Neutral 0.52% and HYPO-CHLOR Neutral 0.25 % (Meta-SPC 2)**

The applicant has commissioned efficacy data for the product HYPO-CHLOR Neutral 0.52% which will be read across to its straight dilution HYPO-CHLOR Neutral 0.25 %.
Those two products are similar to the products HYPO-CHLOR 0.52% and HYPO-CHLOR 0.25 % but they also contain pH regulators. The pH of the mixture is 7-8. A higher concentration of hypochlorous acid is produced at neutral pH. Higher content of hypochlorous acid makes the solution more efficacious but also more unstable. This product range is mixed a maximum of 24 hours before use to ensure efficacious use.

Claim: *Bactericidal claim for disinfection of clean hard surfaces, materials and equipment by immersion without mechanical action with a contact time of 3 minutes at 20°C for HYPO-CHLOR Neutral 0.52% or HYPO-CHLOR Neutral 0.25% in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries*

- EN 1276 to support bactericidal claims. The product HYPO-CHLOR Neutral 0.52% passed the test at 97 and 50% (v/v) under clean conditions (0.3 g/l bovine albumin), at 3 minutes contact time and 20°C. See IUCLID 6.7.8 HYPO-CHLOR Neutral 0.52% EN 1276:2009.
- EN 13697 to support bactericidal claims. The product HYPO-CHLOR Neutral 0.52% passed the test at 97 and 50% % (v/v) under clean conditions (0.3 g/l bovine albumin), at 6 minutes contact time and 20°C. See IUCLD 6.7.9 HYPO-CHLOR Neutral 0.52% EN 13697:2015.

The claim is validated for HYPO-CHLOR Neutral 0.52 % and HYPO-CHLOR Neutral 0.25 % (Meta-SPC 2) when used neat with a contact time of 6 minutes at 20°C, under clean conditions.

Claim: *Yeasticidal claims for disinfection of clean hard surfaces, materials and equipment by immersion without mechanical action with a contact time of 3 minutes at 20°C for HYPO-CHLOR Neutral 0.52% or HYPO-CHLOR Neutral 0.25 % in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries*

- EN 1650 to support yeasticidal claims. The product HYPO-CHLOR Neutral 0.52% passed the test at 50% (v/v) under clean conditions (0.3 g/l bovine albumin), at 3 minutes contact time and 20°C. See IUCLID 6.7.10 HYPO-CHLOR Neutral 0.52% EN 1650:2013.
- EN 13697 to support yeasticidal claims. The product HYPO-CHLOR Neutral 0.52% passed the test at 50% (v/v) under clean conditions (0.3 g/l bovine albumin), at 3 minutes contact time and 20°C. See IUCLID 6.7.11 HYPO-CHLOR Neutral 0.52% EN 13697:2015.

The claim is validated for HYPO-CHLOR Neutral 0.52 % and HYPO-CHLOR Neutral 0.25 % (Meta-SPC 2) when used neat with a contact time of 3 minutes at 20°C, under clean conditions.

Claim: *Fungicidal claims for disinfection of clean hard surfaces, materials and equipment by immersion without mechanical action with HYPO-CHLOR Neutral 0.52% and a contact time of 3 minutes at 20°C and with HYPO-CHLOR Neutral 0.25% and a contact time of 6 minutes at 20°C in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.*

- EN 1650 to support fungicidal claims. The product HYPO-CHLOR Neutral 0.52% passed the test at 97% (v/v) under clean conditions (0.3 g/l bovine albumin), at 3 minutes contact time and 20°C, and at 50%(v/v) under clean conditions (0.3 g/l bovine albumin) at 6 minutes contact time and 20°C. See IUCLID 6.7.10 HYPO-CHLOR Neutral 0.52% EN 1650:2013.
- EN 13697 to support fungicidal claims. The product HYPO-CHLOR Neutral 0.52% passed the test at 50% (v/v) under clean conditions (0.3 g/l bovine albumin), at 3 minutes contact time and 20°C. See IUCLID 6.7.11 HYPO-CHLOR Neutral 0.52% EN 13697:2015.

The claim is validated for HYPO-CHLOR Neutral 0.52 % when used neat with a contact time of 3 minutes at 20°C, under clean conditions and for HYPO-CHLOR NEUTRAL 0.25% (Meta-SPC 2) when used neat with a contact time of 6 minutes at 20°C, under clean conditions.

Claim: *Sporicidal claims for disinfection of clean hard surfaces, materials and equipment by immersion without mechanical action with HYPO-CHLOR Neutral 0.52% and a contact time of 20 minutes at 20°C and with HYPO-CHLOR Neutral 0.25% and a contact time of 30 minutes at 20°C in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.*

- EN 13704 to support efficacy against bacterial spores. HYPO-CHLOR Neutral 0.52% passed the test at 97% (v/v) under clean conditions (0.3 g/l bovine albumin), at 20 minutes contact time and 20°C, and at 50% (v/v) under clean conditions (0.3 g/l bovine albumin), at 30 minutes contact time and 20°C. See IUCLID 6.7.12 HYPO-CHLOR Neutral 0.52% EN 13704:20158
- Currently there is not phase 2, step 2 test validated method for sporicidal claims. It is considered that a suspension test will be sufficient.

The sporicidal claim is validated for HYPO-CHLOR Neutral 0.52 % (Meta-SPC 2) when used neat with a contact time of 20 minutes at 20°C, under clean conditions, and for HYPO-CHLOR NEUTRAL 0.25% (Meta-SPC 2) when used neat with a contact time of 30 minutes at 20°C, under clean conditions.

Claim: *Virucidal claims for disinfection of clean hard surfaces, materials and equipment by immersion, without mechanical action with HYPO-CHLOR* Neutral 0.52% *with a contact time of 20 minutes at 20°C in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries.*

- EN 14476 to support efficacy against viruses. The product HYPO-CHLOR Neutral 0.52% passed the test at 80.0% (v/v) under clean conditions (0.3 g/l bovine albumin), at 20 minutes contact time and 20°C on Murine norovirus, Poliovirus and Adenovirus. See IUCLID 6.7.15 HYPO-CHLOR Neutral 0.52% EN 14476:2013+A2:2019

- EN 16777 to support efficacy against viruses. The product HYPO-CHLOR Neutral 0.52% passed the test when tested neat under clean conditions (0.3 g/l bovine albumin), at 15 minutes contact time and 20°C on Murine norovirus and Adenovirus. See IUCLID 6.7.16 HYPO-CHLOR Neutral 0.52% EN 16777:2018.

The virucidal claim is validated for HYPO-CHLOR Neutral 0.52 % (Meta-SPC 2) when used neat with a contact time of 20 minutes at 20°C, under clean conditions.

Conclusion on the efficacy of the product

French competent authorities (FR CA) assessed that the products of the HYPO-CHLOR FAMILY biocidal product family, have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), for the following uses claimed:

- Meta SPC 1: Concentrate PT2

  Use 1: Disinfection of hard non-porous surfaces by immersion or with a mop/cloth/wipe/mechanical spray device without mechanical action, in clean conditions, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries (PT 02) (except the uses covered by the medical device regulation):

  - Mandatory target organisms:
    - Bacteria and yeasts: 5% v/v, 8 min, 20 °C
  - Other target organisms:
    - Fungi (moulds): 5% v/v, 8 min, 20 °C
    - Viruses: 10% v/v, 20 min, 20 °C
    - Bacterial spores: 10% v/v, 25 min, 20 °C or 5% v/v, 40 min, 20°C

No efficacy data have been submitted to demonstrate that products of meta-SPC 1 are still effective after 6 months. Justification for the acceptance of a degradation of the active substance greater than 10% is given in section 2.2.3.

- Meta SPC 2: Ready to use products PT2

  Use 1: Disinfection of hard non-porous surfaces by immersion or with a mop/cloth/wipe/mechanical spray device with non-mechanical action, in clean conditions, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries (PT 02) (except the uses covered by the medical device regulation):

  - Mandatory target organisms:
    - Bacteria and yeasts: 100% v/v, 8 min, 20 °C
  - Other target organisms:
    - Fungi (moulds): 100% v/v, 8 min, 20 °C
    - Bacterial spores: 100% v/v, 40 min, 20 °C

Since products of a same Meta-SPC must have the same uses and similar efficacy, virucidal activity is not validated for the meta-SPC 2 as this activity is not demonstrated for the products HYPO-CHLOR NEUTRAL 0.25% and HYPO-CHLOR 0.25%. Regarding contact time, the worst case between the four tested products has been validated.

Conclusion on the efficacy of the product following WG-IV-2021

Regarding Meta-SPC 2:
- The EFF WG agreed to increase the lowest limit of active chlorine to 0.25% for products in the current meta-SPC 2.
- The EFF WG agreed based on the outcome of the APCP WG discussion to add a virucidal claim for the products with 0.52% sodium hypochlorite. However, the minimum active chlorine of the meta-SPC 2B is 0.47% and no worst-case product (0.47% active chlorine without buffer) has been tested to cover the virucidal activity for the whole meta-SPC 2B. Therefore, virucidal activity is not validated.
- The instructions for use of meta-SPC 1 and 2 are amended as followed: *"For mop/cloth/wipe applications, apply (Spray/Pour) the product onto the surface to be disinfected and then use a cloth/mop/wipe in order to have a uniform distribution of the product on the surface. Make sure to wet surfaces completely with the product. Allow to take effect for the required contact time."*

Thus, based on the outcome of WG-IV-2021, it has been decided to split meta SPC 2 into two 2 separate Meta-SPC, one containing the products HYPO-CHLOR 0.52% and HYPO-CHLOR neutral 0.52% and another one containing the products HYPO-CHLOR 0.25% and HYPO-CHLOR Neutral 0.25%.
Follollowing uses can be validated for these Meta-SPC:

- Meta SPC 2A (0.25% active chlorine): Ready to use products PT2

  Use 1: Disinfection of hard non-porous surfaces by immersion or with a mop/cloth/wipe/mechanical spray device with non-mechanical action, in clean conditions, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries (PT 02) (except the uses covered by the medical device regulation):

  - Mandatory target organisms:
    - Bacteria and yeasts: 100% v/v, 8 min, room temperature
  - Other target organisms:
    - Fungi (moulds): 100% v/v, 8 min, room temperature
    - Bacterial spores: 100% v/v, 40 min, room temperature

- Meta SPC 2B (0.47 to 0.50% active chlorine): Ready to use products PT2

  Use 1: Disinfection of hard non-porous surfaces by immersion or with a mop/cloth/wipe/mechanical spray device with non-mechanical action, in clean conditions, in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic industries (PT 02) (except the uses covered by the medical device regulation):

  - Mandatory target organisms:
    - Bacteria and yeasts: 100% v/v, 8 min, room temperature
  - Other target organisms:
    - Fungi (moulds): 100% v/v, 8 min, room temperature
    - Bacterial spores: 100% v/v, 40 min, room temperature

2.2.6.11 Occurrence of resistance and resistance management

According to the assessment report of the active substance, although different species vary in their sensitivity to active chlorine, development of acquired resistance is not expected since its multiple molecular sites of attack on the surface and within the microbial cells. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003 and Submission to SCENIHR, February 2008)] as one of the biocides where acquired resistance is least likely to develop. For the same reasons cross-resistance is not to be expected, nor has it been observed. Despite its use for almost a century in purifying drinking water, where very low (sub ppm) concentrations are continuously maintained, the development of acquired resistance has not been observed. Adaptation of organisms to hypochlorite can be determined by comparison of the Minimum Inhibitory Concentration (MIC) but this is not relevant in practice as the actual use concentrations are much higher and thus a sufficient margin of safety is provided.

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

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.6.12 Known limitations

Regarding the "Hypo-Chlor Neutral" formulations of the Meta-SPC 2, products have to be used within a maximum of 24 hours after mixing in order to ensure efficacious use. This instruction will be added in the SPC.

Regarding meta-SPC 1, the following instruction will be added in the SPC: “The diluted solution should be used immediately”.

2.2.6.13 Evaluation of the label claims

Please refer to efficacy conclusions in section 2.2.6.11.

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

These biocidal products are not intended to be used in combination with other biocidal products.

2.2.7 Risk assessment for human health

NOTE
The applicant submitted a BPF composed of 2 meta-SPCs: Meta-SPC 1 and Meta-SPC 2. After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs, Meta-SPC 2A and Meta-SPC 2B both containing ready to use products (HYPO-CHLOR 0.25% and HYPO-CHLOR 0.25% NEUTRAL for Meta-SPC 2A and HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL for Meta-SPC 2B). However, the evaluation was held on the initial BPF composition.

Hence, these changes were considered in the efficacy and APCP sections but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions.When the splitting was of no consequence for the evaluation, the evaluation refers to Meta-SPC 2 (meaning both Meta-SPC 2A and 2B).

Sodium chlorate is a relevant impurity of the active substance Sodium hypochlorite and can also be formed during the storage of the product.
For each Meta-SPC, the long-term stability test (please refer to the Physical, Chemical and technical part) shows a content of sodium chlorate at final time (expressed as % of active chlorine content) above the specification limit for sodium chlorate, which is of maximum 5.4% w/w of available chlorine.
As chlorate presents an acute toxicity by oral route (current harmonised classification Acute Tox. 4 – H302), it is not covered by the toxicity of the active substance. Therefore, the content of sodium chlorate at final time of the stability study will be taken into account for the classification of the different meta-SPC
To be noted that the recently adopted RAC opinion (10 June 2021) agreed that sodium chlorate should be classified as Acute Tox 3; H301, adding an ATE = 100 mg/kg bw by using the converted Acute Toxicity point Estimate (cAtpE) for category 3 based on human case reports. This has no impact on the acute oral toxicity of this product.

Please refer to Confidential Annex.

Moreover the final content of chlorate experimentally measured for each meta-SPC should be used to perform a systemic risk assessment..
However, in the absence of harmonisation of the reference values for chlorate, no risk assessment can be performed. This should be adressed at the renewal of the active substance.

2.2.7.6 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
In vitro skin corrosion: membrane barrier test. OECD 435 (2006). GLP. Klimisch 1	HYPO-CHLOR 5.25% w/w, applied undiluted	The CORROSITEX™ Assay was used	No corrosive effects were observed. The mean time required to active the CDS (chemical detection system) was > 60 min (observation was terminated after 240 min without activation of the CDS)	There were no deviations and the assay acceptance criteria were met. Negative (citric acid 10% in aqua dest.) and positive (nitric acid 69%) controls tested in parallel confirmed the validity of the assay	[redacted]

No data on skin corrosion/irritation are available for the remaining products in the HYPO-CHLOR product family. A waiver is presented for this endpoint on the basis that classification of the products in the biocidal product family can be addressed based on classification of the individual components, according to the guidance given in the CLP Regulation (EC No 1272/2008).

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Skin irritant (Meta SPC 1) and No classification (Meta SPC 2)
Justification for the value/conclusion	The active substance is classified in Skin Corrosion Category 1B (H314) according to Annex VI of the CLP Regulation. The active substance is present in the products in the product family at concentrations ranging from approximately 0.24 to 5.25% w/w. Several products in the product family (e.g. HYPOCHLOR 0.52% w/w active; HYPOCHLOR 0.25% w/w active;; HYPOCHLOR Neutral SimpleMix 0.24% w/w and HYPOCHLOR Neutral SimpleMix 0.52% w/w) contain the active substance at < 1% w/w and no other corrosive components. These products do not require classification according to the CLP Regulation (active content is below the generic concentration limit for corrosive component of >1% w/w). One product in the product family (HYPOCHLOR concentrate 5.25% w/w active)) contains the active substance at a concentration of 5.25% w/w. An *in vitro* skin corrosion (CORROSITEX™) assay is available for HYPOCHLOR 5.25% (Lehmeier, 2011) that demonstrates the undiluted product is not corrosive to skin. The CORROSITEX™ assay can only distinguish between corrosive and non-corrosive substances, it cannot be used for classification of irritants. The active substance content in this product exceeds the generic concentration limit for corrosive components in a mixture which have a high pH (i.e. > 11.5) of 1% w/w. Therefore, whilst classification as corrosive is not required based on experimental data, a precautionary classification as a Category 2 Skin Irritant is required for this product.
Classification of the product according to CLP and DSD	The product that contains 5.25% active substance (META SPC 1) were shown to be non-corrosive in an *in vitro* assay, and are therefore classified for skin irritation in Category 2 (H315) according to the CLP regulation. Products containing < 1% w/w sodium hypochlorite (META SPC 2) and no other corrosive/irritating components do not require classification for corrosion/irritation.

Further information for consideration in the risk assessment
HYPO-CHLOR 5.25% w/w is supplied as a concentrated product that is diluted prior to use; recommended in-use dilutions are 1 in 10 (10% dilution) and 1 in 20 (5% dilution). Both

the 1 in 10 dilution and 1 in 20 dilution will contain sodium hypochlorite at a concentration below the 1% w/w cut-off and are therefore not considered to be irritating.

HYPO-CHLOR Neutral SimpleMix 0.52% w/w and 0.25% w/w are supplied with two components (the active substance product and a pH buffer solution) held in separate compartments of the packaging ready for 'activation' at the time of use. The classification for these products is based on the 'post-mix' mixture as the packaging prevents exposure to the concentrated product during the mixing and loading phase. The secondary bottles of the HYPO-CHLOR Neutral SimpleMix formulations are not classified.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Corrosive
Justification for the value/conclusion	The active substance is classified in Skin Corrosion Category 1B (H314) according to Annex VI of the CLP Regulation. The active substance is present in the products in the product family at concentrations ranging from approximately 0.24 to 5.25% w/w. Several products in the product family (e.g. HYPO-CHLOR 0.52% w/w active; HYPO-CHLOR 0.25% w/w active; HYPO-CHLOR Neutral SimpleMix 0.24% w/w and HYPO-CHLOR Neutral SimpleMix 0.52% w/w) contain the active substance at < 1% w/w and no other corrosive components. These products do not require classification according to the CLP Regulation. One product in the product family (HYPO-CHLOR concentrate 5.25% w/w active) contains the active substance at a concentration of 5.25% w/w. The active substance content in this product exceeds the generic concentration limit for corrosive components in a mixture which have a high pH (i.e. > 11.5) of 1% w/w. Therefore, classification as a Category 1 Eye Irritant is required for these products.
Classification of the product according to CLP and DSD	Based on their high pH, products which contain the active substance at concentrations exceeding 1% w/w (Meta SPC 1) require classification for Category 1 Serious eye damage, H318 according to the CLP Regulation Products containing < 1% active substance (Meta SPC 2) are below the concentration limit that would trigger classification of the mixture, and therefore classification for eye irritation is not required.

HYPO-CHLOR 5.25% w/w is supplied as a concentrated product that is diluted prior to use; recommended in-use dilutions are 1 in 10 (10% dilution) and 1 in 20 (5% dilution) . Both the 1 in 10 dilution and 1 in 20 dilution will contain sodium hypochlorite at a concentration below the 1% w/w cut-off and are therefore not considered to be irritating.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The active substance is not classified as a respiratory tract irritant. The PT2 and PT4 Assessment Reports for Active chlorine released from sodium hypochlorite (January 2017) note that sodium hypochlorite aerosols may be irritant to the respiratory tract. According to the Guidance on the Application of the CLP Criteria, a classification for corrosivity is considered to implicitly cover the potential to cause respiratory tract irritation. Consequently, it was concluded that no additional classification is required.
Classification of the product according to CLP and DSD	None

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin
Justification for the value/conclusion	The active substance is not classified as a skin sensitiser. None of the co-formulants in the products in the biocidal product family are classified as skin sensitisers. On this basis, none of the products require classification for skin sensitisation according to the CLP Regulation.
Classification of the product according to CLP and DSD	None

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not a respiratory sensitiser
Justification for the value/conclusion	The active substance is not classified as a respiratory sensitiser. None of the co-formulants are classified for respiratory sensitisation and none of the products in the biocidal product family are classified as skin sensitisers. It is therefore considered that there is no indication that the products will induce respiratory sensitisation, and classification according to CLP is not required.
Classification of the product according to CLP and DSD	None

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic by the oral route
Justification for the selected value	The active substance is not classified as acutely toxic by the oral route. None of the co-formulants in the products of the biocidal product family are classified for acute oral toxicity. On this basis, none of the products in the biocidal product family require classification for acute oral toxicity according to the CLP Regulation.
Classification of the product according to CLP and DSD	None

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic by the inhalation route
Justification for the selected value	The active substance is not classified as acutely toxic by the inhalation route. None of the co-formulants present in the biocidal product family are classified as acutely toxic by the inhalation route. Therefore, based on the guidance given in CLP on the classification of mixtures for acute toxicity, classification of the formulations is not required. The active substance is classified on Annex VI of the CLP Regulation with additional labelling phrase EUH031 – Contact with acids liberates toxic gas, with a specific concentration limit of ≥5%. Therefore, all formulations in the biocidal product family containing ≥5% sodium hypochlorite must be classified as EUH031.
Classification of the product according to CLP and DSD	Not classified for acute inhalation toxicity EUH031 – Contact with acids liberates toxic gas

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic by the dermal route
Justification for the selected value	The active substance is not classified as acutely toxic by the dermal route. None of the co-formulants present in the biocidal product family are classified as acutely toxic by the dermal route. Therefore, based on the guidance given in CLP on the classification of mixtures for acute toxicity, classification of the formulations is not required.
Classification of the product according to CLP and DSD	None

Information on dermal absorption

Active chlorine released from Sodium hypochlorite:

It was considered in the Assessment Reports that dermal absorption is not relevant because chlorine-related toxicity is based on local effects only (with secondary systemic effects occurring only at high doses). Dermal absorption values are not deemed necessary.

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

None of the co-formulants meet the criteria and therefore no substances of concern are identified for the products in the biocidal product family.

Available toxicological data relating to a mixture

No data

ED assessment

No concern has been identified with regards to endocrine disruption potential of HYPO-CHLOR product family co-formulants. Please refer to the confidential annex.

Other

Not relevant.

2.2.7.7 Exposure assessment

The HYPO-CHLOR® product family (Product type 2) may be applied to hard, non-porous surfaces found in clean rooms and controlled areas in pharmaceutical and aseptic manufacturing facilities. The product is applied indoors by industrial users (only) in strictly controlled, occupational settings (members of the public will be excluded from areas where these products will be used).

The HYPO-CHLOR® product family is composed of the following 2 Meta SPCs:

Product Meta SPC	**Product name**	**Active chlorine content % w/w (concentrated product)**	**Active chlorine content % w/w (applied dilution)**
Meta SPC 1 (concentrate)	HYPO-CHLOR 5.25%	5.0	0.27 – 0.55
Meta SPC 2 (ready to use)	HYPO-CHLOR 0.52%	0.5	0.5
	HYPO-CHLOR 0.25%	0.24	0.24
	HYPO-CHLOR NEUTRAL SimpleMix 0.52% w/w	0.47	0.47
	HYPO-CHLOR NEUTRAL SimpleMix 0.25% w/w	0.23	0.23

The active substance releaser Sodium hypochlorite is characterised by primarily local effects (i.e corrosion or irritation due to direct chemical reactivity). According to the Assessment Report (Italy, 2017) any systemic effects observed in toxicity studies were considered as secondary effects. Consequently, a local risk assessment was performed for the products of Hypochlor BPF.

Exposure assessment is performed for $Na(OCl)_2$ as available chlorine (avCl) according to the assessment report of the active substance Sodium hypochlorite.

In water, sodium hypochlorite ($Na(OCl)_2$) hydrolyzes to hypochlorous acid (HClO). Furthermore, hypochlorous acid participates in the following equilibrium with chlorine (Cl_2)
$HClO + H_3O^+ + Cl^- \leftrightarrow Cl_2 + 2H_2O$

The ratio of Cl_2/HClO/ClO^- is pH and temperature dependent. At pH values > 10, the hypochlorite anion (ClO-) is the predominant species and only exposure to aerosols of Na(OCl)2 (as avCl) is considered relevant. The minute fraction of volatile hypochlorous acid (HClO) is considered negligible.

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

The product of the family are to be diluted in water with a pH higher than 10. Therefore only exposure to aerosols of Na(OCl)2 (as avCl) is considered relevant. The minute fraction of volatile hypochlorous acid (HClO) is considered negligible. No exposure to vapour should be considered as it is assumed to be negligible.

Considering this:

- A quantitative local risk assessment is performed for inhalation exposure to Na(OCl)2 (as avCl) aerosols;

- A qualitative local risk assessment is performed for dermal exposure to Na(OCl)2 (as avCl); the concentration of avCl in the product being directly compared to the dermal NOAEC value of 1% w/w avCl.

No oral exposure is assessed based on the claimed uses.

Secondary exposure of professional bystanders/non users upon dermal contact with treated surfaces is considered to be non-relevant. The 2017 eCA (Italy) assessment reports (ARs) for active chlorine released from sodium hypochlorite[2] concluded that secondary dermal exposure to dry treated surfaces or equipment may be considered non-relevant. Due to the high reactivity of chlorine species such as $Na(OCl)_2$, residues on surfaces degrade very rapidly. Decomposition to physiological sodium and chloride ions takes place which are not expected to arise any health risk. Furthermore, the applied in-use solutions are of a low concentration.

2 ECHA (2017) Competent Authority (Italy) Assessment Report for Active chlorine released from sodium hypochlorite Product types 2-4. Evaluation of active substances: Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of $Na(OCl)_2$. Only inhalation exposure after application of $Na(OCl)_2$ is considered relevant for the assessment of secondary exposure.

In considering the active chlorine content of the HYPO-CHLOR® BPF formulations and the proposed in-use applications rates:

- For meta-SPC 1, the worst-case content of active chlorine to take into account is 5% w/w active chlorine for the concentrated product and 0.55% w/w active chlorine for the dilution.
- For meta-SPC 2 (ready-to-use products), the max content of active chlorine to take into account is 0.5% w/w active chlorine.

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

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

Exposure assessment for Meta SPC 1 and 2

Use 1: Disinfectant, fungicidal, virucidal and sporicidal:

The surfaces to be disinfected must be pre-cleaned before the application of the products.

There are several types of application for use 1 of META SPC 1 and 2:

- application by mopping
- application with a cloth / wiping
- immersion (soaking)
- application with a mechanical spray device.

After use, the surfaces must be rinsed and then the surface is allowed to air dry or wiped dry with a sterilized cloth wiper.

The claimed dose is 35 mL/m² for both META SPC.
For META SPC 1, the product must be diluted by 1/10: 100 ml/L (10%v/v) or by 1/20: 50ml/L (5% v/v).
For META SPC 2, the products are ready to use.

Dermal and inhalation exposure is expected during the spray application and application with mop or cloth and only dermal exposure is expected during the mixing&loading, rinsing and post-application of the product.

For meta-SPC2, there are products with buffer and products without buffer. Products with buffer have a specific packaging (simpleMix bottle) with a trigger spray. For these products only application by spraying has been considered.

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)
Use 1: Application with a mechanical spray device		
1. Mixing and loading (manual pouring of concentrated product) META SPC 1 and 2	**Primary exposure:** An industrial user dilutes the concentrated product HYPOCHLOR 5.25% prior to its application or an industrial user loads the RTU product in a trigger spray.	Industrial
2. Surface disinfection by spraying (trigger sprayer) META SPC 1 and 2	**Primary exposure:** An industrial user applies the diluted product 'HYPO-CHLOR 5.25%' or the RTU products to hard surfaces using a hand held trigger sprayer	Industrial
3. Post-application: Rinsing META SPC 1 and 2	**Primary exposure:** An industrial user rinses the diluted product or RTU product with a wet cloth	Industrial
4. Surface disinfection by coarse spraying (1-3 bar pressure) META SPC 1 and 2	**Primary exposure:** An industrial user disinfects hard surfaces using a compression sprayer (1-3 bar pressure) containing the diluted product 'HYPO-CHLOR 5.25%' or the RTU products	Industrial
5. Post-application: Rinsing META SPC 1 and 2	**Primary exposre:** An industrial user rinses the diluted product with water using the compression sprayer	Industrial
Use 1: Application with a cloth or mop (wiping or mopping)		
6. Surface disinfection by wiping or mopping (wet cloth) META SPC 1 and 2	**Primary exposure:** Industrial worker disinfects hard surfaces (floors, walls etc.) by wiping or mopping the diluted product HYPO-CHLOR 5.25%' or the RTU products.	Industrial
7. Post-application: Rinsing (META SPC 1 and 2)	**Primary exposure:** An industrial user rinses the diluted product or RTU product with water using a cloth or mop	Industrial
Use 1: Immersion (soaking)		
8. Mixing and loading of product Meta SPC 1 and 2	**Primary exposure :** An industrial user dilutes the product HYPOCHLOR 5.25% prior its application or pours the ready to use products of meta-SPC 2 before application	Industrial

9. Equipment disinfection by immersion. META SPC 1 and 2	**Primary exposure:** Industrial worker disinfects equipment using an immersion bath containing the diluted product 'HYPO-CHLOR 5.25%' or the RTU products of meta-SPC 2	Industrial
10.Post-application: Rinsing (META SPC 1 and 2)	**Primary exposure:** An industrial user rinses the diluted product with water	Industrial
Use 1: Post application scenarios for all types of application		
11. Post-application Disposal of treatment solution/ rinsing mop/cloth and bucket META SPC 1 and 2	Primary exposure: Industrial worker cleaning the equipment used during the mixing and loading and the application step (bucket, cloth/mop, immersion bath, sprayer…). Exposure to the in use solution.	Industrial
12. Post-application Handling of empty containers META SPC 1 and 2	Primary exposure: Industrial worker handling empty containers. Exposure is considered negligible.	Industrial
Use 1: Secondary (indirect) exposure for all types of application		
13 Inhalation exposure META SPC 1 and 2	Secondary exposure: A bystander (worker) is present during the mixing and loading and/or application of the product 'HYPO-CHLOR 5.25%' or RTU products	Bystanders (workers)
14. Dermal exposure after product application META SPC 1 and 2	Secondary exposure: A bystander (worker) touches the wet surfaces after application of the products.	Bystanders (workers)

Industrial exposure

Primary Exposure

Primary exposure to biocidal products occurs in the individual who directly uses/applies the product. The industrial use of the HYPO-CHLOR® product family may result in primary exposure, via skin contact or via inhalation. Industrial operators are unlikely to ingest the product during the intended uses. The oral route is not therefore considered further.

Use 1: Application with a mechanical spray device

The user is disinfecting hard surfaces by spraying using a trigger spray or coarse spray (1 – 3 bars) with the diluted product from Meta-SPC 1 or the RTU products of Meta-SPC 2. Hence, a dilution step is required before the disinfection for product of Meta-SPC 1 and products of meta-SPC 2 should be loaded in trigger spray or coarse spray.

As packaging up to 200L are available for the two meta-SPC, manual or automated loading should be considered.
Therefore a manual or automated mixing and loading step is required for products of both meta-SPC.

For the rinsing step, it considered that it is done with a wet cloth after application with trigger spray and with water in the coarse spray for the application with coarse spray.

Scenario 1 - Primary exposure of an industrial user during dilution of the product HYPOCHLOR 5.25% or loading of the RTU products

Scenario 1: Primary exposure of an industrial user during dilution of the product HYPOCHLOR 5.25% or loading of theRTU products			
Product of meta-SPC 1 is diluted in water according to the claimed dose or products of meta-SPC 2 is loaded in a trigger spray. Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the product of the meta-SPC 1 and 2, vapours of HClO are negligeable. Exposure to aerosol is also considered negligeable for manual loading due to small quantities and for automated loading as no exposure is expected. For dermal route exposure, the concentration of active chlorine in the product is directly compared to the dermal NOAEC value of 1% w/w active chlorine. Content of active chlorine in the product of meta-SPC 1 is 5% w/w and 0.5% w/w in products of meta-SPC 2.			
Tier	**Parameters**	**Value**	**Source**
1	Concentration of active chlorine in the product 'HYPO-CHLOR 5.25%' - META SPC 1	5% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5%	Applicant's data

Calculations for scenarios 1:

Local exposure to sodium hypochlorite

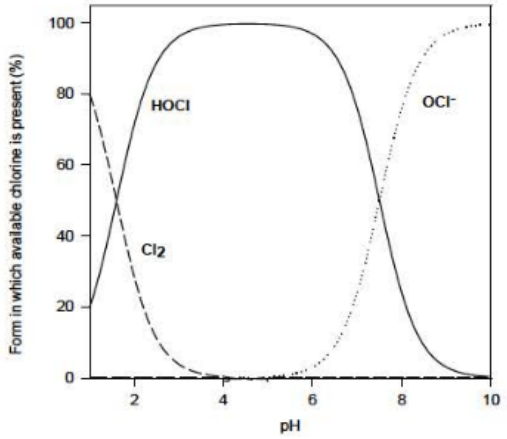
Scenario 1: Primary exposure of an industrial user during dilution of the product HYPOCHLOR 5.25% or loading of theRTU products		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
META SPC 1		
Tier 1 (No PPE)	5	negligible
META SPC 2		
Tier 1 (No PPE)	0.5	negligible

Scenario 2 - Primary exposure: An industrial user applies the diluted product 'HYPO-CHLOR 5.25%' or the RTU products to hard surfaces using a hand held trigger sprayer.

The diluted product 'HYPO-CHLOR 5.25%' for meta-SPC 1 and the RTU products of meta-SPC 2 may be applied using a hand-held trigger sprayer as a surface disinfectant.
Exposure is via the dermal and inhalation routes.

For meta-SPC 1, as the product and dilution as a pH>10, only inhalation exposure during application task to aerosol of sodium hypochlorite is assessed.
For meta-SPC 2, for some products after activation of the buffer solution, pH of the products are around 7.6-7.9. At these pH, exposure to HClO vapour can be expected. Inhalation exposure to aerosol of sodium hypochlorite and HClO vapour is assessed.
For products of meta-SPC 2 without buffer, pH is higher than 10, therefore only inhalation exposure during application task to aerosol of sodium hypochlorite is assessed.

For meta-SPC 2, a concentration of HClO as 50% of the content of active chlorine in the products (0.25% avCl) was considered for the assessment of vapour exposure based on the repartition of the different forms of chlorine species at a pH around 7.6-7.9.



For the exposure assessment, several parameters have been chosen based on the Recommendation no. 15 of the BPC Ad hoc Working group on Human exposure: "Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger spray":

As a worst-case and based on the claimed uses (between laboratories and cleanrooms), the data for laboratories has been chosen. Indeed, Recommendation no.15 focuses on routine in-between disinfection of surfaces by lab workers which correspond to the claimed uses.
Considering the application duration of 1min/0.5m^2 and 10 events per day, the surface disinfected is 5m^2 per day which takes 10min.
Considering an application dose of 35 mL/m², 17,5mL of product is needed to clean 0.5m^2.
Taking into account a density of 1.0205 for the product, 17,5mL of product corresponds to 17,9g of product.
The release area corresponds to the surface cleaned of 0.5m^2

For products of meta-SPC 2 without buffer, exposure is considered cover by the exposure to products of meta-SPC 1 (0.55% av Cl for meta-SPC 1 cover the content of 0.5% av Cl for meta-SPC 2).

Scenario 2: Primary exposure in an industrial user applying 'HYPO-CHLOR 5.25%' or the RTU products to hard, non-porous surfaces using a hand held trigger sprayer.

As explained above, only exposure by inhalation to NaOCl aerosols (expressed as avCl) is expected for meta-SPC 1 and products without buffer of meta-SPC 2 and exposure by inhalation to NaOCl aerosol and HClO vapour is expected for products with buffer of meta-SPC 2.

For dermal route exposure, the concentration of avCl in the product is directly compared to the dermal NOAEC value of 1% w/w avCl.

To assess inhalation exposure during application of products, the **Consumer spraying and dusting model 2- Handheld trigger Spray** from BHHEM (p.244) is used.

The exposure value from the model is as follow:

- 10.5 mg/m^3 (inhalation, 75th percentile indicative value)

The maximum concentration of active chlorine in the diluted product of meta-SPC 1 is 0.55% w/w (10%v/v*1.097*5%w/w=0.55%w/w). For meta-SPC 2, the maximum concentration of active chlorine in the products is 0.5% w/w.

For products of META SPC 2 with buffer, the exposure to vapour of HClO has been assessed using Consexpo "Disinfection factsheet" evaporation model and several parameters have been chosen based on the Recommendation no. 15 of the BPC Ad hoc Working group on Human exposure: "Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger spray".

Tier	Parameters	Value	
1	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' (10% dilution) - META SPC 1	0.55% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5% (w/w)	Applicant's data
	Concentration of HClO as active chlorine in the RTU products with buffer (worst-case) - vapour exposure - META SPC 2	0.25% (w/w)	Applicant's data
	Exposure duration- min	10 min	Recommendation no. 15
	Product amount - g	17,9g	See calculation above
	Room volume- m^3	25m^3	Recommendation no. 15
	Ventilation rate- per hour	8/h	Recommendation no. 15
	Inhalation rate (adult) - m^3/hour	1.25 m^3/h	Recommendation no. 14

Vapour pressure HClO - Pa	196Pa	
Temperature	20°C	
Molecular weight (HClO)- g/mol	52.5g/mol	
Molecular weight matrix- g/mol	18g/mol	Consexpo "Disinfection factsheet" evaporation model
Mass transfer coefficient - m/hour	10m/h	Recommendation no. 15
Release area – m^2	0.5m^2	Recommendation no. 15
Emission duration – min	45min	Recommendation no. 15
Frequency	10/day	Recommendation no. 15

Calculations for scenario 2:

Local exposure to sodium hypochlorite

Scenario 2: Primary exposure to active chlorine in an industrial user disinfecting hard surfaces using a hand-held trigger sprayer containing the diluted product 'HYPO-CHLOR 5.25%' or the RTU products.			
META SPC 1- Meta SPC 2-Products without buffer			
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)	
Tier 1 (No PPE)	0.55	0.058	
META SPC 2- Products with buffer			
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (as avCl in mg/m^3)	
		NaOCl	HClO
Tier 1 (No PPE)	0.50	0.053	0.0642

The model chosen to assess the inhalation exposure to vapour for buffered products has been discussed during the WG IV2021. Both ConsExpo and the 2-component model (HEAdhoc Recommendation 16) could be used even if they do not describe pH-dependent equilibrium (as it is the case for chlorine) and no measured vapour data are available.

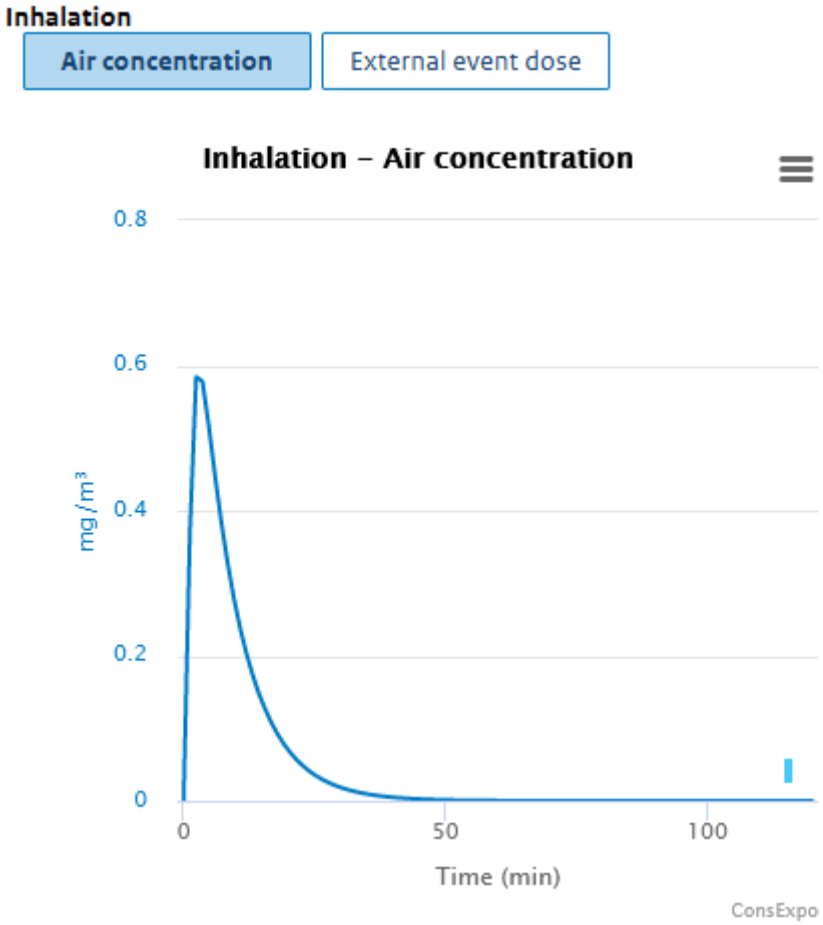
Using Consexpo, the exposure assessment has been performed and leads to acceptable risks as the AEC is not exceeded in air.

During the peer review, the applicant has provided an updated exposure assessment with the recommendation 16, considered as a very worst case in modelling, and using updated parameters of recommendation 15 in order to fit with the use of the products in clean room only. This assessment is reported below. Considering these parameters, the AEC is not

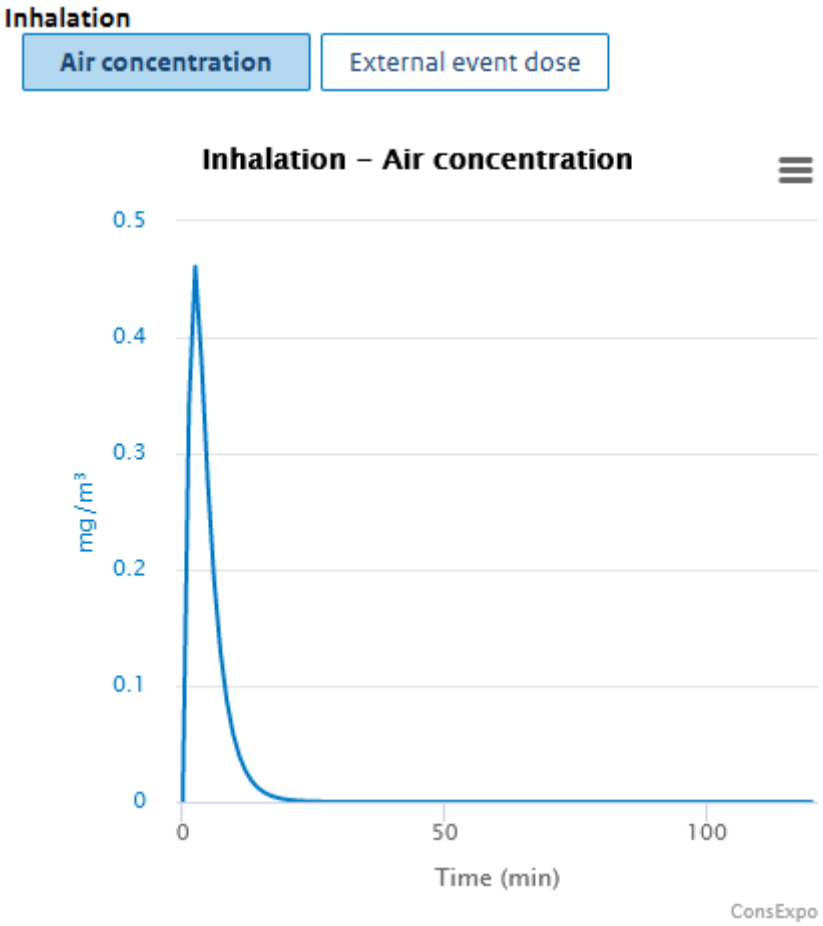
exceeded in air and no unacceptable risk is thus triggered if a ventilation rate of 20/h is taken into account (Tier 2). No re-entry scenario is therefore needed.
This ventilation rate has been specified as a risk mitigation measure.

Tier	Parameters	Value	
1	Weight fraction substance	100%	Recommendation no. 16 (substance in pure form) considering that concentration of HClO as 50% of the content of active chlorine in the products (0.25% avCl)
	Product amount - g	0.0448g	
	Exposure duration- min	120 min	Applicant's data
	Room volume- m^3	55m^3	Applicant's data
	Ventilation rate- per hour	8/h	Recommendation no. 15
	Inhalation rate (adult) - m^3/hour	1.25 m^3/h	Recommendation no. 14
	Vapour pressure HClO - Pa	196Pa	
	Temperature	20°C	
	Molecular weight (HClO)- g/mol	52.5g/mol	
	Mass transfer coefficient - m/hour	10m/h	Recommendation no. 15
	Release area – m^2	0.5m^2	Recommendation no. 15
	Application duration – min	1min	Recommendation no. 15
	Frequency	10/day	Recommendation no. 15
2	Ventilation rate- per hour	20/h	Recommendation no. 15

Tier 1: Ventilation rate at 8/h



Tier 2: Ventilation rate at 20/h



Scenario 3-Primary exposure: An industrial user rinses the diluted product after a contact time using a wet cloth

Scenario 3: Primary exposure of an industrial user rinsing the surface using a wet cloth - Contact to the diluted product 'HYPO-CHLOR 5.25%'or the RTU products.

After a contact time, the product is rinsed off with a wet cloth.

According to the ConsExpo Disinfectant Products Factsheet (4.2.2.3), during rinsing, dermal exposure can occur.
Exposure by inhalation is considered negligeable as no vapour is expected for product of meta-SPC 1 and products without buffer of meta-SPC 2. Indeed, as pH > 10 for the dilution for meta-SPC 1 or RTU products without buffer of the meta-SPC 2, vapours of HClO are negligeable.
Exposure by inhalation to HClO vapour is expected for products with buffer of meta-SPC 2 as pH below 10.

For dermal exposure, the concentration of active chlorine is directly compared to the dermal NOAEC value of 1% w/w avCl.

Dermal and inhalation exposure during rinsing is covered by the application of the dilution / RTU product. As a worst case, the user will be exposed at a concentration not higher than the concentration of avCl in the dilution or RTU product.

The maximum concentration of available chlorine in the diluted product is 0.55% w/w for meta-SPC 1 and 0.5% w/w for meta-SPC 2.

Tier	Parameters	Value	Source
1	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	0.55% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5% (w/w)	Applicant's data

Calculations for scenario 3:

Local exposure to sodium hypochlorite

Scenario 3: Primary exposure of an industrial user rinsing the surface using a wet cloth - Contact to the diluted product 'HYPO-CHLOR 5.25%'or the RTU products.		
META SPC 1 - Meta SPC 2-Products without buffer		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.55	negligeable
META SPC 2 (products with buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	0.0642

Scenario 4 - Primary exposure: An industrial user disinfects hard surfaces using a compression sprayer (1-3 bar pressure) containing the diluted product 'HYPO-CHLOR 5.25%' or the RTU products.

Scenario 4: Primary exposure in an industrial user disinfecting surfaces using a compression sprayer (1-3 bar pressure) containing the diluted product 'HYPO-CHLOR 5.25%'or the RTU products.

The user applies the diluted product 'HYPO-CHLOR 5.25%' for meta-SPC 1 or the ready to use products of meta-SPC 2 using a compression sprayer (1-3 bar pressure). Exposures are via the dermal and inhalation routes.

For dermal route exposure, the concentration of active chlorine in the product is directly compared to the dermal NOAEC value of 1% w/w avCl.

For meta-SPC 1 and products without buffer of meta-SPC 2, as the concentrated or RTU product and dilution as a pH>10, vapours of HClO are negligeable. Only inhalation exposure during mixing and loading and application tasks to aerosol of sodium hypochlorite is expected.

To assess dermal and inhalation exposure during the spray application, the **Spraying model 1** from BHHEM (p.281), has been used. This model covers the mixing and loading and application tasks. As exposure to aerosol is not expected during the mixing and loading, the concentration of available chlorine in the diluted product is used for meta-SPC 1 for inhalation.

The exposure values from model are as follow:
- 104 mg/m3 (inhalation)

For meta-SPC 1, the concentrated product 'HYPO-CHLOR 5.25%' contains 5% w/w active chlorine and is applied as at max 10% v/v product dilution (containing 0.55% w/w active chlorine).
For meta-SPC 2 the concentration of 0.5% w/w active chlorine have been used as worst-case.

Tier	Parameters	Value	Source
1	Concentration of active chlorine in the product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	5% (w/w)	Applicant's data
	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	0.55% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case)- META SPC 2	0.5% (w/w)	Applicant's data
2	Respiratory protective equipment	APF 4 (meta-SPC 1 and 2)	BHHEM

Calculations for scenario 4:

Local exposure to sodium hypochlorite

Scenario 4: Primary exposure to active chlorine in an industrial user disinfecting surfaces using a compression sprayer (1-3 bar pressure) containing the diluted product 'HYPO-CHLOR 5.25%' or the RTU products.		
META SPC 1		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	5	0.57
Tier 2 (APF 4)	5	0.143
META SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	0.52
Tier 2 (APF 4)	0.5	0.13

Scenario 5-Primary exposure: An industrial user rinses the diluted product after a contact time using the compression sprayer

Scenario 5-Primary exposure: An industrial user rinses the diluted product after a contact time using the compression sprayer containing water			
After the contact time, the user rinses the diluted product 'HYPO-CHLOR 5.25%' for meta-SPC 1 or the ready to use products of meta-SPC 2 using a compression sprayer. Exposures are via the dermal and inhalation route. Same model is used as for the application for inhalation: **Spraying model 1** The exposure values from model are as follow: - 104 mg/m3 (inhalation) Dermal and inhalation exposure during rinsing is covered by the application of the dilution / RTU product. As a worst case, the user will be exposed at a concentration not higher than the concentration of avCl in the dilution or RTU product..			
Tier	**Parameters**	**Value**	**Source**
1	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	0.55% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case)- META SPC 2	0.5% (w/w)	Applicant's data
2	Respiratory protective equipment	APF 4 (meta-SPC 1and 2)	BHHEM

Calculations for scenario 5:

Local exposure to sodium hypochlorite

Scenario 5: Primary exposure to active chlorine in an industrial user disinfecting surfaces using a compression sprayer (1-3 bar pressure) containing the diluted product 'HYPO-CHLOR 5.25%' or the RTU products.		
META SPC 1		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.55	0.57
Tier 2 (APF 4)	0.55	0.143
META SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	0.52
Tier 2 (APF 4)	0.5	0.13

Use 1: Application by mopping or wiping

The user is disinfecting hard surfaces by wiping using a cloth and a bucket or by mopping with mop and bucket with the diluted product from meta-SPC 1 or the RTU products of meta-SPC 2. Hence, a dilution step is required before the disinfection for product of meta-SPC 1.

For the rinsing step, it is done in the same way as for the application: with cloth and bucket or mop and bucket based on applicant's data.

Scenario 6 - Primary exposure: An industrial user applies the diluted product 'HYPO-CHLOR 5.25%'or the RTU products' to hard surfaces using a cloth or mop and bucket.

Scenario 6: Primary exposure in an industrial user disinfecting hard surfaces using a cloth or mop and bucket containing the diluted product 'HYPO-CHLOR 5.25%' or the RTU products.

The user disinfects hard surfaces using a wet cloth or mop and bucket containing the diluted product 'HYPO-CHLOR 5.25%' for meta-SPC 1 or the ready to use products of meta-SPC 2.

For the dermal exposure route, the concentration of active chlorine in the product has been compared with the relevant dermal 'no observed adverse effect concentration' (NOAEC) value (1% w/w).

For meta-SPC 1 and products without buffer of meta-SPC 2, as the concentrated or RTU product and dilution as a pH>10, vapours of HClO are negligeable. Only inhalation exposure during mixing/loading and application tasks to aerosol of sodium hypochlorite is expected.

To assess inhalation exposure during the application of products by wiping from Meta SPC 1 and 2, the **Surface disinfection model 1 and 3**, from the TNsG 2002 (part 3, p. 197) has been used. This model covers both mixing and loading and application tasks. As exposure to aerosol is not expected during the mixing and loading, the concentration of active chlorine in the diluted product is used for meta-SPC 1 for inhalation.

The exposure value from the model is as follows :

- 22.2 mg/m^3 (inhalation).

For meta-SPC 1, the concentrated product 'HYPO-CHLOR 5.25%' contains 5% w/w active chlorine and is applied as at max 10% v/v product dilution (containing 0.55% w/w active chlorine).
For meta-SPC 2, the RTU products contains max 0.5% w/w active chlorine.

Tier	Parameters	Value	Source
1	Concentration of active chlorine in the product 'HYPO-CHLOR 5.25%' - META SPC 1	5% (w/w)	Applicant's data
	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' - META SPC 1	0.55% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5% (w/w)	Applicant's data
	Inhalation exposure value - mg product/m^3	22.2 mg/m^3	Surface disinfection model 1

Calculations for scenario 6:

Local exposure to sodium hypochlorite

Scenario 6: Primary exposure to active chlorine in an industrial user disinfecting hard surfaces using a cloth or mop and bucket containing the diluted product 'HYPO-CHLOR 5.25%'or the RTU products.		
META SPC 1		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	5	0.13
META SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	0.11

Scenario 7-Primary exposure: An industrial user rinses the diluted product after a contact time using a cloth or mop and water

Scenario 7-Primary exposure: An industrial user rinses the diluted product after a contact time using a cloth or mop and water

After the contact time, the user rinses the diluted product 'HYPO-CHLOR 5.25%' for meta-SPC 1 or the ready to use products of meta-SPC 2 using a mop or cloth and bucket.

Exposures are via the dermal and inhalation routes.

Same model is used as for the application for inhalation: **Surface disinfection model 1**
The exposure value from the model is as follow:

- 22.2 mg/m^3 (inhalation)

Dermal and inhalation exposure during rinsing is covered by the application of the dilution / RTU product. As a worst case, the user will be exposed at a concentration not higher than the concentration of avCl in the dilution or RTU product.

Tier	**Parameters**	**Value**	
Sodium hypochlorite			
1	Concentration of active chlorine in the product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	0.55% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case)- META SPC 2	0.5% (w/w)	Applicant's data
	Inhalation exposure value - mg product/m^3	22.2 mg/m^3	Surface disinfection model 1

Calculations for scenario 7:

Local exposure to sodium hypochlorite

Scenario 7: Primary exposure to active chlorine in an industrial user disinfecting surfaces using a *wet cloth*.		
META SPC 1		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1a (No PPE)	0.55	0.13
META SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1a (No PPE)	0.5	0.11

Use 1: Immersion (soaking)

The user is disinfecting the equipments or the materials using an immersion bath containing the diluted product from meta-SPC 1 or the RTU products of meta-SPC 2. Hence, a dilution step is required before the disinfection for product of meta-SPC 1.

Exposure during rinsing step is considered negligeable. The industrial user will rinse the equipments in an immersion bath containing water.

Scenario 8 - Primary exposure - mixing and loading: An industrial user pours manually the product HYPOCHLOR 5.25% and makes the dilution prior its application or manually pours the ready to use products of meta-SPC 2 before application

Description of Scenario [8]: Primary exposure - mixing and loading: An industrial user pours the product HYPOCHLOR 5.25% and makes the dilution prior its application or pours the ready to use products of meta-SPC 2 before application
The user poures the concentrated product 'HYPO-CHLOR 5.25%' into a receiving vessel and then dilutes with water prior to application or poures the ready to use products of meta-SPC 2 prior to application. Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the product of the meta-SPC 1 and 2, vapours of HClO are negligeable. Exposure to aerosol is also considered negligeable for manual loading due to small quantities and for automated loading as no exposure is expected. For dermal route exposure, the concentration of active chlorine in the product is directly compared to the dermal NOAEC value of 1% w/w active chlorine. Content of active chlorine in the product of meta-SPC 1 is 5% w/w and 0.5% w/w in products of meta-SPC 2.

Tier	Parameters	Value	Source
1	Concentration of active chlorine in the product 'HYPO-CHLOR 5.25%' - META SPC 1	5% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5%	Applicant's data

Calculations for Scenario [8]

Local exposure to sodium hypochlorite

Scenario 10: Primary exposure - mixing and loading: An industrial user pours the product HYPOCHLOR 5.25% and makes the dilution prior its application or pours the ready to use products of meta-SPC 2 before application		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m3)
Meta SPC 1		
Tier 1 (No PPE)	5	negligeable
Meta-SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	negligeable

Scenario 9 - Primary exposure - application: An industrial user disinfects equipment using an immersion bath containing the diluted product 'HYPO-CHLOR 5.25% or the RTU products'.

Scenario 9: Primary exposure (application): an industrial user disinfecting equipment using an immersion bath containing the diluted product 'HYPO-CHLOR 5.25%'or the RTU products.			
The product 'HYPO-CHLOR 5.25%' after dilution ot the RTU products are used to disinfect equipment or components via the use of a small-scale immersion bath. Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the product of the meta-SPC 1 and 2, vapours of HClO are negligeable. For dermal route exposure, the concentration of active chlorine in the product is directly compared to the dermal NOAEC value of 1% w/w active chlorine. For meta-SPC 1, the concentrated product 'HYPO-CHLOR 5.25%' contains 5% w/w active chlorine and is applied as at max 10% v/v product dilution (containing 0.55% w/w active chlorine). For meta-SPC 2, the RTU products contains max 0.5% w/w active chlorine.			
Tier	**Parameters**	**Value**	**Source**
1	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	0.55% (w/w)	Applicant's data
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5% (w/w)	Applicant's data

Calculations for scenario 9:

Local exposure to sodium hypochlorite

Scenario 9: Primary exposure (application): an industrial user disinfecting equipment using an immersion bath containing the diluted product 'HYPO-CHLOR 5.25%'.		
META SPC 1		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl or HClO as avCl in mg/m^3)
Tier 1 (No PPE)	0.55	negligeable
META SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	negligeable

Scenario 10-Primary exposure: An industrial user rinses the diluted product after a contact time

Dermal and inhalation exposure is considered negligible during rinsing as it is considered that the equipment will be rinsed in a bath with water using a basket.

Use 1: Post application scenarios for all types of application

Scenario 11 - Primary exposure: An industrial user cleans the equipment used during mixing and loading and application step: disposal of treatment solution/ rinsing mop and bucket.

Scenario 11: Primary exposure of an industrial user cleaning equipment: disposal of treatment solution/ rinsing mop and bucket containing the diluted product 'HYPO-CHLOR 5.25%'or the RTU products.		
An industrial user cleans the equipment used during mixing and loading and application step: disposal of treatment solution/ rinsing bucket, mop, cloth, immersion bath, sprayer…). For the dermal exposure route, the concentration of active chlorine in the in use dilution has been compared with the relevant dermal 'no observed adverse effect concentration' (NOAEC) value (1% w/w). Exposure by inhalation is considered negligeable for this task. For meta-SPC 1 and products without buffer of meta-SPC 2, as the concentrated or RTU product and dilution as a pH>10, vapours of HClO are negligeable. For meta-SPC 1, the concentrated product 'HYPO-CHLOR 5.25%' contains 5% w/w active chlorine and is applied as at max 10% v/v product dilution (containing 0.55% w/w active chlorine). For meta-SPC 2, the RTU products contains max 0.5% w/w active chlorine for the worst-case. For products with buffer of meta-SPC 2, products are used with their commercial packaging, therefore this scenario is not relevant for these products.		
Tier	**Parameters**	**Value**
Sodium hypochlorite		
1	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	0.55% (w/w)
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5% (w/w)

Calculations for scenario 11:

Local exposure to sodium hypochlorite

Scenario 11: Primary exposure to active chlorine in an industrial user cleaning equipment used to prepare and apply the diluted product 'HYPO-CHLOR 5.25% or the RTU products'.		
META SPC 1		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.55	negligeable
META SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	negligeable

Scenario 12- Primary exposure: Handling of empty containers

Description of Scenario 12: Primary exposure: handling of empty containers
According to the active substance assessment report, exposure is considered negligible (for both inhalation and dermal route).

Secondary exposure

Scenario 13 - Secondary exposure: A bystander (worker) is present during the mixing and loading and/or application of the product 'HYPO-CHLOR 5.25%' or RTU products

Secondary exposure to the concentrated or diluted product 'HYPO-CHLOR 5.25%' for meta-SPC 1 or RTU products for meta-SPC 2 may occur where an individual is present in a room during the mixing and loading and/or application of the product.

Description of Scenario [13]: Secondary exposure: A bystander (worker) is present during the mixing and loading and/or application of the product 'HYPO-CHLOR 5.25%' or RTU products
The PT 2 eCA Assessment Report (2017, pg.30) states '*Secondary exposure of industrial or non-professional bystanders/non-users upon dermal contact with treated surfaces is considered to be non-relevant. Due to the high reactivity of chlorine species such as NaOCl, residues on surfaces degrade very rapidly. Decomposition to physiological sodium and chloride ions takes place which are not expected to arise any health risk. Furthermore, the applied in-use solutions are of a low concentration and/or are further diluted during the water-rinse procedure which takes normally place. Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of NaOCl'. Only inhalation exposure after application of $Na(OCl)_2$ is considered relevant for the assessment of secondary exposure.* The HYPO-CHLOR® product family is used in controlled industrial / manufacturing settings (e.g. clean rooms; controlled areas of pharmaceutical manufacturing facilities). If bystanders are present during disinfection activities, they would not be exposed to in-air concentrations greater than those experienced by the worker performing the cleaning task. Therefore for each mode of application, exposure by inhalation of the bystander is the same as the exposure assessed for the worker performing the task.

Scenario 14- Secondary exposure: a bystander (worker) touches the wet surfaces after application of the products.

Description of Scenario [14]: Secondary exposure: a bystander (worker) touches the wet surfaces after application of the products.		
Bystander (worker) can touch the wet surface during the contact time of the dilution for meta SPC 1 or RTU product for meta-SPC 2. To assess this dermal exposure, the concentration of active chlorine in the dilution or RTU product is directly compared to the dermal NOAEC value of 1% w/w avCl.		
Tier	**Parameters**	**Value**
Sodium hypochlorite		
1	Concentration of active chlorine in the diluted product 'HYPO-CHLOR 5.25%' – Meta-SPC 1	0.55% (w/w)
	Concentration of active chlorine in the RTU products (worst-case) - META SPC 2	0.5% (w/w)
*ECHA (2015) The Biocides Human Health Exposure Methodology Document. Source: European Chemicals Agency		

Calculations for scenario 14:

Local exposure to sodium hypochlorite

Scenario 14: Secondary exposure: a bystander (worker) touches the wet surfaces after application of the products.		
META SPC 1		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.55	nr
META SPC 2 (products without buffer)		
Tier/PPE	Estimated Local dermal exposure (NaOCl as avCl in %)	Estimated Local inhalation exposure (NaOCl as avCl in mg/m^3)
Tier 1 (No PPE)	0.5	nr

Combined scenarios

Combined exposure is not relevant based on the absence of systemic effects after exposure towards sodium hypochlorite. The primary mode of action of NaOCl is characterised by local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent.
For this reason, only the highest exposure level (concentration as % avCl or mg avCl/m3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application, rinsing and post-application/ maintenance) is not relevant.

Professional exposure

Not relevant, the products in the family are used by industrial users only in industrial/manufacturing settings (pharmaceutical manufacture/clean rooms).

Non-professional exposure

Not relevant, the products in the family are used by industrial users only in industrial/manufacturing settings (pharmaceutical manufacture/clean rooms).

Exposure of the general public

There are no general public exposure scenarios relevant to the use of the HYPO-CHLOR® product family in controlled industrial/manufacturing premises; the biocidal product is intended for industrial use only. Exposure to the general public has not been considered further.

Disinfection by-products exposure

Not assessed, as there are no guidance for these types of uses

Dietary exposure

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected.

Residue definitions
Not relevant.

List of scenarios
Not relevant.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection products	Disinfectant – in irrigation water applied by watering tree – indoor use for mushroom crop. Not approved as a PPP active substance.	ADI: 0.15 mg/kg bw/d ARfD: not applicable Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005.

[1] e.g. plant protection products, veterinary use, food or feed additives
[2] e.g. MRLs. Use footnotes for references.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant.

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

Not relevant.

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

Not relevant.

Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value

Sodium hypochlorite					
$NOAEC_{oral}$	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
$NOAEC_{dermal}$	Human (dermatitis patients) 48 h-patch test study	1%	1	-	1% avCl
$AEC_{inhalation}$ (chlorine)*	Monkey 52-wks subchronic repeated dose inhalation study Human volunteer single dose inhalation study (4-8 h) Human volunteer repeated dose inhalation study (3 d, 6 h/d)	NOAEC 1.5 mg/m³	3.2 (intra-species toxicodynamic factor)	-	0.5 mg/m³ avCl
Hypochlorous acid					
$AEC_{inhalation}$ (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 $AEC_{inhalation}$ based on chlorine data (please see above)				0.5 mg avCl/m³
Chlorate					
ARfD (Oral)	Based on human 12-wks repeated dose oral (drinking water) clinical study according to EFSA CONTAM Panel (EFSA Journal 2015;13(6):4135	Not applicable	Not applicable	Not applicable	36 µg chlorate/kg bw

ADI (Oral)	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

MRLs or other relevant reference values	**Reference**	**Relevant commodities**	**Value**
Drinking water limit – chlorate	WHO, 2005 WHO/SDE/WSH/05.08/86[3]	**Drinking water**	**0.7 mg/L**
Drinking water limit – chlorate	Water Directive Proposed limit (EC 2020[4])	Drinking water except for disinfection method	0.25 mg/L
MRL chlorate - SANTE/10684/2015. (ScoPaFF February 2020)	MRL fixed based on monitoring data and target sampling on Food commodities	Raw food commodities plant and animal matrices	From 0.05 to 0.7 mg/kg
MRL - Sodium hypochlorite	Plant Protection Products	Default: No longer approved pesticide	0.01 mg/kg

[3] WHO, 2005. Chlorite and chlorate in drinking-water. Background document for development of WHO Guidelines for drinking-water quality. WHO/SDE/WSH/05.08/86

[4] EC 2017/0332(COD) : Proposal for a Directive of the European Parliament and of the Council on the quality of water intended for human consumption (recast Brussels, 5 February 2020, 5813/20 ENV 60 SAN 36 CONSOM 18 CODEC 82)

Risk for industrial users

Risk assessment for Meta-SPC 1

Local effects (Sodium hypochlorite)

- Quantitave risk assessment (inhalation exposure)

Expo	Task/ Scenario	Tier	Exposure ($Na(OCl)_2$ and/or HClO as avCl in mg/m3)	% AEC NOAEC inhalation : 0.5 mg/m3 avCl
Use 1: Application with a mechanical spray device (trigger spray)				
I	Scenario [1]	Tier 1	negligible	-
I	Scenario [2]	Tier 1	0.058	12
I	Scenario [3]	Tier 1	negligible	-
Use 1: Application with a mechanical spray device (coarse spray)				
I	Scenario [4]	Tier 1	0.57	114
I	Scenario [4]	Tier 2 (APF 4)	0.143	29
I	Scenario [5]	Tier 1	0.57	114
I	Scenario [5]	Tier 2 (APF 4)	0.143	29
Use 1: Application by mopping or wiping				
I	Scenario [6]	Tier 1	0.13	24
I	Scenario [7]	Tier 1	0.13	24
Use 1: Application by immersion				
I	Scenario [8]	Tier 1	negligible	-
I	Scenario [9]	Tier 1	negligible	-
I	Scenario [10]	Tier 1	negligible	-
Post application - all modes of application				
I	Scenario [11]	Tier 1	negligible	-
I	Scenario [12]	Tier 1	negligible	
Secondary exposure - all modes of application				
II	Scenario [13]	Tier 1/2	Idem application	
II	Scenario [14]	Tier 1	Nr	

For all scenarios, the estimated inhalation concentration of NaOCl is below the AEC inhalation of 0.5 mg/m3.

- Qualitative risk assessment (dermal exposure)

For dermal exposure during the mixing and loading task, the maximal NaOCl concentration handled by professional is 5%. This concentration is above the NOAEC value of 1% derived for the active substance NaOCl. The product is classified Skin irritant (H315) and Severe Eye Irritant (H318) and is intended to be applied by industrial. Considering that, a qualitative risk assement is performed. Please refer to the table 1 below.

For dermal exposure during application, rinsing and post-application and secondary exposure to wet surface, the concentration of NaOCl in the dilution (0.55%) is below the NOAEC value of 1% leading to no unacceptable risk.

Table 1- Local effects- Qualitative assessment for Sodium hypochlorite during Mixing and loading task - exposure to concentrated products in meta-SPC1: Product of Meta SPC 1 are skin irritant and Severe Eye Irritant

Hazard		Exposure								Risk
Hazard Category	Effects in terms of C&L	PT	Who is exposed?	Uses	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM	Relevant PPE	Conclusion on risk
Low	Skin Irritation Category 2, H315	2	Industrial worker	Mixing and loading	Skin	10 minutes per day	Concentrated product 5% av Cl dermal contact	Technical and organisational RMM adequate for the high hazard category are achievable* <u>Labelling</u> • Labelling according to CLP <u>Trained personnel</u> • Professional workers • instructions for use minimizing exposure for professionals	Use of appropriate personal protective equipment: <u>Hand protection:</u> Substance/task appropriate gloves <u>Body protection:</u> protection coverall <u>Face shield</u> <u>Eye protection:</u> Chemical goggles	Acceptable: + Professionals using PPE + Professionals following instructions for use + Low duration (few minutes per day)
High	Severe Eye Irritation Category1, H318				Eye		Concentrated product 5% av Cl hand to eye transfer, splashes			

Conclusion for meta-SPC 1

For the product of meta-SPC 1, risk is acceptable considering the local effects of sodium hypochlorite with a respiratory protective equipment (APF 4) for application and rinsing with coarse spray and with gloves, protection coverall and face shield for mixing and loading task for all modes of application.
For bystanders (worker), the following RMM should be added "Do not be present in the treatment area during disinfection process by compression sprayer (1-3 bars). If it is necessary to be present, wear same RPE and PPE as the user."

Risk assessment for META SPC 2:

Local effects (Sodium hypochlorite)

- Quantitave risk assessment (inhalation exposure)

Expo	Task/ Scenario	Tier	Exposure ($Na(OCl)_2$ and/or HClO as avCl in mg/m3)	% AEC NOAEC inhalation : 0.5 mg/m3 avCl
Use 1: Application with a mechanical spray device (trigger spray)				
I	Scenario [1]	Tier 1	negligeable	-
I	Scenario [2] (product without buffer)	Tier 1	0.058	12
I	Scenario [2] (product with buffer)	Tier 1	0.11	23
I	Scenario [3] (product without buffer)	Tier 1	negligible	-
I	Scenario [3] (product with buffer)	Tier 1	0.0642	13
Use 1: Application with a mechanical spray device (coarse spray)				
I	Scenario [4]	Tier 1	0.52	104
I	Scenario [4]	Tier 2 (APF 4)	0.13	26
I	Scenario [5]	Tier 1	0.52	104
I	Scenario [5]	Tier 2 (APF 4)	0.13	26
Use 1: Application by mopping or wiping				
I	Scenario [6]	Tier 1	0.11	22
I	Scenario [7]	Tier 1	0.11	22
Use 1: Application by immersion				
I	Scenario [8]	Tier 1	negligible	-
I	Scenario [9]	Tier 1	negligible	-
I	Scenario [10]	Tier 1	negligible	-
Post application - all modes of application				
I	Scenario [11]	Tier 1	negligible	-
I	Scenario [12]	Tier 1	negligible	-
Secondary exposure - all modes of application				
II	Scenario [13]	Tier 1/2	Idem application	

II	Scenario [14]	Tier 1	Nr

For all scenarios, the estimated inhalation concentration of NaOCl is below the AEC inhalation of 0.5 mg/m3.

- Qualitative risk assessment (dermal exposure)

For dermal exposure during the mixing and loading task, application, rinsing and post-application and secondary exposure to wet surface, the maximal NaOCl concentration handled by professional is 0.5%. This concentration is below the NOAEC value of 1% derived for the active substance NaOCl leading to no unacceptable risk.

Conclusion for meta-SPC 2

For the products of meta-SPC 2, risk is acceptable considering the local effects of sodium hypochlorite with a respiratory protective equipment (APF 4) for application and rinsing with coarse spray.
For bystanders (worker), the following RMM should be added "Do not be present in the treatment area during disinfection process by compression sprayer (1-3 bars). If it is necessary to be present, wear same RPE and PPE as the user."

Risk for consumers via residues in food

Not relevant. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore, residue in food or feed are not expected.

2.2.8 Risk assessment for animal health

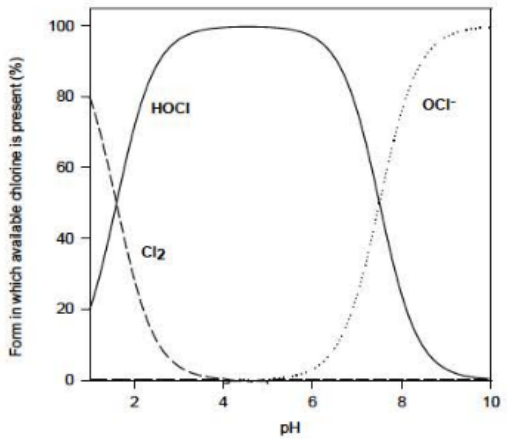
The HYPO-CHLOR® BPF has no uses that would result in animal/livestock exposure.

2.2.9 Risk assessment for the environment

NOTE
The applicant submitted a BPF composed of 2 meta-SPCs: Meta-SPC 1 and Meta-SPC 2. After discussion in WG-IV-APCP held in 2021, it was decided to split the META-SPC 2 as submitted by the applicant in two Meta-SPCs, Meta-SPC 2A and Meta-SPC 2B both containing ready to use products (HYPO-CHLOR 0.25% and HYPO-CHLOR 0.25% NEUTRAL for Meta-SPC 2A and HYPO-CHLOR 0.52%; HYPO-CHLOR 0.52% NEUTRAL for Meta-SPC 2B). However, the evaluation was held on the initial BPF composition.

Hence, these changes were considered in the efficacy and APCP sections but not systematically in human health and environment sections, as a risk envelop approach was performed. However, this has no impact on the overall conclusions. When the splitting was of no consequence for the evaluation, the evaluation refers to Meta-SPC 2 (meaning both Meta-SPC 2A and 2B).

The HYPO-CHLOR® sodium hypochlorite product family has the intended uses falling under Product Type PT 2 (disinfectants not intended for direct application to humans or animals). The active substance of all products within the family is active chlorine released from sodium hypochlorite (CAS: 7681-52-9).



The active substance released from sodium hypochlorite in water is active chlorine. According to the active substance's assessment report (2017), 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.

TRC (total residual chlorine) is a measurement of both Free Available Chlorine or FAC (in practice, only HClO and OCl- are usually present because Cl_2 is formed only at pH <4) and combined chlorine (such as chloramines). It is difficult to separate the contribution to toxicity of FAC from that of the combined chlorine species. For studies where the percentage of FAC in TRC was measured, the toxicity endpoints were expressed as FAC/L as well.

Available chlorine (or free chlorine) is expressed as equivalent content of Cl_2 (AR, 2017). The active chlorine equivalent content is:

- 1 g of sodium hypochlorite is equivalent to 0.953 g active chlorine (MW_{Cl2} / MW_{NaClO} = 71/74.5)

- Or 1 g active chlorine equivalent to 1.05 g sodium hypochlorite (MW_{NaClO} / MW_{Cl2} = 74.5 / 71).

Substance of concern

No substance of concern has been identified (see confidential annex for further details).

Chlorate formation during storage

The maximal sodium chlorate content after storage exceeds the reference specification (between 9.99% w/w to 21.6% w/w while the limit is 5.4% w/w). Consequently, a risk assessment for chlorate formed during storage is needed.

No harmonized endpoints are currently available for chlorate. As agreed during the WG-I-2020-Part B meeting, considering that chlorate (EC_{50} = 10 mg/L) is less toxic than the active substance (EC_{50} = 0.023 mg free available chlorine/L), it can be assessed qualitatively for all the environmental compartments including groundwater.
Chlorate is a substance relevant in relation to human health risks. Then, a semi qualitative assessment of chlorate in groundwater and surface water intended for the abstraction of drinking water have been performed (worst case assessment based on the maximal chlorate concentration, *i.e.* at the end of the storage period, as proposed for the HH assessment).

Disinfection by-products (DBPs)

An environmental risk assessment of DBPs has been provided by the applicant and is given in Annex 3.7. As underlined by the applicant, the risk assessment is still under development and will be amended when PNEC values and exposure concentration of DBPs will be agreed at Working Group level. Indeed, a harmonization of the environmental risk assessment for DBPs is currently under investigation at EU level. Consequently, and according to the WG-I-2020 Part B meeting agreements, any conclusion on the risk of DBPs for the environment cannot be drawn for the time being.
This should be adressed at the renewal of the active substance.

2.2.9.1 Effects assessment on the environment

Short and long-term toxicity data from literature are available for fish, invertebrates, algae and microorganisms, resulting from flow-through or static tests. Most tests with a static test design result in a factor of 100-500 higher end-points (NOEC, LC_{50}) than studies performed according to a flow-through design. Due to very fast hypochlorite decay, a static test system is continuously exposed to the same hypochlorite concentration. When data from literature were considered not valid or incomplete for the risk assessment, new toxicity laboratory studies were performed and included in the CAR.

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:

Agreed PNECs for active chlorine released from sodium hypochlorite

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 partitioning from aquatic data using a theoretical K_{oc} of 13.22 L/kg. Calculated according to the Guidance part B, vol. IV.
soil	-	-	0.015 µg FAC/kg wwt	
groundwater	Reference value for groundwater = 0.1 µg/L			
atmosphere	At environmental pH (6.5-8.5) half of the active chlorine is available as the unvolatile hypochlorite ion; half as hypochlorous acid with a Henry's law constant as 0.11 Pa 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				

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

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

The products are formulations containing the active substance, various co-formulants and water, none of which are likely to alter the ecotoxicity profile of the active substance or drive the environmental hazard classification. Therefore, classification of the products with regard to environmental hazard is based on data available for the active substance only and no further studies have been conducted on the products.
The most conservative chronic NOEC presented in the sodium hypochlorite Assessment Report(s) (2017a,b,c) is 0.0021 mg FAC/L from a 7 day freshwater algal toxicity study (Periphytic community) and the substance is regarded as rapidly degradable. Under the harmonised classification (Annex VI) of the 'Classification, labelling and packaging of substances and mixtures (CLP) Regulation (1272/2008)', the acute and chronic aquatic toxicity of sodium hypochlorite are classified as 'H400: Very toxic to aquatic life' (with an M factor of 10) and 'H410: Very toxic to aquatic life with long-lasting effects' (with an M factor of 1), respectively.

The products do not contain any ingredients other than the active substance (active chlorine released from sodium hypochlorite) which are classified to the aquatic environment. Thus, the environmental hazard classification of the products is driven by the active substance classification and has been calculated via the summation method. The amount of active substance within the products varies across the product families, ranging from 0.25 (Meta SPC 2) to 5% (meta-SPC 1) of active chlorine.

In conclusion, the Meta SPC 1 is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 2 (H411). For all the products of the Meta SPC 2, ranging from 0.25 to 0.5 % of active chlorine, there are classified as Aquatic Chronic 3 (H412).

Further Ecotoxicological studies

No further ecotoxicological studies have been conducted on active chlorine or the active chlorine releasing product supported in this document. All information on the ecotoxicology of the products can be extrapolated from the information on the active substances.

Ecotoxicity data for the active substances are summarised in the Competent Authority Reports[5]. No additional testing with the products is, therefore, considered necessary.

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)

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

Data waiving	
Information requirement	Not relevant
Justification	No additional tests 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

The products are not in the form of bait or granules and therefore this endpoint does not apply.

Data waiving	
Information requirement	Not relevant
Justification	Non-target organism exposure will not occur following normal intended use.

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

The products are not in the form of bait or granules and therefore this endpoint does not apply.

Data waiving	
Information requirement	Not relevant
Justification	Products within the HYPO-CHLOR product family do not occur in the form of bait or granules

[5] Assessment Report, Active chlorine released from sodium hypochlorite, PT2, January 2017 and Assessment Report, Active chlorine released from sodium hypochlorite, PT4, January 2017

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

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

Data waiving	
Information requirement	Not relevant
Justification	No additional tests on secondary ecological effects are 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

Please refer to section Fate and Distribution in exposed environmental compartments.

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

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology and environmental fate data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

Data waiving	
Information requirement	Not relevant
Justification	No further studies on fate and behaviour in the environment are needed on the basis of intended uses, data available on the active substance or risk assessment.

Leaching behaviour (ADS)

The performance of a study on leaching (e.g. from treated surfaces) is neither applicable nor relevant for the intended uses within PT 2.

The product family consists of formulated products and not treated articles. In addition, the products are not intended for addition to a matrix or impregnation into another material. The products are intended for disinfectant use indoors via mop, cloth, wipe, immersion or mechanical spray device. As such, testing on leaching behaviour is neither relevant nor required for this product type according to the Guidance on the Biocidal Product Regulation, Volume IV, Part A.

Testing for distribution and dissipation in soil (ADS)

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

Data waiving	
Information requirement	Not relevant
Justification	No additional tests on distribution and dissipation in soil are 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)

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

Data waiving	
Information requirement	Not relevant
Justification	No additional tests on distribution and dissipation in water and sediment are needed on the basis of intended uses, data available on the active substance or risk assessment.

Testing for distribution and dissipation in air (ADS)

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

Data waiving	
Information requirement	Not relevant
Justification	No additional tests on distribution and dissipation in air are 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)

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology and environmental fate data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

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)

The products are intended for use indoors (PT2) and therefore there will be no direct exposure of the environment.

Ecotoxicology and environmental fate data are available on the active substance and risk assessments have been conducted which demonstrate safe uses. No further testing is considered necessary.

2.2.9.2 Exposure assessment

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1: Sanitary purposes (industrial use) Scenario 2: Industrial areas (industrial use)
ESD(s) used	Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products, JRC 2011. Assessment Report, Active chlorine released from sodium hypochlorite, Product-type 2 (Disinfectants and algaecides not intended for direct application to humans or animals), January 2017.
Approach	Consumption based

Distribution in the environment	Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1, 2 Production: No Formulation No Use: Yes Service life: No
Remarks	Exposure based on worst case assumptions and relevant guidance

The representative product of the Meta SPC 1 is a liquid concentrate which require dilution to appropriate concentration prior to use. The maximum technical concentration of the active substance (active chlorine) is 5% w/w at a dose rate of 35 mL/m². According to the intended uses, the product should be diluted to 1/10 in water leading to a concentration of 0.5% of active substance.

Products of the Meta SPC 2 are a ready-to-use products with a concentration ranging 0.25 to 0.5% w/w of active chlorine.

Therefore, the exposure scenarios will be based on a concentration of 0.5% w/w to cover all the products of both Meta SPC.

Emission estimation

Scenario 1: Sanitary purposes (industrial use)
The products within the HYPO-CHLOR product family are intended for industrial indoor disinfectant use for sanitary purposes. None of these products are intended for non-professional use. General purpose (i.e. application to tiles, floors, sinks) and lavatory sanitary applications are assumed for all products. The products occur as either liquid concentrates which require dilution to the appropriate concentration prior to use and ready-to-use liquids. The products are applied at rates of 35 mL/m^2 via mop, cloth, wipe, immersion or mechanical spray device application methods for concentrate and ready-to-use liquid products. Following application, the products are left wet for the set contact time and allowed to air dry. The maximum in use rate (i.e. applied dilution) of active substance from products used for sanitary purposes is 0.5% w/w active chlorine as a worst case.

Default values were chosen for the number of inhabitants feeding one STP (10000), the fraction released to wastewater (1) and the penetration factor of disinfectant (0.5). The consumption per capita was set to 0.007 $L.cap^{-1}.d^{-1}$ (i.e. assuming general purpose (tiles, floors, sink) and lavatory use) as a worst case assumption. The amount of active substance in product was set to 0.005 kg/L (i.e. 0.5% w/w active chlorine) based on the in use rate for concentrate products.

Input parameters for calculating the local emission				
Input	**Unit**	**Symbol**	**Value**	**Remarks**
Scenario 1: Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption.				
Number of inhabitants feeding one STP	cap	Nlocal	10000	Default
Fraction released to wastewater	[-]	Fwater	1	Default
Concentration of active substance in the product	Kg/L	Cproduct	0.005485	Based on in use active substance concentration of 0.5% w/w and product density of 1.097
Concentration of ClO3- from storage in the product	Kg/L	Cproduct	0.0008776	Based on the maximum concentration of chlorate obtained in long term stability assay: 0.08% w/w chlorate (diluted product)
Consumption per capita	L/cap/d	Vproduct	0.007	Pick list (per ESD Table 2.2): As a tier 1 worse case general purpose (tiles, floors, sinks) + Lavatory was

				chosen. Worse case assumed
Density	[-]	D	1.097	Density of the product HYPO CHLOR 5.25%
Penetration factor of disinfectant	[-]	Fpenetr	0.5	Default
Output				
Emission rate to wastewater (standard STP)	Kg/d	Elocalwater	1.92E-01	As Active chlorine eq. Cl2
Emissions rate to wastewater (standard STP)	Kg/d	Elocalwater	3.07E-02	As Chlorate

Degradation of hypochlorite in the sewer system was considered. Based on the assessment report of active chlorine released from sodium hypochlorite, the DT50 is 56 seconds at 12°C for hypochlorite in the sewer system. This value is used for the emission estimation. No degradation was considered for chlorates.

A sewer residence time of 1h is proposed a default value in the ESD, based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

Calculation: $M_{t1} = M_{t0} * EXP^{(-k * t1)}$ M_{t1} = total amount of substance present at time 1 [kg/d] M_{t0} = total amount of substance at time 0 [kg/d] k = rate constant (k = 44.6 h^{-1}, calculated from the DT_{50} at 12°C: $ln2/DT_{50}$) t 1 = time [h] (= 1 h)	$Elocal_{water}$ = 8.54E-21 kg av Cl/d

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

The emission rates of chlorate in the local STP was calculated to be **3.07E-02 kg Chlorate/d.**

Scenario 2: Industrial areas (industrial use)

The products within the HYPO-CHLOR product family are intended for industrial indoor use in the disinfection of hard surfaces in industrial areas. None of these products are intended for non-professional use. The products occur as either liquid concentrates which require dilution to the appropriate concentration prior to use and ready-to-use liquids. The products are applied at rates of 35 mL/m^2 via mop, cloth, wipe, immersion or mechanical spray device

application methods for concentrate and ready-to-use liquid products. Following application, the products are left wet for the set contact time and allowed to air dry.

Default values were chosen for the fraction released to wastewater (1) and the fraction of substance disintegrated during or after application (0). The application rate of biocidal product to surfaces was set to 0.035 L/m^2. The surface area to be disinfected was set to 1000 m^2 (i.e. large-scale application) as a worst-case assumption. The concentration of active substance in the product was set to 5 g/L (i.e. 0.5% w/w of active substance), based on the in use rate for concentrate products used for disinfection of hard surfaces in industrial areas.

Input parameters for calculating the local emission				
Input	**Symbol**	**Unit**	**Value**	**Remarks**
Scenario 2: Emission scenario for calculating the releases of disinfectants used in industrial areas				
Application rate of biocidal product	Vform	L/m²	0.035	Based on liquid products application rate
Concentration of active substance in the product	Cform	g/L	5.485	Based on worst-case in use active substance concentration of 0.5% w/w and a product density of 1.097
Concentration of ClO3- in the product	Cform	g/L	0.8776	Based on the maximum concentration of chlorate obtained in long term stability assay: 0.08% w/w chlorate (diluted product)
Surface area to be disinfected	AREAsurface	m²	1000	Pick-list: Large scale application
Density	[-]	D	1.097	Density of the product HYPO CHLOR 5.25%
Fraction of substance disintegrated during or after application (before release to the sewage system)	Fdis	[-]	0	Default
Fraction released to wastewater	Fwater	[-]	1	Default
Output				

Emission rate to wastewater (standard STP)	Kg/d	Elocalwater	1.92E-01	As Active chlorine eq. Cl2
Emissions rate to wastewater (standard STP)	Kg/d	Elocalwater	3.07E-02	As Chlorate

Degradation of hypochlorite in the sewer system was considered. Based on the assessment report of active chlorine released from sodium hypochlorite, the DT50 is 56 seconds at 12°C for hypochlorite in the sewer system. This value is used for the emission estimation. No degradation was considered for chlorates.

A sewer residence time of 1h is proposed a default value in the ESD, based upon an average distance of 4.5 km from the point of release to the STP and an estimated flow rate of 1.5 km in 20 minutes in the municipal canal sewer system.

Calculation: $M_{t1} = M_{t0} * EXP^{(-k * t1)}$ M_{t1} = total amount of substance present at time 1 [kg/d] M_{t0} = total amount of substance at time 0 [kg/d] k = rate constant (k = 44.6 h^{-1}, calculated from the DT_{50} at 12°C: $ln2/DT_{50}$) t 1 = time [h] (= 1 h)	$Elocal_{water}$ = 8.54E-21 kg av Cl/d

Considering the very low emission rate to the STP because of the degradation of hypochlorite in the sewer systems, further calculations are not necessary and a qualitative assessment is proposed as stated at WGI2020.

The emission rates of chlorate in the local STP was calculated to be **3.07E-02 kg Chlorate/d.**

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) shows that hypochlorite is eliminated during transport in the sewer within the first minutes. The $HClO/ClO^-$ (expressed as FAC) concentration drops quickly in the sewer, parallel to a sharp increase of the chloramine concentration, which can be explained by the high availability of

ammonia in the sewer. Chloramine further reacts as an oxidant during additional transport in the sewer, the STP and in the river. The extensive degradation of chloramine in the activated sludge can be explained by the presence of reduced organic material. At environmental pH values (6.5-8.5) half of the active chlorine is present in the undissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion. Only the hypochlorous acid fraction is volatile, but the amount of hypochlorous acid that could volatilise from water into air is expected to be very low.

Identification of relevant receiving compartments based on the exposure pathway – Av Cl					
	Freshwater	Marine water	STP	Air	Soil incl. groundwater
Scenario 1	Q	Q	Q	Q	Q
Scenario 2	Q	Q	Q	Q	Q

Q: Qualitative assessment

Identification of relevant receiving compartments based on the exposure pathway – Chlorate					
	Freshwater	Marine water	STP	Air	Soil incl. groundwater
Scenario 1	a	a	a	A	SQ
Scenario 2	a	a	a	A	SQ

SQ: semi qualitative assessment a: covered by the active substance assessment

Input parameters (only set values) for calculating the fate and distribution in the environment – Chlorate			
Input	Value	Unit	Remarks
Molecular weight	83.5	g/mol	
Vapour pressure (at 25°C)	3.5E-07	Pa	-
Water solubility (at 25°C)	7.36E+05	mg/L	at pH 4.49 to 8.70
Organic carbon/water partition coefficient (Koc)	31.62	L/kg	QSAR (KOCWIN v2.00)
Henry's Law Constant (at 20°C)	5.2E-09	$Pa/m^3/mol$	Estimated (HENRYWIN)
Biodegradability	Not applicable to inorganic substances	[-]	Not readily biodegradable
DT_{50} for degradation in soil	1E+06	d (at 12°C)	Not readily biodegradable (EUSES)
Rate constant for soil biodegradation	6.96E-07	d-1 (at 12°C)	-

The distribution of chlorate within STP using the SimpleTreat 4.0 Model:

Compartment	Percentage [%]	Remarks
Air	1E-08	-
Water	99.6	-
Sludge	0.394	-
Degraded in STP	0	-

Calculated PEC values

Summary table on calculated PEC values – Active chlorine						
PT	**Scenario**	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
2	Scenario 1	-	-	-	-	-
	Scenario 2	-	-	-	-	-

- Negligible emissions based on a qualitative assessment

Summary table on calculated PEC values – Chlorate						
PT	**Scenario**	**PEC_{STP}**	**PEC_{water}[1]**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]
2	Scenario 1	-	1.53E-03	-	-	3.33
	Scenario 2	-	1.53E-03	-	-	3.33
[1] Freshwater intended for the abstraction of drinking water						

- Negligible emissions based on a qualitative assessment

Primary and secondary poisoning

Active chlorine does not bio-accumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. Primary poisoning is not expected for the intended uses.

2.2.9.3 Risk characterisation

Due to high reactivity of the active substance with organic matter, indirect releases from the disinfection of toilets bowls, drain pipes and hard surfaces lead to negligible environmental concentrations and risks are acceptable for all compartments.
A qualitative risk characterisation of chlorate is presented for all the environmental compartments as covered by the active substance, except for groundwater as chlorate is a substance of concern in relation to human health. Then, a semi-qualitative risk assessment is proposed for groundwater for information purposes only.

Atmosphere

Qualitative conclusion: Hypochlorite might enter the atmosphere due to volatilisation from the STP. Exposure assessment in the AR showed emission to air via this pathway is negligible. As the adsorption of hypochlorite to aerosol particles, the volatilisation from water into air and the adsorption of hypochlorite onto soil are all very low, hypochlorite will remain in the aqueous phase and degrade very rapidly. Exposure of the atmosphere is thus considered to be negligible. 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.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values			
PT	**Scenario**	**NaOCl**	**Chlorate**
2	Scenario 1	Negligible	Negligible
	Scenario 2	Negligible	Negligible

Conclusion: Risk are considered acceptable for scenario 1 and 2 based on a qualitative assessment with negligible emissions.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
PT	**Scenario**	**NaOCl**	**Chlorate**	**PEC/PNEC$_{\text{Freshwater intented for the abstraction of drinking water}}$* for chlorate**
2	Scenario 1	Negligible	Negligible	2.19E-03
	Scenario 2	Negligible	Negligible	2.19E-03

* drinking water limit value of 700 µg chlorate/L (WHO drinking Water Limit) for water disinfected by chloration.

Conclusion: Risk are considered acceptable for scenario 1 and 2 considering a qualitative assessment with negligible emissions, as well as semi qualitative assessment for chlorate in freshwater intended for the abstraction of drinking water.

Terrestrial compartment

Summary table on calculated PEC/PNEC values			
PT	**Scenario**	**NaOCl**	**Chlorate**

2	Scenario 1	Negligible	Negligible
	Scenario 2	Negligible	Negligible

Conclusion: Risk are considered acceptable for scenario 1 and 2 based on a qualitative assessment with negligible emissions.

Groundwater

Summary table on calculated PEC/PNEC values			
PT	**Scenario**	**NaOCl**	**Chlorate***
2	Scenario 1	Negligible	4.76E-03
	Scenario 2	Negligible	4.76E-03

* compared to the drinking water limit value of 700 µg chlorate/L (WHO drinking water limit) for water disinfected by chloration.

Conclusion: Risk are considered acceptable for scenario 1 and 2 based on a qualitative assessment with negligible emissions.

Primary and secondary poisoning

Active chlorine does not bioaccumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. Primary poisoning is not expected for the intended uses.

Mixture toxicity

Non-relevant as the product contain only one active substance and none of the coformulants are of environmental concern.

Aggregated exposure (combined for relevant emission sources)

According to the WG-I-2020 Part B, a qualitative assessment for the active substance has been performed due to its high reactivity with organic matter. Consequently, the aggregated exposure is not relevant.

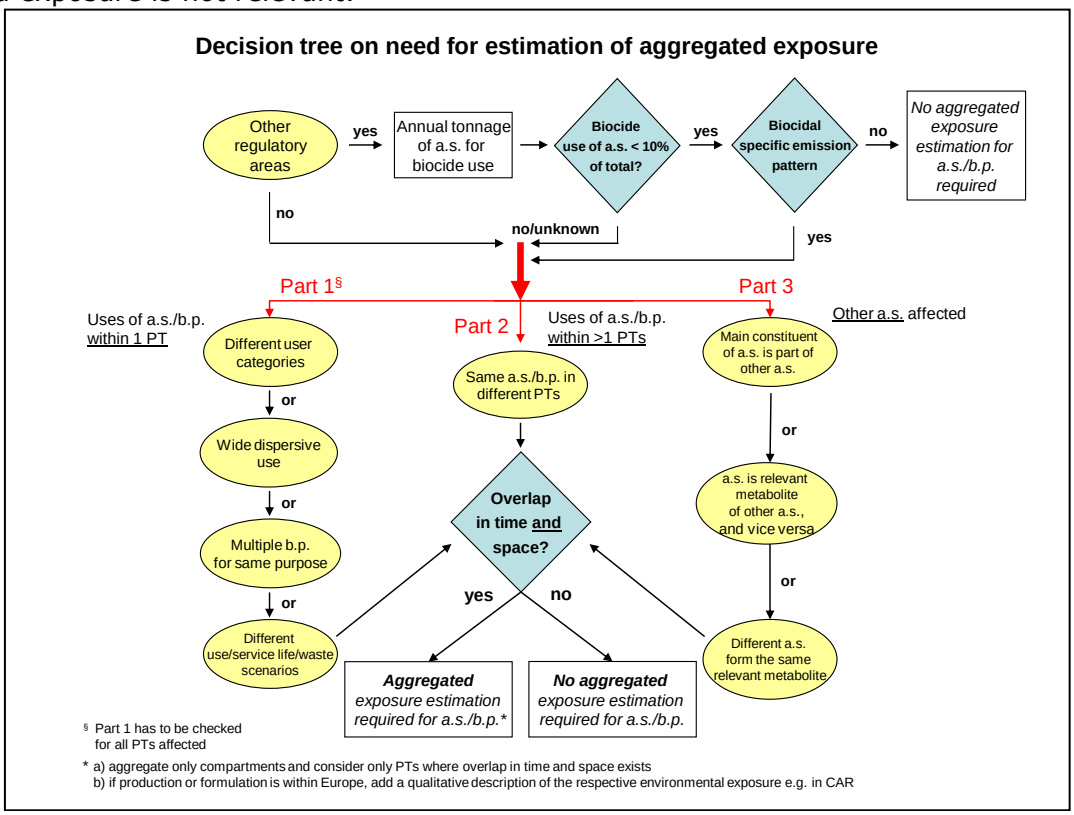


Figure 1: Decision tree on the need for estimation of aggregated exposure

The aggregate risks assessment presented below sums up the chlorate emissions from all uses:

Summary table on calculated ΣPEC/PNEC values						
	$\Sigma PEC/PNEC_{STP}$	**$\Sigma PEC/PNEC_{water}$**	**$\Sigma PEC/PNEC_{sed}$**	**$\Sigma PEC/PNEC_{soil}$**	**ΣPEC_{GW} (µg/L)**	**ΣPEC_{air}**
	NR	4.37E-03	NR	NR	6.66	NR

NR; not relevant

Conclusion: Aggregated risks for chlorate are acceptable for all compartments based on the drinking water limit value of 700 µg chlorate/L (WHO drinking Water Limit) for water disinfected by chloration.

Overall conclusion on the risk assessment for the environment of the product

Risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance NaOCl and chlorate formed during storage leading to negligible emissions to the environment for:

- PT02 disinfectant used for sanitary purpose in industrial area (Meta-SPC 1 and 2).

Risks linked to chlorate formed during storage are acceptable for all uses considering a semi-qualitative assessment for groundwater and surface water intended for drinking water.

2.2.10 Measures to protect man, animals and the environment

Please refer to the SPC.

2.2.11 Assessment of a combination of biocidal products

Not relevant

2.2.12 Comparative assessment

Not relevant

3 Annexes[6]

3.2 List of studies for the biocidal product (family)

Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	2019a	HYPO-CHLOR 5.25% SHC-02-5.25: Accelerated Storage Stability and Corrosion Characteristics - Time 0 Interim Product Safety Labs Report No 50840 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2017	Product Chemistry Testing: HYPO-CHLOR Neutral Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121, United States Report No A22909 GLP Unpublished	Yes	Veltek Associates, Inc.

6 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	2017	Product Chemistry Testing: Hypo-Chlor Neutral 0.25% Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121, United States Report No A24466 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2012	Product Properties Parts A & B: HYPO-CHLOR 5.25%® Veltek Associates, Inc., Chemistry Lab, 15 Lee Boulevard, Malvern, PA 19355-1234, United States / Technology Sciences Group Inc., 1150 18th Street N.W., Washington, D.C. 20036, United States Report No. VAI 2010-004 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019a	HYPO-CHLOR 5.25% SHC-02-5.25: Physical and Chemical Characteristics: Density/Relative Density Product Safety Labs Report No. 50884 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019c	Hypo-Chlor Neutral 0.52% 16oz Simple Mix: Accelerated Storage Stability and Corrosion Characteristics - Time 0 Interim Product Safety Labs Report No 50842 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019b	HYPO-CHLOR 5.25% SHC-02-5.25: Storage stability and Corrosion Characteristics - Time 0 Interim Report Product Safety Labs Report No 50841 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019d	Hypo-Chlor Neutral 0.52% 16 oz Simple Mix: Storage Stability and Corrosion Characteristics - Time 0 Interim Report Product Safety Labs Report No 50843 GLP Unpublished	Yes	Veltek Associates, Inc.

Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	2019	Long Term Storage Stability of Test Substances: HYPO-CHLOR Neutral 0.52% Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121, United States Report No A22960 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2020	Spray Characterization: Following CIPAC MT 187 and ISO 13320:2009 guidelines for - Particle size analysis by laser diffraction Aerosol Research and Engineering Laboratories, Inc. Report No. 10875.1 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2018	Spectral Transmission of HYPO-CHLOR 5.25% Eurofins Lancaster Laboratories, Inc. Report No. Sample group NG-2016947; Report distribution 418749 Non-GLP Unpublished	No	Veltek Associates, Inc.
[redacted]	2018	TR-47 Lab Determine Foaming of Hypo-Chlor 5.25% Veltek Associates, Inc., Chemistry Lab, 15 Lee Boulevard, Malvern, PA 19355-1234, United States Report No GS04092018 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019b	HYPO-CHLOR 5.25% SHC-02-5.25 Product Safety Labs Report No. 50883 GLP Unpublished	No	Veltek Associates, Inc.
[redacted]	2019c	Hypo-Chlor Neutral 0.52% 16oz Simple Mix: Surface Tension Product Safety Labs Report No. 50885 GLP Unpublished	No	Veltek Associates, Inc.

Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	2011a	Physical and Chemical Characteristics: Viscosity. HYPO-CHLOR 0.52% Eurofins PSL, 2394 US Highway 130, Dayton, NJ 08810, United States Report No 30091 Non GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2011b	Physical and Chemical Characteristics: Viscosity. HYPO-CHLOR 5.25% Eurofins PSL, 2394 US Highway 130, Dayton, NJ 08810, United States Report No 30092 Non GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2017	Product Chemistry Testing: HYPO-CHLOR Neutral Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121, United States Report No A22909 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2017	Product Chemistry Testing: Hypo-Chlor Neutral 0.25% Accuratus Lab Services, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121, United States Report No A24466 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2018	BPR Corrosion Testing of HYPO-CHLOR Neutral 0.25% Case Laboratories, Inc., 622 Route Ten, Whippany, NJ 07981, United States Report No 5480-12 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019	BPR Corrosion Testing of HYPO-CHLOR Neutral 0.25% Case Laboratories, Inc., 622 Route Ten, Whippany, NJ 07981, United States Report No 5480-15 GLP Unpublished	Yes	Veltek Associates, Inc.

Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
[redacted]	2019a	HYPO-CHLOR 5.25% SHC-02-5.25: Accelerated Storage Stability and Corrosion Characteristics - Time 0 Interim Product Safety Labs Report No 50840 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2018	Enforcement Analytical Titration Validation for Chemical Characterization Accuratus Lab Services, Eagan, MN 55121 Report No A25551 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019	Enforcement Analytical Titration Validation for Chemical Characterization Accuratus Lab Services, Eagan, MN 55121 Report No A27204 GLP Unpublished	Yes	Veltek Associates, Inc.
[redacted]	2019d	Hypo-Chlor Neutral 0.52% 16 oz Simple Mix: Storage Stability and Corrosion Characteristics - Time 0 Interim Report Product Safety Labs Report No 50843 GLP Unpublished	Yes	Veltek Associates, Inc.

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Section 6						

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 6.7	6.7.3	[redacted]	2019	Quantitative suspension test for evaluation of bactericidal efficacy of Chemical disinfectants and antiseptics used in food, industrial domestic and institutional areas (Phase 2 Step1). BS EN 1276:2019 J001198-1 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.4	[redacted]	2019	Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (Phase 2, step 2). BS EN 13697:2015+A1:2019 J001198-3 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.5	[redacted]	2019	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (Phase 2, step 1). BS EN 1650:2019 J001198-2 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.6	[redacted]	2019	Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (Phase 2, step 2). BS EN 13697:2015+A1:2019 J001258 Unpublished	Yes	Veltek Associates, Inc.

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 6.7	6.7.7	[redacted]	2019	Chemical disinfectants – Quantitative suspension tests for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – (Phase 2, step 1). BS EN 13704:2018 J001198-4 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.8	[redacted]	2019	Quantitative suspension test for evaluation of bactericidal efficacy of Chemical disinfectants and antiseptics used in food, industrial domestic and institutional areas (Phase 2 Step1). BS EN 1276:2019 J001197-1 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.9 and 6.7.11	[redacted]	2019	Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas (Phase 2, step 2). BS EN 13697:2015+A1:2019 J001197-3 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.10	[redacted]	2019	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (Phase 2, step 1). BS EN 1650:2019. J001197-2 Unpublished	Yes	Veltek Associates, Inc.

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 6.7	6.7.12	[redacted]	2019	Chemical disinfectants – Quantitative suspension tests for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – (Phase 2, step 1). BS EN 13704:2018. J001197-4 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.13	[redacted]	2019	Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1). BS EN 14476:2013+A2:2019 (J001198-6) J001198-6 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.13	[redacted]	2020	Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1). BS EN 14476:2013+A2:2019 (J001307-4) J001307-4 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.14	[redacted]	2019	Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area -Test method and requirements (phase 2/step 2) (J001198-7) J001198-7 Unpublished	Yes	Veltek Associates, Inc.

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 6.7	6.7.14	[redacted]	2020	Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area -Test method and requirements (phase 2/step 2) (J001307-2) J001307-2 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.15	[redacted]	2019	Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1). BS EN 14476:2013+A2:2019 (J0011977-6) J001197-6 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.15	[redacted]	2020	Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1). BS EN 14476:2013+A2:2019 (J0011977-6) J001197-6-adeno-retest Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.15	[redacted]	2020	Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1). BS EN 14476:2013+A2:2019 (J001307-3) J001307-3 Unpublished	Yes	Veltek Associates, Inc.

BPR reference No	IUCLID Section No. / Reference No.	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB 6.7	6.7.16	[redacted]	2019	Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area -Test method and requirements (phase 2/step 2) (J001197-7) J001197-7 Unpublished	Yes	Veltek Associates, Inc.
IIIB 6.7	6.7.16	[redacted]	2020	Chemical disinfectants and antiseptics – Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area -Test method and requirements (phase 2/step 2) (J001307-1) J001307-1 Unpublished	Yes	Veltek Associates, Inc.
-	Study 114966	[redacted]	2011	In vitro Skin Corrosion – Membrane Barrier test with HYPO-CHLOR 5.25% w/w	Yes	Veltek Associates, Inc.

3.3 Output tables from exposure assessment tools

[redacted]

3.4 New information on the active substance

3.5 Residue behaviour

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected.

3.6 Summaries of the efficacy studies (B.5.10.1-xx)[7]

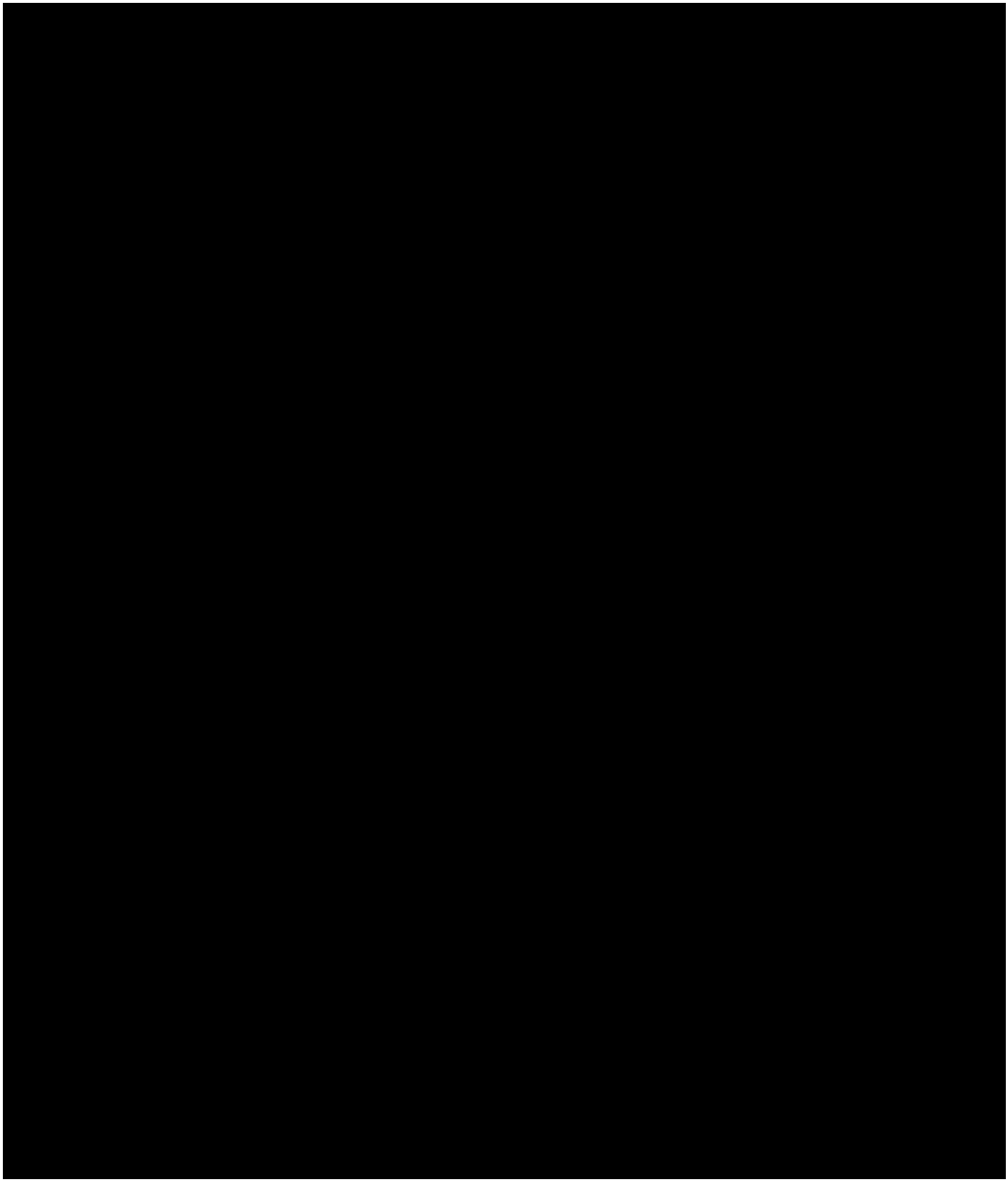
3.7 Confidential annex

See the confidential Annex.

3.7 Other

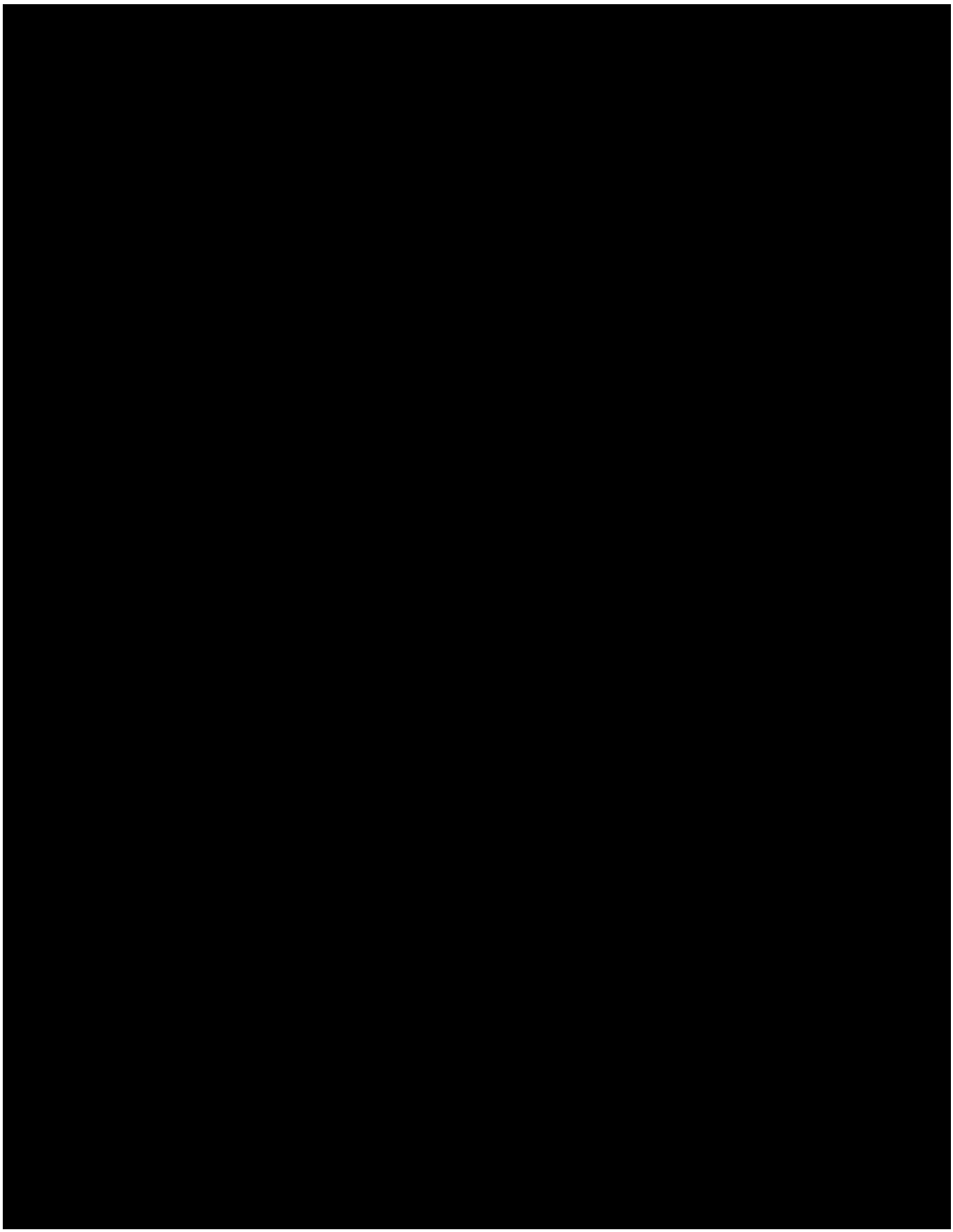
[redacted]

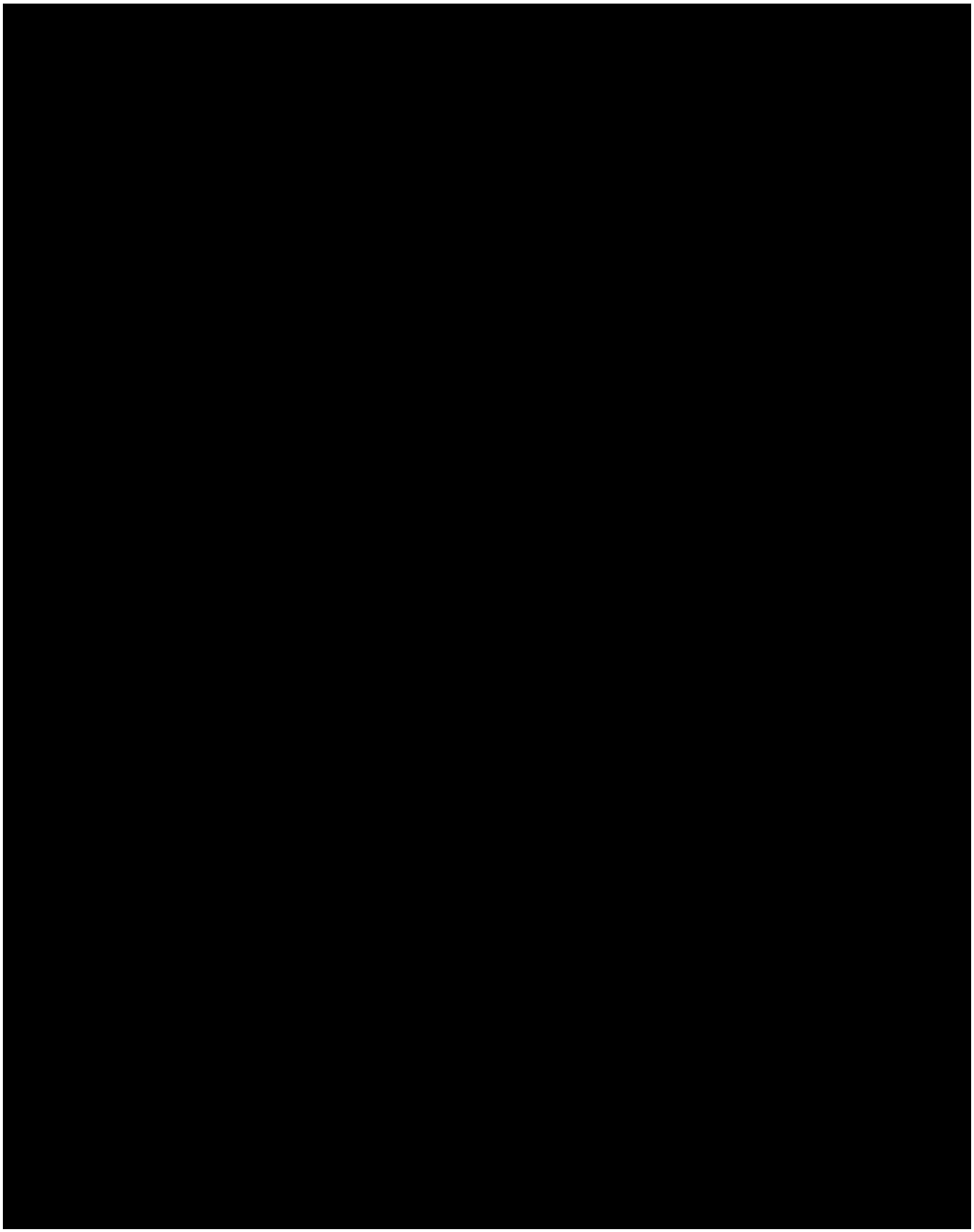
7 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.
8 European Union Risk Assessment Report. Sodium Hypochlorite. Final report, November 2007

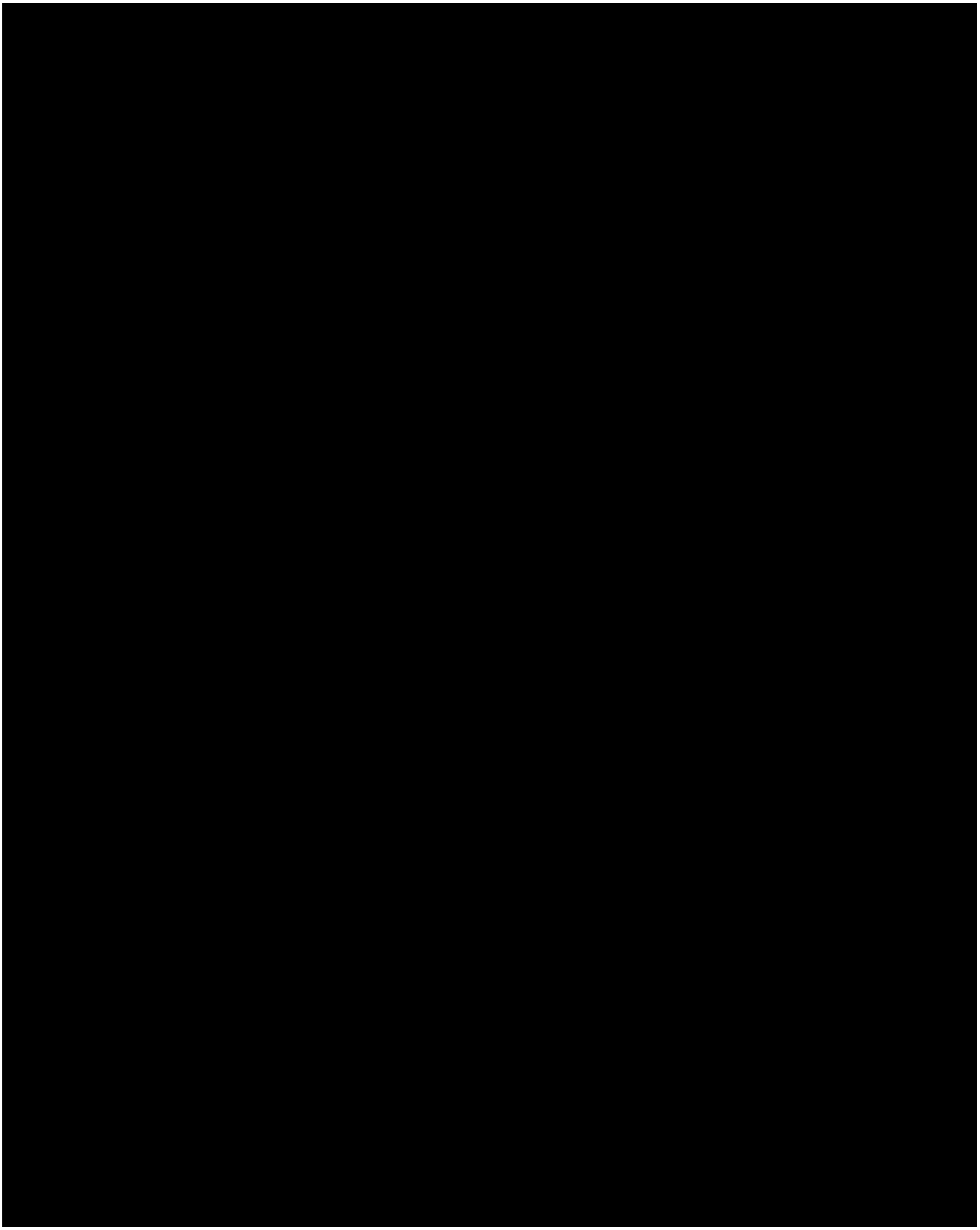


[redacted]

9 EU Risk Assessment. Chloroform Risk Assessment. Final Report (2007). France
10 Guidance on BPR: Vol IV Environment Parts B+C, Version 2.0. October 2017

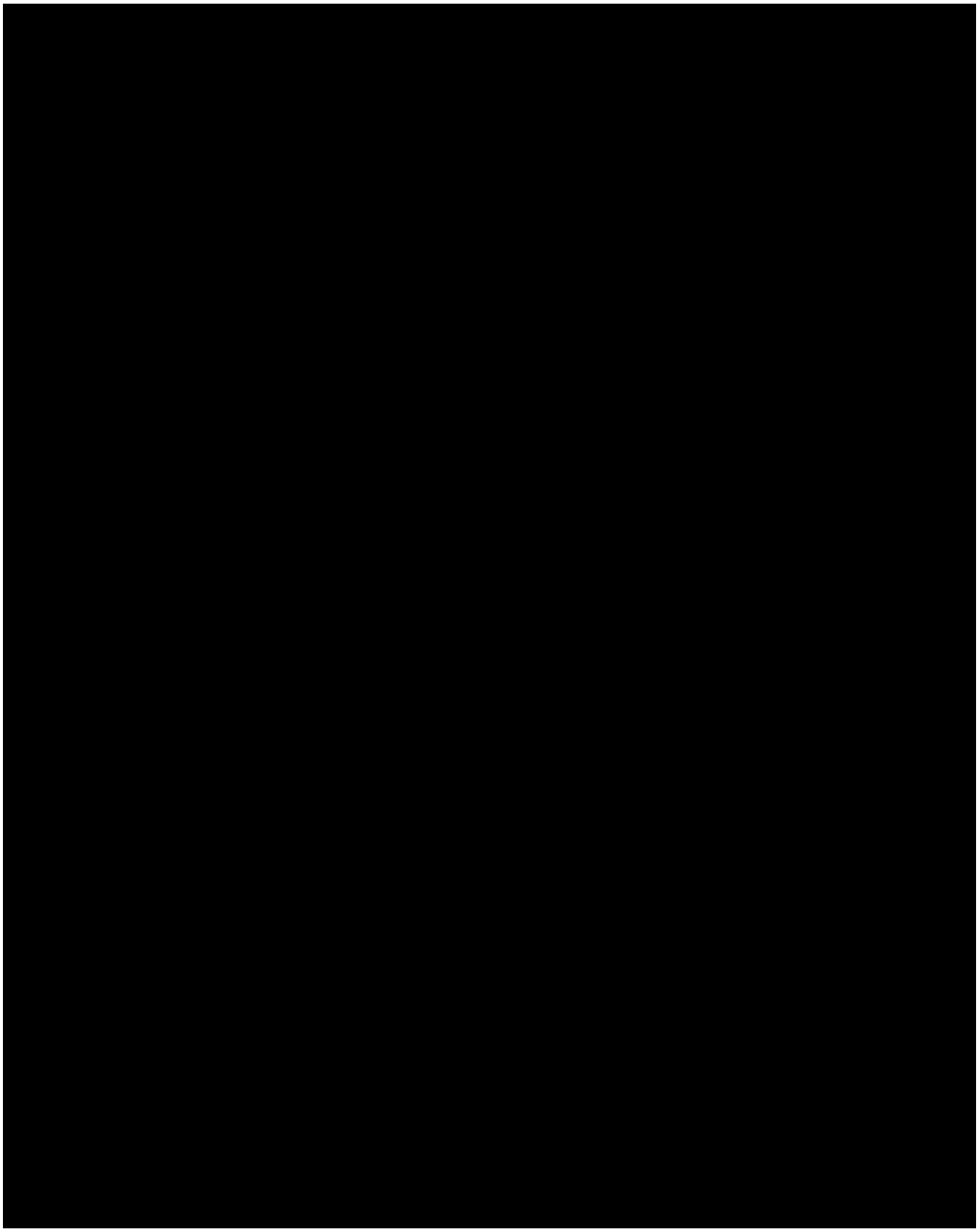






11 Guidance on BPR: Vol IV Environment Parts B+C, Version 2.0. October 2017

12 Roberts J. F., Egmond R., Price O. R. (2010) Toxicity of haloacetic acids to freshwater algae. *Ecotoxicology and Environmental Safety*, **73**, 56 – 61.



13 Johnson I., Pickup J. A., van Wijk D. (2006) A perspective on the environmental risk of halogenated by-products from uses of hypochlorite using a whole effluent toxicity based approach. *Environmental Toxicology and Chemistry*, **25**, 1171 – 1177.