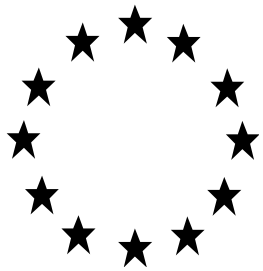
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE

Product types 2, 4

Active chlorine released from Sodium hypochlorite as included in the Union list of approved active substances

Case Number in R4BP: BC-JQ047866-10
Case Number NA-MIC in R4BP: BC-AY078940-08

Evaluating Competent Authority: France

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0 DOSSIER'S HISTORY

Note to the reader

This consolidated PAR for the **minor** change application of the product authorisation is based on the PAR of the first authorisation, in which all necessary addenda have been included.
In part 1 and 2 of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post authorisation data...) the assessments related to the minor change of the product are at the end of each section and are highlighted in grey.

In part 3 of the consolidated PAR: the summary of product characteristics is pointed out and corresponds to the decision for the minor change application.

History of the dossier

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	MSCA-France	BC-JQ047866-10	14.03.2022	Initial assessment	
NA-MIC	MSCA-France	BC-AY078940-08	06.11.2023	Minor change application : - Modifications of the soiling conditions during use for all Meta SPCs - Increase of the self-life for Meta SPCs 1, 3 and 8. - Addition of trade names - Additions of two manufacturers and three manufacturing sites of the active substance	

1 CONCLUSION

The biocidal products family, BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE, is based on 1.575% to 15,225 % of sodium hypochlorite, are product types 2 and 4 intended for disinfection. The products of this biocidal family are in the form of, liquid soluble concentrates (meta SPC 1, 2, 5, 8), or as liquid to be applied undiluted (meta SPC 3) for means of disinfection against bacteria, fungi and yeast, by professional and non-professional users.
The BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE is composed of 8 Meta-SPC, 3 of which have been abandoned by the applicant:

- Meta-SPC 1– sodium hypochlorite 2.73%
- Meta-SPC 2 – sodium hypochlorite 10.08-15.23%
- Meta-SPC 3 – sodium hypochlorite 1.575%
- Meta-SPC 4 – abandoned
- Meta-SPC 5 – sodium hypochlorite 5.145%
- Meta-SPC 6 – abandoned
- Meta-SPC 7 – abandoned
- Meta-SPC 8 - sodium hypochlorite 2.73%

The biocidal product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE is claimed to be used for:

PTs	Claimed uses	META SPC concerned
2, 4	Use # 1 – Disinfection of surfaces by spraying	1, 2, 3, 5, 8
2, 4	Use # 2 – Disinfection of surfaces by wiping with mop/cloth	1, 2, 5, 8

Conclusions of the assessments of each section are given below:

- **Physico chemical properties and analytical methods**

The physico-chemical properties of the biocidal product family have been described and considered acceptable in the conditions of use detailed in the SPC.

The products of the family should not be stored above 30°C and should be kept protected from direct sunlight. Products of Meta SPC 5 and 8 are foaming formulations.

Shelf life of the Meta SPC 1: 9 months
Shelf life of the Meta SPC 2: 3 months
Shelf life of the Meta SPC 3: 9 months
Shelf life of the Meta SPC 5: 8 months
Shelf life of the Meta SPC 8: 9 months

Due to the nature of the active ingredient, products should not be used in conjunction with acids or ammonia. For products with a content of active chlorine higher than 5% (products of Meta SPC 2 and 5), the mention EUH031 "contact with acids liberates toxic gas" is proposed. For products sold to general public and with a content of active chlorine higher than 1% (Meta SPC 1, 2, 3, 5 and 8), the mention EUH 206: "Warning! Do not use together with other products. May release dangerous gases (chlorine)" is applied.

All the products of the family are classified corrosive to metal H290 Met Corr. I.
For Meta SPC 5 and 8, DSC tests (performed on one product of each Meta SPC) are required in post authorisation to confirm the non classification for self-reactive properties of the products.

The analytical methods provided are validated for the determination of sodium hypochlorite and sodium chlorate in the biocidal product family.

For Meta SPC 3, the spray particles size distribution after storage is required in post authorisation.

- **Efficacy**

First application (2022)

The product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE has shown sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 and EN 14885:2015 standard for the following uses:

META SPC 1

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30% v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

- Use 2: Disinfection of surfaces by wiping with mop/clothincluded (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

META SPC 2

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 0.525% w/w active chlorine, 15 min, 20 °C

  Efficacy against fungi is not demonstrated for a shelf-life of 3 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use aplication rate.

- Use 2: Disinfection of surfaces by wiping with mop/cloth(PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 0.525% w/w active chlorine, 15 min, 20 °C

  Efficacy against fungi is not demonstrated for a shelf-life of 3 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use aplication rate.

META SPC 3

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 100% v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 100% v/v, 20 min, 20 °C

META SPC 5

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 15 % v/v, 15 min, 20 °C

  Efficacy against fungi is not demonstrated for a shelf-life of 8 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.

- Use 2: Disinfection of surfaces by wiping with mop/cloth(PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 15 % v/v, 15 min, 20 °C

  Efficacy against fungi is not demonstrated for a shelf-life of 8 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.

META SPC 8

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

- Use 2: Disinfection of surfaces by wiping with mop/cloth(PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

It has to be noted that according to the efficacy tests submitted, pre-cleaning step has been added and contact time have been increased.

Moreover, the applicant claimed also an efficacy against smell generating organisms. The argumentation provided by the applicant: "Smell generating organisms are bacteria and fungi. As the products have been reported efficient for these organisms, the claim for desodorising is considered relevant". Nevertheless, as no efficacy data according to the requirements of the Efficacy guidance Vol II Part B/C, section 5.4.0.5.4 were provided, we consider that this claim has not been demonstrated.

- **Substances of concern**

One substance of concern, Dodecanenitrile, has been identified for the environnement.

None of the co-formulants contained in the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE family are regulatory identified as endocrine disruptors or have significant ED properties.

- **Human Health**

For professional users, risks are acceptable for products of meta-SPC 1, 2, 3, 5 and 8 considering the semi-quantitative and qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) and the condition to wear the personal protective equipment (PPE) listed below:

- Meta-SPC 1 and 2:
  - For mixing and loading (use 1 and 2): gloves, body protection and chemical goggles

- Meta-SPC 3:
  - For application by spraying and post-application task (use 1 only): gloves, body protection and chemical goggles

- For meta-SPC 5 and 8, risks are acceptable for the application by spraying and wiping with a mop with a handle, with the application of risk mitigation measures (RMM) and the condition to wear the personal protective equipment (PPE) listed below:
  - For mixing and loading and post-application task (use 1 and 2) gloves, body protection and chemical goggles
  - For application by spraying (use 1 only): gloves, body protection, chemical goggles and respiratory protective equipment
  - For application by mopping or wiping (use 2 only): gloves, body protection and chemical goggles / Do not dip your hands in the bucket / Apply the product only with a mop with a handle.

Risk is not acceptable for products of meta-SPC 5 and 8 for the application by wiping with a cloth or a mop without a handle, considering the semi-quantitative and qualitative risk assessment for local effects.

For non-professional users, risks are acceptable for products of meta-SPC 1 and 3 considering the semi-quantitative and qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) listed below:

- Meta-SPC 1:
  - Washing on hands after use

- Meta-SPC 3:
  - Washing on hands after use
  - The product has to be sprayed downward (use 1 only)

For non-professional users, risk is not acceptable for products of meta-SPC 2, 5 and 8 considering the semi-quantitative and qualitative risk assessment for local effects.

RMM (general pubic) (all uses):
- Do not touch the surface until the surface is dried;
- Children should not be present during disinfection.

- **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.

For PT 4 uses, residues in food, feed or drink must be further investigated.
Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly. Hence, residue formation (other than chlorate) is assumed to be negligible for aqueous solutions of chlorine. Conversely, chlorate residues, a stable metabolite that can be formed from hypochlorite sodium in aqueous chlorine solutions, are considered relevant for dietary exposure from the uses of active substance as food area disinfectant.

Regarding professional use in industrial field, considering the current knowledge about chlorate and the official chlorate limits in food[1], there is no concern for the general public from indirect exposure to either available chlorine or chlorate in food, feed and drinking water.

Considering the non-professional uses, a food contamination with chlorate via treated surface was estimated using maximalist scenario. No concern for general public from indirect exposure to either available chlorine or chlorate in food is observed when a rinsing of treated surfaces occurs.

- **Environment**

Risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance NaOCl leading to negligible emissions to the environment, considering a semi-qualitative assessment of chlorate for groundwater and surface water intended for the abstraction of drinking water, for the following uses:

- PT 2/4: Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth.
- PT 2/4: Disinfection of surfaces by spraying : hard surface (ustensils, equipment, furniture)

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

Risks are acceptable for all the environmental compartments considering a quantitative assessment of the substance of concern: Dodecanenitrile (CAS n° 2437-25-4) only in meta-SPC 8, for the following uses:

- PT 2: Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth.
- PT 2: Disinfection of surfaces by spraying : hard surface (ustensils, equipment, furniture)

For meta SPC 8, in PT04, unacceptable risks in surface water and STP are foreseen for disinfection of hard surfaces in contact with food in the scenario 1 (professional applications on large scale catering kitchen and canteens, slaughterhouse). Risks are acceptable for the disinfection in private areas.

This restriction will be indicated in the SPC for the PT04 uses of META-SPC 8 (for which the SoC is relevant): **'The disinfection of hard surfaces in contact with food is restricted to domestic areas'.**

General conclusion

Overall conclusions for the claimed uses:

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

Meta SPC	PT	Target organisms	Application rate	Uses	Conclusions
1 3	2 & 4	Bacteria Yeast Fungi		Disinfection of hard non porous surfaces by spraying with and without previous cleaning. Professionals & non-professionals Contact time:5 min	**Unacceptable**: Efficacy not demonstrated without previous cleaning and within the revendicated contact time.
1				Disinfection of hard non porous surfaces by wipping with and without previous cleaning. Professionals & non-professionals Contact time: 5 min	
2				Disinfection of hard non porous surfaces by spraying with and without previous cleaning. Professionals & non-professionals Contact time: 5min	**Unacceptable**: Efficacy not demonstrated without previous cleaning and within the revendicated contact time. Efficacy against fungi not demonstraded with respect to the shelflife. Unacceptable risks for for non-professionnal users due to local effects
				Disinfection of hard non porous surfaces by wipping with and without previous cleaning. Professionals & non-professionals Contact time: 5 min	
5				Disinfection of hard non porous surfaces by spraying with and without previous cleaning. Professionals & non-professionals Contact time: 5min	**Unacceptable**: Efficacy not demonstrated without previous cleaning and within the revendicated contact time. Furthermore, efficacy against fungi is not demonstraded with respect to the shelflife. Unacceptable risks for for non-professionnal users due to local effects. Unacceptable risks for the application by wiping with a cloth or a mop without a handle by professional user due to local effects.
				Disinfection of hard non porous surfaces by wipping with and without previous cleaning. Professionals & non-professionals Contact time: 5 min	
8	2 & 4			Disinfection of hard non porous surfaces by spraying with and without previous cleaning. Professionals & non-professionals Contact time: 5 min	**Unacceptable**: Efficacy not demonstrated without previous cleaning and

				Disinfection of hard non porous surfaces by wipping with and without previous cleaning. Professionals & non-professionals Contact time: 5 min.	within the revendicated contact time. Unacceptable risks for for non-professionnal users due to local effects. Unacceptable risks for the application by wiping with a cloth or a mop without a handle by professional user due to local effects Risks for the environment for PT4 uses except disinfection of domestic surfaces.
1	**2 & 4**	Bacteria Yeast Fungi	Dilution : 30 % v/v	Disinfection of hard non porous surfaces by spraying after previous cleaning. Professionals & non-professionals Contact time: - Bacteria & yeast: 15 min. Fungi: 20 min.	**Acceptable**
				Disinfection of hard non porous surfaces by wipping after previous cleaning. Professionals & non-professionals Contact time: - Bacteria & yeast: 15 min. Fungi: 20 min.	**Acceptable**
2	**2 &** 4	Bacteria Yeast	0.525% w/w active chlorine	Disinfection of hard non porous surfaces by spraying after previous cleaning. Professionals Contact time: Bacteria & yeast: 15 min.	**Acceptable**
				Disinfection of hard non porous surfaces by wipping after previous cleaning Professionals Contact time: Bacteria & yeast: 15 min.	**Acceptable**
3	**2 & 4**	Bacteria Yeast Fungi	Ready to use	Disinfection of hard non porous surfaces by spraying after previous cleaning. Professionals & non-professionals Contact time: - Bacteria & yeast: 15 min. - Fungi: 20 min.	**Acceptable**

5	**2 & 4**	Bacteria Yeast	Dilution : 15 % v/v	Disinfection of hard non porous surfaces by spraying after previous cleaning. Professionals Contact time: - Bacteria & yeast: 15 min.	**Acceptable**
				Disinfection of hard non porous surfaces by wipping with a mop with a handle after previous cleaning Professionals Contact time: Bacteria & yeast: 15 min.	**Acceptable**
8	**2**	Bacteria Yeast Fungi	Dilution : 30 % v/v	Disinfection of hard non porous surfaces by spraying after previous cleaning. Professionals Contact time: - Bacteria & yeast: 15 min. Fungi: 20 min.	**Acceptable**
				Disinfection of hard non porous surfaces by wipping with a mop with a handle after previous cleaning Professionals Contact time: - Bacteria & yeast: 15 min. Fungi: 20 min.	**Acceptable**
	4			Disinfection of hard non porous surfaces, in domestic areas, by spraying after previous cleaning. Professionals Contact time: - Bacteria & yeast: 15 min. Fungi: 20 min.	**Acceptable**
				Disinfection of hard non porous surfaces in domestic areas by wipping with a mop with a handle after previous cleaning Professionals Contact time: - Bacteria & yeast: 15 min. Fungi: 20 min.	**Acceptable**

- **NA-MIC minor change application 2022**

Minor change description:

- Modifications of the soiling conditions during use for all Meta SPCs
- Increase of the self-life for Meta SPCs 1, 3 and 8.
- Addition of trade names
- Additions of manufacturers and manufacturing sites of the active substance

Conclusion

- **Physico chemical properties and analytical methods minor change**

Final long term stability studies were provided in the framework of this dossier for products of Meta SPC 1, 3, and 8. Results allow to grant a shelf life 18 months for Meta SPC 1, 24 months for Meta SPC 3 and 18 months for Meta SPC 8. Physico-chemical properties remain unchanged after storage.

- **Efficacy minor change**

The elements presented in the dossier are not sufficient to demonstrate the efficacy of the product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE under dirty conditions, in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy Parts B+C as no acceptable P2S2 test against bacteria under dirty conditions has been provided. Efficacy assessment supports the shelf-life.

- **Human health and Indirect exposure via food : minor change application 2022**

The minor change regarding the extension of the shelf-life for Meta-SPCs 1, 3 and 8 induces an increase of the sodium chlorate concentration at final time in these Meta-SPCs.
These new concentrations have been used to perform the classification according to the classification rules. To be noted that the recently adopted RAC opinion (10 June 2021) agreed that sodium chlorate should be classified as Acute Tox 3; H301, with an ATE of 100 mg/kg bw. This new ATE has also be used to review the classification of the meta-SPCS.
These changes have no impact on the classification of the meta-SPCs, the identification of substances of concern and the human health risk assessment.

-
- **Environnement : minor change application**

The minor change regarding the extension of the self-life for Meta SPCs 1, 3 and 8 induces an increase of the chlorate concentrations. However, according to the WG-I-2020, it has been decided that chlorate can be assessed qualitatively for all the environmental compartments. Therefore this minor change has no impact on the environmental risk assessment. Moreover, the highest in-use concentration of chlorate used in the risk assessment remains unchanged as it comes from meta SPC 2. Concerning the other minor changes (modification of the soiling conditions during use for all Meta SPCs; addition of trade names; addition of manufacturing sites of the active substance), they have no impact on classification of the biocidal product, nor on the analysis of the substance of concern, nor on the environmental risk assessment as they do not changes the intended dose rates.

2 ASSESSMENT REPORT

PART I - FIRST INFORMATION LEVEL

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[2]	**Country (if relevant)**
BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Notilia
	Address	ZI de Grezan 1284 chemin du Mas de Sorbier 30000 Nîmes France
Authorisation number	FR-2022-0017	
Date of the authorisation	10/03/2022	
Expiry date of the authorisation	09/03/2032	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Notilia
Address of manufacturer	ZI de Grezan, 1284 chemin du Mas de Sorbier 30000 Nîmes France
Location of manufacturing sites	ZI de Grezan, 1284 chemin du Mas de Sorbier 30000 Nîmes France

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

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Inovyn
Address of manufacturer	Runcorn site HQ, South Parade PO Box 9, Cheshire, WA7 4JE, Runcorn, United Kingdom
Location of manufacturing sites	Runcorn site HQ, South Parade PO Box 9, Cheshire, WA7 4JE, Runcorn, United Kingdom

2 Please fill in here the identifying product name from R4BP.

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Inovyn Belgium SA (Acting for Inovyn Europe Limited (UK))
Address of manufacturer	Rue Solvay, 39 5190 Jemeppe-sur-Sambre Belgium
Location of manufacturing sites	Via Lodi Vecchio 10 26838 TAVAZZANO CON VILLAVESCO Italy

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Inovyn Belgium SA (Acting for Inovyn Europe Limited (UK))
Address of manufacturer	Rue Solvay, 39 5190 Jemeppe-sur-Sambre Belgium
Location of manufacturing sites	2 Avenue de la République 39500 TAVAUX France

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Ercros SA
Address of manufacturer	Av. Diagonal, 598 08014 Barcelona Spain
Location of manufacturing sites	Autovia Tarragona - Salou C31-B, km 6 43480 VILA-SECA 1 Spain

2.1.2 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 ☐

2.1.2.1 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
Minimum purity / content	15.225% (Purity of NaOCl solution), in compliance with the EN 901:2013 (Aqueous solution with an available / active chlorine concentration ≤18% w/w) Sodium chlorate has been identified as a relevant impurity in technical material (max content: 5.4% of active chlorine/available chlorine equiv. to 0.081 – 0.783 % w/w in the biocidal product family).
Structural formula	Na^+ Cl–O^-

2.1.2.2 Candidate(s) for substitution

Active chlorine released from sodium hypochlorite is not candidate for substitution in accordance with Article 10 of BPR.

Common name		**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
						Min	**Max**
Sodium hypochlorite as TK with a purity of 15.225%	Pure sodium hypochlorite	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	1.575	15.225
	Active chlorine from sodium hypochlorite					1.5	14.5
Dodecanenitrile		-	Surfactant	2437-25-4	219-440-1	0	0.05

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family[2]

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 152.25g/kg (15.225%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.

The biocidal product family comprises 5 Meta SPC (8 at the initial submission of the dossier but 3 are no longer supported). The full composition of the family is included in the confidential annex.

2.1.2.4 Information on technical equivalence

Technical equivalence is not necessary because the source of active substance is part of the reference sources of the CAR of sodium hypochlorite.

2.1.2.5 Information on the substance(s) of concern

One substance of concern, Dodecanenitrile, has been identified for the environnement. Please see the confidential annex for further details.

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

None of the co-formulants contained in the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE family are regulatory identified as endocrine disruptors or have significant ED properties.
However, that are indications that some co-formulants have ED properties and they should be further assessed in the frame of REACH Regulation.
Hence, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not before the end of the assessment. In case any co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.
Please refer to the Confidential Annex.

2.1.2.7 Type of formulation

SL – Soluble concentrate (Meta SPC 1, 2, 5, 8) AL - Any other liquid (Meta SPC 3)

PART II - SECOND INFORMATION LEVEL - META SPC 1

2.1.3 Meta SPC 1 administrative information

2.1.3.1 Meta SPC identifier

Identification	Meta SPC 1

2.1.3.2 Suffix to the authorisation number

2.1.3.3 Product type(s)

Product type(s)	2
	4

2.1.4 Meta SPC 1 composition

2.1.4.1 Qualitative and quantitative information on the composition of the meta SPC 1

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*	2.73 *(2.6)*

2.1.4.2 Type(s) of formulation of the meta SPC 1

SL – Soluble concentrate

2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Met. Corr. 1 Skin Irri. 2 Eye Irri. 2 Aquatic acute 1 Aquatic chronic 2

Classification	
Hazard statement	H290: May be corrosive to metals H315: Causes skin irritation H319: Causes serious eye irritation H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long-lasting effects.
Labelling	
Signal words	Warning
Hazard statements	H290: May be corrosive to metals H315: Causes skin irritation H319: Causes serious eye irritation H410: Very toxic to aquatic life with long lasting effect.
Precautionary statements	P234: Keep only in original packaging P264: Wash … thoroughly after handling. P273: Avoid released to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321: Specific treatment (see … on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash before reuse. P390: Absorb spillage to prevent material damage P391: Collect spillage P406: Store in a corrosion-resistant/… container with a resistant inner liner P501: Dispose of contents/container in accordance with the national regulation
Note	EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). The precausionnary statement P280 does not apply to non-professionnal users.

2.1.6 Authorised use(s) of the META SPC 1

2.1.6.1 Use description

Table 1. Use # 1 – Disinfection of surfaces by spraying

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces by spraying (ustensils, equipment, furniture) Without mechanical action

Target organism (including development stage)	Bacteria Yeasts Fungi
Field of use	Indoor
Application method(s)	Spraying on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 30 % v/v dilution in water Contact time: • 15 minutes (bacteria and yeasts) • 20 minutes (fungi) Temperature: 20°C
Category(ies) of users	Professional Non-professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L: bottle, HDPE

2.1.6.1.1 Use-specific instructions for use

-

2.1.6.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.6.2 Use description

Table 2. Use # 2 – Disinfection of surfaces by wiping with mop/cloth

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket. Without mechanical action
Target organism (including development stage)	Bacteria Yeasts Fungi
Field of use	Indoor
Application method(s)	Wiping with mop/cloth on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 30 % v/v dilution in water Contact time: • 15 minutes (bacteria and yeasts) • 20 minutes (fungi) Temperature: 20°C
Category(ies) of users	Professional Non-professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L: bottle, HDPE

2.1.6.2.1 Use-specific instructions for use

-

2.1.6.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.7 General directions for use of the meta SPC 1

2.1.7.1 Instructions for use

- Comply with the instructions for use.
- Make sure to wet surfaces completely.
- Allow to take effect for at least 15 to 20 minutes, depending on the activity.
- Mix at a rate of 300 mL of product for 700 mL of water.
- Clean carefully the surfaces before application of the product.
- Products should not be used in conjunction with acids or ammonia.

2.1.7.2 Risk mitigation measures

- For PT 2 use, avoid any direct or indirect contact with food.
- For PT 4 use, rinse surfaces after treatment.
- For mixing and loading task, professional users must wear gloves, body protection and chemical goggles.
- Washing on hands after use
- Do not touch the surface until it is totally dried
- Children should not be present during disinfection

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

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.1.7.4 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.

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

- Keep out of reach of children and non-target animals/pets.
- Do not store above 30°C
- Protect from direct sunlight
- Shelf life: 18 months

2.1.8 Other information

- The applicant should inform professional users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the BIOCIDAL PRODUCT FAMILY.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)	**1 - Eau de javel 2.6% Nectra** **Eau de Javel 2.6% Mieuxa**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*

Trade name(s)	**2 - Eau de javel 2.6% Avix**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*

Trade name(s)	**3 - Eau de javel 2.6% Onyx**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**

Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*

PART II - SECOND INFORMATION LEVEL - META SPC 2

2.1.10 Meta SPC 2 administrative information

2.1.10.1 Meta SPC identifier

Identification	META SPC 2

2.1.10.2 Suffix to the authorisation number

2.1.10.3 Product type(s)

Product type(s)	2
	4

2.1.11 Meta SPC 2 composition

2.1.11.1 Qualitative and quantitative information on the composition of the meta SPC 2

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	10.08 *(9.6)*	15.225 *(14.5)*

2.1.11.2 Type(s) of formulation of the meta SPC 2

SL – Soluble concentrate

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

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Met. Corr. 1 Skin Corr. 1 Eye Dam. 1 Aquatic acute 1 Aquatic chronic 2
Hazard statement	H290: May be corrosive to metals H314: Causes severe skin burns H318: Causes serious eye damage H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long-lasting effects.
Labelling	
Signal words	
Hazard statements	H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H410: Very toxic to aquatic life with long lasting effect.
Precautionary statements	P234: Keep only in original packaging P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash … thoroughly after handling. P273: Avoid released to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P321: Specific treatment (see … on this label). P363: Wash contaminated clothing before reuse. P390: Absorb spillage to prevent material damage P391: Collect spillage P405: Store locked up. P406: Store in a corrosion-resistant/… container with a resistant inner liner P501: Dispose of contents/container in accordance with the national regulation
Note	EUH071: Corrosive to the respiratory tract EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). EUH031: Contact with acids liberates toxic gas

2.1.13 Authorised use(s) of the META SPC 2

2.1.13.1 Use description

Table 3. Use # 1 – Disinfection of surfaces by spraying

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces by spraying: hard surface (ustensils, equipment, furniture) Without mechanical action
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 0.525% w/w active chlorine Contact time: • 15 minutes (bacteria and yeasts) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L, 250ml 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L, 250mL: bottle, HDPE

2.1.13.1.1 Use-specific instructions for use

-

2.1.13.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.13.2 Use description

Table 4. Use # 2 – Disinfection of surfaces by wiping with mop/cloth

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket. Without mechanical action
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Wiping on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 0.525% w/w active chlorine Contact time: • 15 minutes (bacteria and yeasts) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L, 250ml 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L, 250mL: bottle, HDPE

2.1.13.2.1 Use-specific instructions for use

-

2.1.13.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.14 General directions for use of the meta SPC 2

2.1.14.1 Instructions for use

- Comply with the instructions for use. - Make sure to wet surfaces completely. - Allow to take effect for at least 15 minutes. - Clean carefully the surfaces before application of the product. - Products should not be used in conjunction with acids or ammonia.

2.1.14.2 Risk mitigation measures

- For PT 2 use, avoid any direct or indirect contact with food. - For PT 4 use, rinse surfaces after treatment. - For mixing and loading task, professional users must wear gloves, body protection and chemical goggles. - Do not touch the surface until it is totally dried - Children should not be present during disinfection

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

- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. <u>Information to Healthcare personnel/doctor:</u> The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

2.1.14.4 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.

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

- Keep out of reach of children and non-target animals/pets.
- Do not store above 30°C
- Protect from direct sunlight
- Shelf life: 3 months

2.1.15 Other information

- The applicant should inform professional users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the BIOCIDAL PRODUCT FAMILY.

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

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

Trade name(s)	**6 - Concentré de javel 9.6%** **Concentré de javel 9.6% Nectra** **Eau de javel concentrée à 9.6% Mieuxa** **Extrait de javel 9.6% Novopure**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	10.08 *(9.6)*

Trade name(s)	**7 - Extrait de javel 12.5%** **Extrait de javel 12.5 % Nectra**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	13.125 *(12.5)*

Trade name(s)	**7bis - Extrait de javel 13-16%** **Extrait de javel 13-16% Nectra**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	15.225 *(14.5)*

PART II - SECOND INFORMATION LEVEL - META SPC 3

2.1.17 Meta SPC 3 administrative information

2.1.17.1 Meta SPC identifier

Identification	Meta SPC 3

2.1.17.2 Suffix to the authorisation number

2.1.17.3 Product type(s)

Product type(s)	2
	4

2.1.18 Meta SPC 3 composition

2.1.18.1 Qualitative and quantitative information on the composition of the meta SPC 3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	1.575 *(1.5)*	1.575 *(1.5)*

2.1.18.2 Type(s) of formulation of the meta SPC 3

AL - Any other liquid

2.1.19 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Met. Corr. 1 Skin Irri. 2 Eye Irri. 2 Aquatic chronic 3
Hazard statement	H290: May be corrosive to metals H315: Causes skin irritation H319: Causes serious eye irritation H412: Harmful to aquatic life with long-lasting effects.
Labelling	
Signal words	Warning
Hazard statements	H290: May be corrosive to metals H315: Causes skin irritation H319: Causes serious eye irritation H412: Harmful to aquatic life with long-lasting effects.

Classification	
Precautionary statements	P234: Keep only in original packaging P264: Wash … thoroughly after handling. P273: Avoid released to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321: Specific treatment (see … on this label). P332+P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash before reuse. P390: Absorb spillage to prevent material damage P406: Store in a corrosion-resistant/… container with a resistant inner liner P501: Dispose of contents/container in accordance with the national regulation
Note	EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). The precausionnary statement P280 does not apply to non-professionnal users.

2.1.20 Authorised use(s) of the META SPC 3

2.1.20.1 Use description

Table 5. Use # 1 – Disinfection of surfaces by spraying

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces by spraying (ustensils, equipment, furniture) Without mechanical action
Target organism (including development stage)	Bacteria Yeasts Fungi
Field of use	Indoor
Application method(s)	Spraying on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Ready-to-use Spray directly on the surface Contact time: • 15 minutes (bacteria and yeasts) • 20 minutes (fungi) Temperature: 20°C

Category(ies) of users	Professional Non-professional
Pack sizes and packaging material	800mL: spray bottle PEDH (HDPE spray + Viton seal)

2.1.20.1.1 Use-specific instructions for use

-

2.1.20.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.21 General directions for use of the meta SPC 3

2.1.21.1 Instructions for use

- Comply with the instructions for use. - Make sure to wet surfaces completely. - Allow to take effect for at least 15 to 20 minutes, depending on the activity. - Clean carefully the surfaces before application of the product. - Products should not be used in conjunction with acids or ammonia.

2.1.21.2 Risk mitigation measures

- For PT 2 use, avoid any direct or indirect contact with food. - For PT 4 use, rinse surfaces after treatment. - For application by spraying and post-application task, professional users must wear gloves, body protection and chemical goggles. - Washing on hands after use - The product has to be sprayed downward - Do not touch the surface until it is totally dried - Children should not be present during disinfection

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

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin

with water. If skin irritation occurs: Get medical advice.
IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.
IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

2.1.21.4 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.

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

- Keep out of reach of children and non-target animals/pets.
- Do not store above 30°C
- Protect from direct sunlight
- Shelf life: 24 months

2.1.22 Other information

- The applicant should inform professional users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the BIOCIDAL PRODUCT FAMILY.

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	**8 - Spray javel 1.5%** **Spray javel 1.5% Nectra**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	1.575 *(1.5)*

Trade name(s)	**9 - Javel blanchiment anti-verdissures** **Javel blanchiment anti-verdissures Mieuxa**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	1.575 *(1.5)*

PART II - SECOND INFORMATION LEVEL - META SPC 5

2.1.24 Meta SPC 5 administrative information

2.1.24.1 Meta SPC identifier

Identification	Meta SPC 5

2.1.24.2 Suffix to the authorisation number

2.1.24.3 Product type(s)

Product type(s)	2
	4

2.1.25 Meta SPC 5 composition

2.1.25.1 Qualitative and quantitative information on the composition of the meta SPC 5

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Pure Sodium hypochlorite	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	5.145 *(4.9)*	5.145 *(4.9)*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
(Active chlorine released from sodium hypochlorite)						

2.1.25.2 Type(s) of formulation of the meta SPC 5

SL – Soluble concentrate

2.1.26 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Met. Corr. 1 Skin Corr. 1 Eye Dam. 1 Aquatic acute 1 Aquatic chronic 2
Hazard statement	H290: May be corrosive to metals H314: Causes severe skin burns H318: Causes serious eye damage H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long-lasting effects.
Labelling	
Signal words	
Hazard statements	H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H410: Very toxic to aquatic life with long lasting effect.

Classification	
Precautionary statements	P234: Keep only in original packaging P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash … thoroughly after handling. P273: Avoid released to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P321: Specific treatment (see … on this label). P363: Wash contaminated clothing before reuse. P390: Absorb spillage to prevent material damage P391: Collect spillage P405: Store locked up. P406: Store in a corrosion-resistant/… container with a resistant inner liner P501: Dispose of contents/container in accordance with the national regulation
Note	EUH071: Corrosive for the respiratory tract. EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine). EUH031: Contact with acids liberates toxic gas

2.1.27 Authorised use(s) of the META SPC 5

2.1.27.1 Use description

Table 6. Use # 1 – Disinfection of surfaces by spraying

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces by spraying: hard surface (ustensils, equipment, furniture) Without mechanical action
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Spraying on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: dilution of 15 % v/v in water prior spraying Contact time:

	• 15 minutes (bacteria and yeasts) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 20L,10L, 5L HDPE bottle

2.1.27.1.1 Use-specific instructions for use

-

2.1.27.1.2 Use-specific risk mitigation measures

- For application by spraying, professional users must wear gloves, body protection, chemical goggles and respiratory protective equipment.

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

-

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

-

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

-

2.1.27.2 Use description

Table 7. Use #2 – Disinfection of surfaces by wiping with mop/cloth

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket. Without mechanical action
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor
Application method(s)	Wiping on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: dilution of 15 % v/v in water prior wiping Contact time: • 15 minutes (bacteria and yeasts) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 20L,10L, 5L HDPE can

2.1.27.2.1 Use-specific instructions for use

-

2.1.27.2.2 Use-specific risk mitigation measures

- For application by mopping or wiping, professional users must wear gloves, body protection and chemical goggles.
- Do not dip your hands in the bucket.
- Apply the product only with a mop with a handle.

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

-

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

-

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

-

2.1.28 General directions for use of the meta SPC 5

2.1.28.1 Instructions for use

- Comply with the instructions for use.
- Make sure to wet surfaces completely. Allow to take effect for at least 15 minutes
- Mix at a rate of 150 mL of product for 850 mL of water.
- Clean carefully the surfaces before application of the product.
- Products should not be used in conjunction with acids or ammonia.

2.1.28.2 Risk mitigation measures

- For PT 2 use, avoid any direct or indirect contact with food.
- For PT 4 use, rinse surfaces after treatment.
- For mixing and loading and post-application task, professional users must wear gloves, body protection and chemical goggles.
- Do not touch the surface until it is totally dried
- Children should not be present during disinfection

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

2.1.28.4 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.

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

- Keep out of reach of children and non-target animals/pets.
- Do not store above 30°C
- Protect from direct sunlight
- Shelf life: 8 months

2.1.29 Other information

- The applicant should inform professional users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the BIOCIDAL PRODUCT FAMILY. - Products are foaming formulations

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

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

Trade name(s)	**19 - Al'k Chlore Essentiel** **Al'k Chlore Essentiel Nectra**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	5.145 *(4.9)*

Trade name(s)	**20 - Perfo Alka mousse** **Perfo Alka mousse Hygial**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	5.145 *(4.9)*

PART II - SECOND INFORMATION LEVEL - META SPC 8

2.1.31 Meta SPC 8 administrative information

2.1.31.1 Meta SPC identifier

Identification	META SPC 8

2.1.31.2 Suffix to the authorisation number

2.1.31.3 Product type(s)

Product type(s)	2
	4

2.1.32 Meta SPC 8 composition

2.1.32.1 Qualitative and quantitative information on the composition of the meta SPC 8

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*	2.73 *(2.6)*
Dodecanenitrile	-	Surfactant	2437-25-4	219-440-1	0	0.05

2.1.32.2 Type(s) of formulation of the meta SPC 8

SL – Soluble concentrate

2.1.33 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 8

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

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

Classification	
Hazard category	Met. Corr. 1 Skin Corr. 1 Eye Dam. 1 Aquatic acute 1 Aquatic chronic 2

Classification	
Hazard statement	H290: May be corrosive to metals H314: Causes severe skin burns H318: Causes serious eye damage H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long-lasting effects.
Labelling	
Signal words	
Hazard statements	H290: May be corrosive to metals H314: Causes severe skin burns and eye damage H410: Very toxic to aquatic life with long lasting effect.
Precautionary statements	P234: Keep only in original packaging P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash … thoroughly after handling. P273: Avoid released to the environment P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor/physician. P321: Specific treatment (see … on this label). P363: Wash contaminated clothing before reuse. P390: Absorb spillage to prevent material damage P391: Collect spillage P405: Store locked up. P406: Store in a corrosion-resistant/… container with a resistant inner liner P501: Dispose of contents/container in accordance with the national regulation
Note	EUH071: Corrosive for the respiratory tract. EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine).

2.1.34 Authorised use(s) of the META SPC 8

2.1.34.1 Use description

Table 8. Use # 1 – Disinfection of surfaces by spraying

Product Type	PT2

Where relevant, an exact description of the authorised use	Disinfection of hard surfaces by spraying (ustensils, equipment, furniture) Without mechanical action
Target organism (including development stage)	Bacteria Yeasts Fungi
Field of use	Indoor
Application method(s)	Spraying on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 30 % v/v dilution in water Contact time: • 15 minutes (bacteria and yeasts) • 20 minutes (fungi) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L: bottle, HDPE

2.1.34.1.1 Use-specific instructions for use

2.1.34.1.2 Use-specific risk mitigation measures

- For application by spraying, professional users must wear gloves, body protection, chemical goggles and respiratory protective equipment.

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

-

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

-

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

-

2.1.34.2 Use description

Table 9. Use # 2 – Disinfection of surfaces by wiping with mop/cloth

Product Type	PT2
Where relevant, an exact description of the authorised use	Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket. Without mechanical action
Target organism (including development stage)	Bacteria Yeasts Fungi
Field of use	Indoor
Application method(s)	Wiping on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 30 % v/v dilution in water Contact time: • 15 minutes (bacteria and yeasts) • 20 minutes (fungi) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L: bottle, HDPE

2.1.34.2.1 Use-specific instructions for use

-

2.1.34.2.2 Use-specific risk mitigation measures

- For application by mopping or wiping, professional users must wear gloves, body protection and chemical goggles.
- Do not dip your hands in the bucket.
- Apply the product only with a mop with a handle.

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

-

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

-

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

-

2.1.34.3 Use description

Table 10. Use # 3 – Disinfection of domestic surfaces by spraying

Product Type	PT 4
Where relevant, an exact description of the authorised use	Disinfection of hard surfaces in domestic areas by spraying (ustensils, equipment, furniture) Without mechanical action
Target organism (including development stage)	Bacteria Yeasts Fungi
Field of use	Indoor
Application method(s)	Spraying on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 30 % v/v dilution in water Contact time: • 15 minutes (bacteria and yeasts) • 20 minutes (fungi) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L: bottle, HDPE

2.1.34.3.1 Use-specific instructions for use

-

2.1.34.3.2 Use-specific risk mitigation measures

- For application by spraying, professional users must wear gloves, body protection, chemical goggles and respiratory protective equipment.

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

-

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

-

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

-

2.1.34.4 Use description

Table 11. Use # 2 – Disinfection of domestic surfaces by wiping with mop/cloth

Product Type	PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces in domestic areas (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket. Without mechanical action
Target organism (including development stage)	Bacteria Yeasts Fungi
Field of use	Indoor
Application method(s)	Wiping on hard non-porous surfaces with prior cleaning
Application rate(s) and frequency	Application rate: 30 % v/v dilution in water Contact time: • 15 minutes (bacteria and yeasts) • 20 minutes (fungi) Temperature: 20°C
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes: 1000L, 20L, 10L, 5L, 2L, 1L 1000L: tank, High density polyethylene (HDPE) 20L, 10L, 5L: can, HDPE 2L, 1L: bottle, HDPE

2.1.34.4.1 Use-specific instructions for use

-

2.1.34.4.2 Use-specific risk mitigation measures

- For application by mopping or wiping, professional users must wear gloves, body protection and chemical goggles.
- Do not dip your hands in the bucket.
- Apply the product only with a mop with a handle.

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

-

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

-

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

-

2.1.35 General directions for use of the meta SPC 8

2.1.35.1 Instructions for use

- Comply with the instructions for use.
- Make sure to wet surfaces completely.
- Allow to take effect for at least 15 to 20 minutes, depending on the activity.
- Clean carefully the surfaces before application of the product.
- Mix at a rate of 300 mL of product for 700 mL of water.
- Products should not be used in conjunction with acids or ammonia.

2.1.35.2 Risk mitigation measures

- For PT 4 use ,the disinfection of hard surfaces in contact with food is restricted to domestic areas
- For PT 2 use, avoid any direct or indirect contact with food.
- For PT 4 use, rinse surfaces after treatment.
- For mixing and loading and post-application task, professional users must wear gloves, body protection and chemical goggles.
- Do not touch the surface until it is totally dried
- Children should not be present during disinfection

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

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid
IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.
IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

2.1.35.4 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.

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

- Keep out of reach of children and non-target animals/pets.
- Do not store above 30°C
- Protect from direct sunlight
- Shelf life: 18 months

2.1.36 Other information

- The applicant should inform professional users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the BIOCIDAL PRODUCT FAMILY.
- Products are foaming formulations

PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

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

Trade name(s)	**12 - Eau de javel 2.6% détergente citron** **Eau de javel 2.6% détergente citron Nectra** **Eau de javel 2.6% détergente citron Mieuxa**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*
Dodecanenitrile	-	Surfactant	2437-25-4	219-440-1	0.05
Trade name(s)	**13 - Eau de javel 2.6% détergente eucalyptus** **Eau de javel 2.6% détergente eucalyptus Nectra**				

	Eau de javel 2.6% détergente eucalyptus Mieuxa **Flash White IPC** **Nettoyant moissures IT2C**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*

Trade name(s)	**14 - Eau de javel 2.6% fraicheur citron** **Eau de javel 2.6% fraicheur citron Nectra** **Eau de javel 2.6% fraicheur citron Mieuxa**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*
Dodecanenitrile	-	Surfactant	2437-25-4	219-440-1	0.05

Trade name(s)	**15 - Eau de javel 2.6% fraicheur eucalyptus** **Eau de javel 2.6% fraicheur eucalyptus Nectra** **Eau de javel 2.6% fraicheur eucalyptus Mieuxa** **Eau de javel 2.6% fraicheur eucalyptus Onyx**				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*

Trade name(s)	**17 - Eau de javel 2.6% détergente**

	Eau de javel 2.6% détergente Nectra				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Pure Sodium hypochlorite *(Active chlorine released from sodium hypochlorite)*	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	2.73 *(2.6)*

2.1.38 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)
Container (Meta SPC 1, 2 and 8)	1000L	HDPE		Professional	Yes
Can/tin (Meta SPC 1, 2, 5 and 8)	20L, 10L	HDPE		Professional, non-professional	Yes
Bottle (Meta SPC 1, 2 and 8)	2L, 1L	HDPE		Professional, non-professional	Yes
Bottle (Meta SPC 2)	250 mL	HDPE		Professional, non-professional	Yes
Spray bottle (Meta SPC 3)	800mL	HDPE	HDPE spray system (TS5 Guala) + Viton seal	Professional, non-professional	Yes

2.1.39 Documentation

2.1.39.1 Data submitted in relation to product application

New studies have been submitted for physico-chemical properties and analytical methods. New data with the product family have been submitted for the demonstration of the efficacy. Please refer to the list of references

2.1.39.2 Access to documentation

A letter of access to the data of the CAR of sodium hypochlorite has been submitted by Euro Chlor (owners of studies on sodium hypochlite for PTs 1, 2, 3, 4, 5, 11 and 12) and allows ARDEA SA, COLDIS, Comptoir Produits Chimiques Entretien and Notilia Group to refer to active substance data.

2.2 Assessment of the biocidal product family

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

Use # 1 – Disinfection of surfaces by spraying (Meta SPC 1, 2, 3, 5, 8)

Table 1. Use # 1 – Disinfection of surfaces by spraying

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces by spraying: hard surface (utensils, equipment, furniture)
Target organism (including development stage)	Bacteria, yeast, fungi
Field of use	Indoor
Application method(s)	Spraying On hard non-porous surfaces with or without prior cleaning, at +20°C during 5 min: Thoroughly rinse the surfaces after disinfection. The product applied by spraying is - a soluble concentrate (SL) to be diluted in drinking water in the sprayer tank, - or a ready to use solution (AL) (see use-specific instruction for use)
Application rate(s) and frequency	Final concentration of active substance on surfaces is 4.1 g/l NaOCl (3900 ppm of active available chlorine). Apply at an adequate frequency based on the hygiene plan in place.
Category(ies) of users	Professional Non-professional
Pack sizes and packaging material	Please see the relevant section.

Use # 2 – Disinfection of surfaces (floors) by wiping with mop/cloth and bucket (Meta SPC 1, 2, 5, 8)

Table 2. Use # 2 – Disinfection of surfaces by wiping with mop/cloth and bucket

Product Type	PT2, PT4
Where relevant, an exact description of the authorised use	Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket
Target organism (including development stage)	Bacteria, yeast, fungi
Field of use	Indoor
Application method(s)	Wiping On hard non-porous surfaces with or without prior cleaning, at +20°C during 5 min: Thoroughly rinse the surfaces after disinfection.

	The product applied by wiping is a soluble concentrate (SL) to be diluted in drinking water. (see use-specific instruction for use)
Application rate(s) and frequency	Final concentration of active substance on surfaces is 4.1 g/l NaOCl (3900 ppm of active available chlorine). Apply at an adequate frequency based on the hygiene plan in place.
Category(ies) of users	Professional Non-professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Physicochemical studies have been undertaken on representative formulations of the family. Those studies are performed on:

- The formulation of Meta SPC 1.
- Three formulations of Meta SPC 2, covering its range of active substance concentrations.
- The formulation of Meta SPC 3.
- The formulation of Meta SPC 5.
- A worst-case formulation of Meta SPC 8 (product sodium hychlorite 2.6% + 5% perfumed detergent). This covers all the product of the Meta SPC 8 as they have the same active substance concentration.

The studies cover the dermination of the relevant physicochemical properties of the test items, as well as their stability when stored at ambient temperature.

Some stability studies are still ongoing. Intermediate results of the stability assessment are available.
All available results are described in the table below.

Dilution of products in authorised uses:

- Meta SPC 1: 30% v/v
- Meta SPC 2: 5% - 7.5% v/v (depending on the content of active substance in the product)
- Meta SPC 3: Ready-to-use products (Sprays)
- Meta SPC 5: 15% v/v
- Meta SPC 8: 30% v/v

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Physical state at 20 °C and 101.3 kPa	Sensory observation	Meta SPC 1 (2.73% sodium hypochlorite)	Liquid	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable
	Sensory observation	Meta SPC 2 (10.08% sodium hypochlorite)	Liquid	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	Sensory observation	Meta SPC 2 (13.125% sodium hypochlorite)	Liquid	E. Servajean, 2021, report 20-30-047-ES Part 1	Acceptable
	Sensory observation	Meta SPC 2 (15.225% sodium hypochlorite)	Liquid	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	Sensory observation	Meta SPC 3 (1.575% sodium hypochlorite)	Liquid	E. Servajean, 2020, report 20-30-017-ES Part 1	Acceptable
	Sensory observation	Meta SPC 5 (5.145% sodium hypochlorite)	Liquid	E. Servajean, 2020, report 20-30-019-ES Part 1	Acceptable
	Sensory observation	Meta SPC 8 (2.73% sodium hypochlorite)	Liquid	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable
Colour at 20 °C and 101.3 kPa	Sensory observation	Meta SPC 1 (2.73% sodium hypochlorite)	Light yellow, translucent	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable
	Sensory observation	Meta SPC 2 (10.08% sodium hypochlorite)	Light yellow, translucent	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	Sensory observation	Meta SPC 2 (13.125% sodium hypochlorite)	Light yellow, translucent	E. Servajean, 2021, report	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
				20-30-047-ES Part 1	
	Sensory observation	Meta SPC 2 (15.225% sodium hypochlorite)	Light yellow, translucent	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	Sensory observation	Meta SPC 3 (1.575% sodium hypochlorite)	Light yellow, translucent	E. Servajean, 2020, report 20-30-017-ES Part 1	Acceptable
	Sensory observation	Meta SPC 5 (5.145% sodium hypochlorite)	Light yellow, translucent	E. Servajean, 2020, report 20-30-019-ES Part 1	Acceptable
	Sensory observation	Meta SPC 8 (2.73% sodium hypochlorite)	Colourless, translucent	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable
Odour at 20 °C and 101.3 kPa	Sensory observation	Meta SPC 1 (2.73% sodium hypochlorite)	Characteristic chlorinated odour	Applicant data	Acceptable
	Sensory observation	Meta SPC 2 (10.08% sodium hypochlorite)	Characteristic chlorinated odour	Applicant data	Acceptable
	Sensory observation	Meta SPC 2 (13.125% sodium hypochlorite)	Characteristic chlorinated odour	Applicant data	Acceptable
	Sensory observation	Meta SPC 2 (15.225% sodium hypochlorite)	Characteristic chlorinated odour	Applicant data	Acceptable
	Sensory observation	Meta SPC 3 (1.575% sodium hypochlorite)	Characteristic chlorinated odour	Applicant data	Acceptable
	Sensory observation	Meta SPC 5 (5.145% sodium hypochlorite)	Characteristic chlorinated odour	Applicant data	Acceptable
	Sensory observation	Meta SPC 8 (2.73% sodium hypochlorite)	Characteristic chlorinated odour or perfumed odour (lemon or eucalyptus) depending on the presence or absence of perfume and on its nature	Applicant data	Acceptable
Acidity / alkalinity	pH: CIPAC MT 75.3	Meta SPC 1 (2.73% sodium hypochlorite)	pH = 12.2 (neat product) pH = 10.3 (1% w/v dilution) Alkalinity = 0.12% w/w (as NaOH) (neat product)	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
	Alkalinity: CIPAC MT 191				
	pH: CIPAC MT 75.3 Alkalinity: CIPAC MT 191	Meta SPC 2 (10.08% sodium hypochlorite)	pH = 12.8 (neat product) pH = 10.9 (1% w/v dilution) Alkalinity = 0.38% w/w (as NaOH) (neat product)	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	pH: CIPAC MT 75.3 Alkalinity: CIPAC MT 191	Meta SPC 2 (13.125% sodium hypochlorite)	pH = 12.9 (neat product) pH = 11.0 (1% w/v dilution) Alkalinity = 0.38% w/w (as NaOH) (neat product)	E. Servajean, 2021, report 20-30-047-ES Part 1	Acceptable
	pH: CIPAC MT 75.3 Alkalinity: CIPAC MT 191	Meta SPC 2 (15.225% sodium hypochlorite)	pH = 13.0 (neat product) pH = 11.0 (1% w/v dilution) Alkalinity = 0.42% w/w (as NaOH) (neat product)	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	pH: CIPAC MT 75.3 Alkalinity: CIPAC MT 191	Meta SPC 3 (1.575% sodium hypochlorite)	pH = 12.0 (neat product) pH = 10.1 (1% w/v dilution) Alkalinity = 0.07% w/w (as NaOH) (neat product)	E. Servajean, 2020, report 20-30-017-ES Part 1	Acceptable
	pH: CIPAC MT 75.3 Alkalinity: CIPAC MT 191	Meta SPC 5 (5.145% sodium hypochlorite)	pH = 12.4 (neat product) pH = 11.6 (1% w/v dilution) Alkalinity = 0.20% w/w (as NaOH) (neat product)	E. Servajean, 2020, report 20-30-019-ES Part 1	Acceptable
	pH: CIPAC MT 75.3	Meta SPC 8 (2.73% sodium hypochlorite)	pH = 12.2 (neat product) pH = 11.4 (1% w/v dilution) Alkalinity = 0.11% w/w (as NaOH) (neat product)	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
	Alkalinity: CIPAC MT 191				
Relative density / bulk density	OECD 109	Meta SPC 1 (2.73% sodium hypochlorite)	D^{20}_4=1.052 (20°C)	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable
	OECD 109	Meta SPC 2 (10.08% sodium hypochlorite)	D^{20}_4=1.18 (20°C)	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	OECD 109	Meta SPC 2 (13.125% sodium hypochlorite)	D^{20}_4=1.218 (20°C)	E. Servajean, 2021, report 20-30-047-ES Part 1	Acceptable
	OECD 109	Meta SPC 2 (15.225% sodium hypochlorite)	D^{20}_4=1.242 (20°C)	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	OECD 109	Meta SPC 3 (1.575% sodium hypochlorite)	D^{20}_4=1.028 (20°C)	E. Servajean, 2020, report 20-30-017-ES Part 1	Acceptable
	OECD 109	Meta SPC 5 (5.145% sodium hypochlorite)	D^{20}_4=1.091 (20°C)	E. Servajean, 2020, report 20-30-019-ES Part 1	Acceptable
	OECD 109	Meta SPC 8 (2.73% sodium hypochlorite)	D^{20}_4=1.051 (20°C)	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable
Storage stability test – **accelerated storage**	CIPAC method MT46.3 Active chlorine method:	0.98% active chlorine Product Javel 0.8% detergente citron – Meta SPC 4 (abandoned)	The test item was stored in glass flasks of 100mL during 14 days at 54°C.	Study report RRCo-000375_01	Not acceptable The degradation of the active content is > 10%.

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td>ANA_MON_102
Sodium chlorate method:
ANA_MON_103</td><td></td><td>
<table>
<tr><th>Parameter</th><th>Initial</th><th>14 days at 54°C</th></tr>
<tr><td>Appearance</td><td colspan="2">Colourless liquid with a typical odour of bleach</td></tr>
<tr><td>Weight change</td><td>-</td><td>No variation</td></tr>
<tr><td>Active chlorine (%w/w)</td><td>0.98</td><td>< LOQ*
(100.0 % of decrease)</td></tr>
<tr><td>Sodium chlorate content (%w/w)</td><td>0.03</td><td>0.13</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>3</td><td>-</td></tr>
<tr><td>pH</td><td>10</td><td>7.8</td></tr>
<tr><td>alkalinity (%w/w as NaOH)</td><td>0.4</td><td>0.0</td></tr>
<tr><td>Dilution stability (at 5% dilution and after 18h)</td><td>No separated material.</td><td>No separated material.</td></tr>
<tr><td>Persistent foaming (mL) (at 100%)</td><td>After 10s: 133
After 1min: 124
After 3min: 123
After 12 min: 122</td><td>No persistent foam</td></tr>
</table>
* LOQ : Limit of quantification i.e. 0.0003%.
</td><td></td><td>The biocidal product is not stable after accelerated storage.
The product should not be stored above 30°C.</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC method MT46.3</td><td>12.78% active chlorine
Product Javel 13-16% - Meta SPC 2</td><td>The test item was stored in glass flasks of 100mL during 14 days at 54°C.</td><td>Study report RRCo-000377_01</td><td>Not acceptable

The degradation of the active content is > 10%.
The biocidal product is not</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><th>Parameter</th><th>Initial</th><th>14 days at 54°C</th></tr>
<tr><td>Appearance</td><td>Yellow liquid with a typical odour of bleach</td><td>Colourless liquid with a typical odour of bleach</td></tr>
<tr><td>Weight change</td><td>-</td><td>No variation</td></tr>
<tr><td>Active chlorine (%w/w)</td><td>12.78</td><td>2.01 (84.2% of decrease)</td></tr>
<tr><td>Sodium chlorate content (%w/w)</td><td>2.57</td><td>7.43</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>20%</td><td>369%</td></tr>
<tr><td>pH</td><td>11.2</td><td>11.2</td></tr>
<tr><td>alkalinity (%w/w as NaOH)</td><td>4.9</td><td>1.4</td></tr>
<tr><td>Dilution stability (at 5% dilution and after 18h)</td><td>Presence of particles in the bottom of the flask and supernatant particles</td><td>Presence of white cloud in the bottom of the flask and supernatant particles.</td></tr>
<tr><td>Persistent foaming (mL) (at 100%)</td><td>No persistent foam</td><td>No persistent foam</td></tr>
</table>
</td><td></td><td>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 human health section regarding conclusion on chlorate content.</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5</td><td>Meta SPC 1 (2.73% sodium hypochlorite)</td><td>Ongoing study (24 months at ambient temperature).
Intermediate results up to 9 months of storage are available.
The test item was stored in HDPE 1L bottles at 18-22°C protected from light.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 6 MONTHS</th><th>AFTER 9 MONTHS</th></tr>
</table>
</td><td>E. Servajean, 2021, report 20-30-009-ES Interim</td><td>The degradation of the active content is >10% after 6 and 9 months of storage.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr>
<td></td>
<td>Chlorate: See section 2.2.5

Appearance and packaging: visual observation

pH: CIPAC MT 75.3

Alkalinity: CIPAC MT 191

Dilution stability: CIPAC MT 41.1</td>
<td></td>
<td>
<table>
<tr><td>Active chlorine</td><td>26.7 g/kg</td><td>22.3 g/kg (83.5% of initial)</td><td>23.2 g/kg (86.9% of initial)</td></tr>
<tr><td>Chlorate</td><td>0.86 g/kg</td><td>1.35 g/kg (156.6% of initial)</td><td>1.39 g/kg (161.4% of initial)</td></tr>
<tr><td>Sodium Chlorate</td><td>1.1 g/kg</td><td>1.7 g/kg</td><td>1.8 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>4.1</td><td>7.7</td><td>7.6</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>0.05%</td><td>0.12%</td></tr>
<tr><td>pH on neat item</td><td>12.2</td><td>N/A</td><td>12.3</td></tr>
<tr><td>Free alkalinity</td><td>0.12% NaOH w/w</td><td>N/A</td><td>0.13% NaOH w/w</td></tr>
<tr><td>Dilution stability in water at 1.0% v/v and after 24h</td><td>No separated material</td><td>N/A</td><td>No separated material</td></tr>
<tr><td>Dilution stability in water at 30% v/v and after 24h</td><td>No separated material</td><td>N/A</td><td>No separated material</td></tr>
</table>
The physicochemical properties were found to be stable throughout the storage period.
</td>
<td></td>
<td>the product could be considered stable after 9 months at ambient temperature, providing that efficacy tests are acceptable.

Moreover, chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage. Please refer to human health section regarding conclusion on chlorate content.</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>The active substance content decreased by more than 10%.
However, this has been taken into account for the determination of the in-use concentration of the product.
It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after 6 and 9 months of storage.</td><td></td><td></td></tr>
<tr><td></td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5

Appearance and packaging: visual observation

pH: CIPAC MT 75.3

Alkalinity: CIPAC MT 191

Dilution stability: CIPAC MT 41.1</td><td>Meta SPC 2 (10.08% sodium hypochlorite)</td><td>The test item was stored in HDPE 1L bottles at ambient temperature for 5.5 months and protected from light.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 3 MONTHS</th><th>AFTER 5.5 MONTHS</th></tr>
<tr><td>Active chlorine</td><td>98.7 g/kg</td><td>70.1 g/kg (71.1% of initial)</td><td>33.9 g/kg (34.4% of initial)</td></tr>
<tr><td>Chlorate</td><td>7.05 g/kg</td><td>13.1 g/kg (185.6% of initial)</td><td>20.4 g/kg (288.9% of initial)</td></tr>
<tr><td>Sodium chlorate</td><td>9 g/kg</td><td>16.7 g/kg</td><td>26 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>9.1</td><td>23.8</td><td>76.7</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>0.03%</td><td>0.06%</td></tr>
<tr><td>pH on neat item</td><td>12.8</td><td>N/A</td><td>12.8</td></tr>
<tr><td>Free alkalinity</td><td>0.38% NaOH</td><td>N/A</td><td>0.38% NaOH w/w</td></tr>
</table></td><td>E. Servajean, 2021, report 20-30-016-ES Part 2</td><td>The degradation of the active content is >10%.
The product could be considered stable after 3 months at ambient temperature, providing that efficacy tests are acceptable.

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 human health section regarding conclusion on chlorate content.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
	Persistent foaming: CIPAC MT 47.3		<table><tr><td></td><td>w/w</td><td></td><td></td></tr><tr><td>Dilution stability in water at 25% v/v and after 24h</td><td>No separated material</td><td>N/A</td><td>Sparse flocculated material at the bottom (< 2mL)</td></tr><tr><td>Dilution stability in water at 50% v/v and after 24h</td><td>No separated material</td><td>N/A</td><td>Sparse flocculated material at the bottom (<2mL)</td></tr><tr><td>Persistent foaming at 25% v/v</td><td>No foam after 1 min</td><td>N/A</td><td>No foam after 1 min</td></tr><tr><td>Persistent foaming at 50% v/v</td><td>No foam after 1 min</td><td>N/A</td><td>2mL of foam after 1 min</td></tr></table> The physicochemical properties were found to be stable throughout the storage period. The active substance content decreased by more than 10%. However, this has been taken into account for the determination of the in-use concentration of the product. It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after storage. Moreover, the max. use rate for this product is covered by the concentation tested (25% v/v).		
	GIFAP monograph no.17 Active chlorine: See section 2.2.5	Meta SPC 2 (13.125% sodium hypochlorite)	Ongoing study (6 months at ambient temperature). Intermediate results up to 3 months of storage are available. The test item was stored in HDPE 1L bottles at 18-22°C protected from light. <table><tr><td>RESULTS</td><td>UPON RECEIPT</td><td>AFTER 3 MONTHS</td></tr></table>	E. Servajean, 2021, report 20-30-047-ES Interim	The degradation of the active content is >10%. The product could be considered

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr>
<td></td>
<td>Chlorate: See section 2.2.5

Appearance and packaging: visual observation

pH: CIPAC MT 75.3

Alkalinity: CIPAC MT 191

Dilution stability: CIPAC MT 41.1

Persistent foaming: CIPAC MT 47.3</td>
<td></td>
<td>
<table>
<tr><td>Active chlorine</td><td>123.5 g/kg</td><td>104.9 g/kg
(85.0% of initial)</td></tr>
<tr><td>Chlorate</td><td>2.02 g/kg</td><td>16.1 g/kg
(797.0% of initial)</td></tr>
<tr><td>Sodium chlorate</td><td>2.6 g/kg</td><td>20.5 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>2</td><td>19.6</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>0.09%</td></tr>
<tr><td>pH on neat item</td><td>12.9</td><td>12.8</td></tr>
<tr><td>Free alkalinity</td><td>0.38% NaOH w/w</td><td>0.38% NaOH w/w</td></tr>
<tr><td>Dilution stability in water at 1.67% v/v in water and after 24h</td><td>2 mL flocculated material at the bottom</td><td>2 mL flocculated material at the bottom</td></tr>
<tr><td>Persistent foaming at 0.2% v/v in water</td><td>No foam after 1 min</td><td>No foam after 1 min</td></tr>
<tr><td>Persistent foaming at 2% v/v in water</td><td>No foam after 1 min</td><td>No foam after 1 min</td></tr>
</table>
</td>
<td></td>
<td>stable after 3 months at ambient temperature, providing that efficacy tests are acceptable.

Chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage. Please refer to human health section regarding conclusion on chlorate content.</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>The physicochemical properties were found to be stable throughout the storage period.
The active substance content decreased by more than 10% and is higher than 50% after 5.5 months. However, this has been taken into account for the determination of the in-use concentration of the product.
It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage.
Moreover, the max. use rate for this product is covered by the concentation tested for the product “10.08% sodium hy-pochlorite” (25% v/v).</td><td></td><td></td></tr>
<tr><td></td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5

Appearance and packaging: visual observation

pH: CIPAC MT 75.3

Alkalinity: CIPAC MT 191</td><td>Meta SPC 2 (15.225% sodium hypochlorite)</td><td>Ongoing study (6 months at ambient temperature).
Intermediate results up to 3 months of storage are available.
The test item was stored in HDPE 1L bottles at 18-22°C protected from light.

<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 3 MONTHS</th></tr>
<tr><td>Active chlorine</td><td>147.1 g/kg</td><td>115.9 g/kg
(78.8% of initial)</td></tr>
<tr><td>Chlorate</td><td>2.43 g/kg</td><td>22.2 g/kg
(913.4% of initial)</td></tr>
<tr><td>Sodium chlorate</td><td>3.1 g/kg</td><td>28.3 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>2.1</td><td>24.4</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>0.13%</td></tr>
<tr><td>pH on neat item</td><td>13.0</td><td>12.9</td></tr>
<tr><td>Free alkalinity</td><td>0.42% NaOH w/w</td><td>0.42% NaOH w/w</td></tr>
<tr><td>Dilution stability</td><td>2 mL flocculated</td><td>2 mL flocculated</td></tr>
</table></td><td>E. Servajean, 2021, report 20-30-042-ES Interim</td><td>The degradation of the active content is >10%.
The product could be considered stable after 3 months at ambient temperature, providing that efficacy tests are acceptable.

Chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage. Please refer to human</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td>Dilution stability: CIPAC MT 41.1

Persistent foaming: CIPAC MT 47.3</td><td></td><td>
<table>
<tr><td>in water at 1.67% v/v in water and after 24h</td><td>material at the bottom</td><td>material at the bottom</td></tr>
<tr><td>Persistent foaming at 0.167% v/v in water</td><td>No foam after 1 min</td><td>No foam after 1 min</td></tr>
<tr><td>Persistent foaming at 1.67% v/v in water</td><td>No foam after 1 min</td><td>No foam after 1 min</td></tr>
</table>
The physicochemical properties were found to be stable throughout the storage period.
The active substance content decreased by more than 10%.
However, this has been taken into account for the determination of the in-use concentration of the product.
It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage.
Moreover, the max. use rate for this product is covered by the concentation tested for the product “10.08% sodium hy-pochlorite” (25% v/v).
</td><td></td><td>health section regarding conclusion on chlorate content.</td></tr>
<tr><td></td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5

Appearance and</td><td>Meta SPC 3 (1.575% sodium hypochlorite)</td><td>Ongoing study (24 months at ambient temperature).
Intermediate results up to 9 months of storage are available.
The test item was stored in HDPE 0.8L bottles with sprayers (TS5 guala) at 18-22°C, protected from light.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 6 MONTHS</th><th>AFTER 9 MONTHS</th></tr>
<tr><td>Active chlorine</td><td>15.5 g/kg</td><td>9.1 g/kg (59.0% of initial)</td><td>13.1 g/kg (84.6% of initial)</td></tr>
<tr><td>Chlorate</td><td>0.48 g/kg</td><td>0.62 g/kg (129.2% of</td><td>0.62 g/kg (130.1% of</td></tr>
</table>
</td><td>E. Servajean, 2021, report 20-30-17-ES Interim</td><td>The degradation of the active content is >10%.
The product could be considered stable after 9 months at ambient temperature, providing that efficacy tests are acceptable.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr>
<td></td>
<td>packaging: visual observation

pH: CIPAC MT 75.3

Alkalinity: CIPAC MT 191

Priming and discharge rate: FEA 643

Spray pattern: FEA 644</td>
<td></td>
<td>
<table>
<tr><td></td><td></td><td>initial)</td><td>initial)</td></tr>
<tr><td>Sodium chlorate</td><td>0.6 g/kg</td><td>0.8 g/kg</td><td>0.8 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>3.9</td><td>8.7</td><td>6</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>0.04%</td><td>0.07%</td></tr>
<tr><td>pH on neat item</td><td>12.0</td><td>N/A</td><td>12.1</td></tr>
<tr><td>Free alkalinity</td><td>0.07% NaOH w/w</td><td>N/A</td><td>0.08% NaOH w/w</td></tr>
<tr><td>Spraying performances - Priming and discharge rate</td><td>Primed on the 6th stroke
Discharge rate
1.30 g (Unit 1)
1.34 g (Unit 2)
No clogging</td><td>N/A</td><td>Primed on the 6th stroke
Discharge rate
1.30 g (Unit 1)
1.31 g (Unit 2)
No clogging</td></tr>
<tr><td>Spraying performances - Spray pattern</td><td>Round shape
20-23 cm diameter</td><td>N/A</td><td>Round shape
15-19 cm diameter</td></tr>
</table>

The physicochemical properties were found to be stable throughout the storage period.
The active substance content decreased by more than 10%. However, this has been taken into account for the determination of the in-use concentration of the product.
</td>
<td></td>
<td>Chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage. Please refer to human health section regarding conclusion on chlorate content.

Moeover, it should be noted that the spray particles size distribution after storage is missing.</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage.

Moreover, the spray particles size distribution has not been performed after 6 and 9 months, as it is planned to be measured only after 24 months.</td><td></td><td></td></tr>
<tr><td></td><td>GIFAP monograph no.17

CIPAC MT 187</td><td>Meta SPC 3 (1.575% sodium hypochlorite)</td><td>Assessment of the spray particles size distribution after storage is ongoing (24-months storage at ambient temperature).</td><td>P. Padilla, study 20-914015-001</td><td>The particles size distribution after storage should be provided in post-authorisation.</td></tr>
<tr><td></td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5

Appearance and packaging: visual observation

pH: CIPAC MT 75.3

Alkalinity: CIPAC MT 191</td><td>Meta SPC 5 (5.145% sodium hypochlorite)</td><td>Storage at ambient temperature for 8 months.
The test item was stored in HDPE 5L cans at 18-22°C protected from light.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 3 MONTHS</th><th>AFTER 5.5 MONTHS</th></tr>
<tr><td>Active chlorine</td><td>48.2 g/kg</td><td>34.2 g/kg (70.8% of initial)</td><td>32.0 g/kg (66.4% of initial)</td></tr>
<tr><td>Chlorate</td><td>2.48 g/kg</td><td>3.71 g/kg</td><td>4.93 g/kg</td></tr>
<tr><td>Sodium chlorate</td><td>3.2 g/kg</td><td>4.7 g/kg</td><td>6.3 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>6.5</td><td>13.8</td><td>19.6</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
</table></td><td>E. Servajean, 2021, report 20-30-019-ES Part 2</td><td>The degradation of the active content is >10%.
The product could be considered stable after 8 months at ambient temperature, providing that efficacy tests are acceptable.

Chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td>Dilution stability: CIPAC MT 41.1

Persistent foaming: CIPAC MT 47.3</td><td></td><td>
<table>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>%</td><td>%</td></tr>
<tr><td>pH on neat item</td><td>12.4</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Free alkalinity</td><td>0.20% NaOH w/w</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Persistent foaming at 1.0% v/v in water</td><td>60 mL of foam after 1 min (30%)</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Persistent foaming at 4.0% v/v in water</td><td>82 mL of foam after 1 min (41%)</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Dilution stability in water at 4.0% v/v</td><td>No separated material</td><td>N/A</td><td>N/A</td></tr>
</table>
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 7 MONTHS</th><th>AFTER 8 MONTHS</th></tr>
<tr><td>Active chlorine</td><td>48.2 g/kg</td><td>32.0 g/kg (66.3% of initial)</td><td>34.5 g/kg (71.6% of initial)</td></tr>
<tr><td>Chlorate</td><td>2.48 g/kg</td><td>4.56 g/kg</td><td>3.84 g/kg</td></tr>
<tr><td>Sodium chlorate</td><td>3.2 g/kg</td><td>5.8 g/kg</td><td>4.9 g/kg</td></tr>
</table>
</td><td></td><td>storage. Please refer to human health section regarding conclusion on chlorate content.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>6.5</td><td>18.1</td><td>14.2</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>0.04%</td><td>0.03%</td></tr>
<tr><td>pH on neat item</td><td>12.4</td><td>N/A</td><td>11.8</td></tr>
<tr><td>Free alkalinity</td><td>0.20% NaOH w/w</td><td>N/A</td><td>0.12% NaOH w/w</td></tr>
<tr><td>Persistent foaming at 1.0% v/v in water</td><td>60 mL of foam after 1 min (30%)</td><td>N/A</td><td>54 mL of foam after 1 min (27%)</td></tr>
<tr><td>Persistent foaming at 4.0% v/v in water</td><td>82 mL of foam after 1 min (41%)</td><td>N/A</td><td>84 mL of foam after 1 min (42%)</td></tr>
<tr><td>Dilution stability in water at 4.0% v/v</td><td>No separated material</td><td>N/A</td><td>No separated material</td></tr>
</table>
The physicochemical properties were found to be stable throughout the storage period.
The active substance content decreased by more than 10%.
However, this has been taken into account for the determination of the in-use concentration of the product.
</td><td></td><td></td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after storage.

For Meta SPC 5, a use rate of 15% has been claimed. The dilution stability and the persistent foaming should have been tested at the max. use rate.
As the foam is > 60 mL at 4% v/v, products of Meta SPC 5 are foamig formulations.</td><td></td><td></td></tr>
<tr><td></td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5

Appearance and packaging: visual observation

pH: CIPAC MT 75.3

Alkalinity: CIPAC MT 191

Dilution stability: CIPAC MT 41.1</td><td>Meta SPC 8 (2.73% sodium hypochlorite)</td><td>Ongoing study (24 months at ambient temperature). The test item was stored in HDPE 1L bottles at 18-22°C protected from light.

Intermediate results up to 9 months of storage are available.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 3 MONTHS</th><th>AFTER 6 MONTHS</th><th>AFTER 9 MONTHS</th></tr>
<tr><td>Active chlorine</td><td>27.0 g/kg</td><td>23.5 g/kg (87.1% of initial)</td><td>20.2 g/kg (74.9% of initial)</td><td>24.0 g/kg (88.7% of initial)</td></tr>
<tr><td>Chlorate</td><td>0.82 g/kg</td><td>1.27 g/kg</td><td>1.36 g/kg</td><td>1.34 g/kg</td></tr>
<tr><td>Sodium chlorate</td><td>1 g/kg</td><td>1.6 g/kg</td><td>1.7 g/kg</td><td>1.7 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>3.9</td><td>6.9</td><td>8.6</td><td>7.1</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>Packaging</td><td>N/A</td><td>No deformation or alteration</td><td>No deformation or alteration</td><td>No deformation or alteration</td></tr>
<tr><td>Weight loss</td><td>N/A</td><td>0.02%</td><td>0.03%</td><td>0.09%</td></tr>
</table></td><td>E. Servajean, 2021, report 20-30-021-ES Interim</td><td>The degradation of the active content is >10%.
The product could be considered stable after 9 months at ambient temperature, providing that efficacy tests are acceptable.

Chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage. Please refer to human health section regarding</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td>Persistent foaming: CIPAC MT 47.3</td><td></td><td>
<table>
<tr><td>pH on neat item</td><td>12.2</td><td>N/A</td><td>N/A</td><td>12.0</td></tr>
<tr><td>Free alkalinity</td><td>0.11% NaOH w/w</td><td>N/A</td><td>N/A</td><td>0.09% NaOH w/w</td></tr>
<tr><td>Dilution stability in water at 1.0% v/v</td><td>No separated material</td><td>N/A</td><td>N/A</td><td>No separated material</td></tr>
<tr><td>Dilution stability in water at 30% v/v</td><td>No separated material</td><td>N/A</td><td>N/A</td><td>No separated material</td></tr>
<tr><td>Persistent foaming at 1.0% v/v</td><td>32 mL of foam after 1 min (16%)</td><td>N/A</td><td>N/A</td><td>30 mL of foam after 1 min (15%)</td></tr>
<tr><td>Persistent foaming at 30% v/v</td><td>100 mL of foam after 1 min (50%)</td><td>N/A</td><td>N/A</td><td>88 mL of foam after 1 min (44%)</td></tr>
</table>
The physicochemical properties were found to be stable throughout the storage period.
The active substance content decreased by more than 10%.
However, this has been taken into account for the determination of the in-use concentration of the product.
It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage.
As the foam is > 60 mL at 30% v/v, products of Meta SPC 8 are foamig formulations.
</td><td></td><td>conclusion on chlorate content.</td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>CIPAC MT 39.3</td><td>Meta SPC 1 (2.73% sodium hypochlorite)</td><td>Storage procedure at 0°C for 7 days.
<table>
<tr><td></td><td>Initial</td><td>7 day at 0°C</td></tr>
<tr><td>Appearance</td><td colspan="2">Light yellow translucent liquid</td></tr>
</table>
</td><td>E. Servajean, 2020, report 20-30-009-ES Part 1</td><td>The product is stable after a storage of 7 days at 0°C.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Available chlorine (g/kg)</td><td>26.7 g/kg</td><td>27.2 g/kg (101.9% of initial)</td></tr>
<tr><td>pH on neat item</td><td>12.2</td><td>12.3</td></tr>
<tr><td>pH of a 1% w/v dilution</td><td>10.3</td><td>10.4</td></tr>
<tr><td>alkalinity (%w/w as NaOH)</td><td>0.12% NaOH w/w</td><td>0.12% NaOH w/w</td></tr>
</table>
No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures.
</td><td></td><td></td></tr>
<tr><td></td><td>CIPAC MT 39.3</td><td>Meta SPC 2 (10.08% sodium hypochlorite)</td><td>
Storage procedure at 0°C for 7 days.
<table>
<tr><td></td><td>Initial</td><td>7 day at 0°C</td></tr>
<tr><td>Appearance</td><td colspan="2">Light yellow translucent liquid</td></tr>
<tr><td>Available chlorine (g/kg)</td><td>98.7 g/kg</td><td>87.2 g/kg (88.3% of initial)</td></tr>
<tr><td>pH on neat item</td><td>12.8</td><td>12.8</td></tr>
<tr><td>pH of a 1% w/v dilution</td><td>10.9</td><td>11</td></tr>
<tr><td>alkalinity (%w/w as NaOH)</td><td>0.38% NaOH w/w</td><td>0.37% NaOH w/w</td></tr>
</table>
No separated solid or oily matter observed at the end of the storage procedure.
A decrease of the active substance contente >10% is observed after storage. However, this degradation is also noted during storage at ambient temperature and is not due to low storage.
The product is therefore considered stable at low temperatures.
</td><td>E. Servajean, 2020, report 20-30-016-ES Part 1</td><td>The product is stable after a storage of 7 days at 0°C.</td></tr>
<tr><td></td><td>CIPAC MT 39.3</td><td>Meta SPC 3 (1.575% sodium hypochlorite)</td><td>
Storage procedure at 0°C for 7 days.
<table>
<tr><td></td><td>Initial</td><td>7 day at 0°C</td></tr>
<tr><td>Appearance</td><td colspan="2">Light yellow translucent liquid</td></tr>
<tr><td>Available chlorine (g/kg)</td><td>15.5 g/kg</td><td>15.2 g/kg (98.2% of initial)</td></tr>
<tr><td>pH on neat item</td><td>12.0</td><td>12.1</td></tr>
<tr><td>pH of a 1% w/v dilution</td><td>10.1</td><td>10.2</td></tr>
</table>
</td><td>E. Servajean, 2020, report 20-30-017-ES Part 1</td><td>The product is stable after a storage of 7 days at 0°C.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>alkalinity (%w/w as NaOH)</td><td>0.07% NaOH w/w</td><td>0.06% NaOH w/w</td></tr>
</table>
No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures.
</td><td></td><td></td></tr>
<tr><td></td><td>CIPAC MT 39.3</td><td>Meta SPC 5 (5.145% sodium hypochlorite)</td><td>
Storage procedure at 0°C for 7 days.
<table>
<tr><td></td><td>Initial</td><td>7 day at 0°C</td></tr>
<tr><td>Appearance</td><td colspan="2">Light yellow translucent liquid</td></tr>
<tr><td>Available chlorine (g/kg)</td><td>48.2 g/kg</td><td>46.2 g/kg (95.9% of initial)</td></tr>
<tr><td>pH on neat item</td><td>12.4</td><td>12.5</td></tr>
<tr><td>pH of a 1% w/v dilution</td><td>11.6</td><td>10.7</td></tr>
<tr><td>alkalinity (%w/w as NaOH)</td><td>0.20% NaOH w/w</td><td>0.19% NaOH w/w</td></tr>
</table>
No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures.
</td><td>E. Servajean, 2020, report 20-30-019-ES Part 1</td><td>The product is stable after a storage of 7 days at 0°C.</td></tr>
<tr><td></td><td>CIPAC MT 39.3</td><td>Meta SPC 8 (2.73% sodium hypochlorite)</td><td>
Storage procedure at 0°C for 7 days.
<table>
<tr><td></td><td>Initial</td><td>7 day at 0°C</td></tr>
<tr><td>Appearance</td><td colspan="2">Colourless translucent liquid</td></tr>
<tr><td>Available chlorine (g/kg)</td><td>27.0 g/kg</td><td>26.4 g/kg (97.5% of initial)</td></tr>
<tr><td>pH on neat item</td><td>12.2</td><td>12.2</td></tr>
<tr><td>pH of a 1% w/v dilution</td><td>11.4</td><td>10.4</td></tr>
<tr><td>alkalinity (%w/w as NaOH)</td><td>0.11% NaOH w/w</td><td>0.09% NaOH w/w</td></tr>
</table>
No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures.
</td><td>E. Servajean, 2020, report 20-30-021-ES Part 1</td><td>The product is stable after a storage of 7 days at 0°C.</td></tr>
<tr><td>Effects on content of the active substance and technical</td><td>Waived</td><td></td><td>Not relevant (The opaque nature of the containers is sufficient to protect the products from the light).</td><td></td><td>According to the CAR of the active</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
characteristics of the biocidal product - **light**					substance, sodium hypochlorite is very sensitive to photolysis in water. An adequate mitigation measure "protect from direct sunlight" should be added on the label of products.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC method MT46.3 accelerated storage procedure in accordance with OECD Guidance document ENV/JM/MONO(2015)32	0.98% and 12.78 % active chlorine	Storage at 54.5°C for 14 days - the analytical results demonstrated a diminution of active chlorine from 0.98 to < 0.0003 % and an augmentation of sodium chlorate from 0.03 to 0.13 %; - the analytical results demonstrated a diminution of active chlorine from 12.78 to 2.01 % and an augmentation of sodium chlorate from 2.57 to 7.43 %; Considering both results, all products of the family should not be stored above 30°C.	Study report RRCo-000377_01 and Study report RRCo-000375_01	The products should not be stored above 30°C.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Assessed during the ongoing stability studies at ambient temperature. No reactivity of the formulations towards the container material was observed.		Acceptable
Wettability	Waived		Not required for SL nor AL formulations.		Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
Suspensibility, spontaneity and dispersion stability	Waived		Not required for SL nor AL formulations.		Acceptable
Wet sieve analysis and dry sieve test	Waived		Not required for SL nor AL formulations.		Acceptable
Emulsifiability, re-emulsifiability and emulsion stability	Waived		Not required for SL nor AL formulations.		Acceptable
Disintegration time	Waived		Not required for SL nor AL formulations.		Acceptable
Particle size distribution, content of dust/fines, attrition, friability	Waived	-	Particle size distribution for products of Meta SPC 3 are reported below with spray characteristics.	-	Acceptable
Persistent foaming	CIPAC MT 47.3	Meta SPC 1 (2.73% sodium hypochlorite)	Covered by Meta SPC 2: no foam is formed.	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable
	CIPAC MT 47.3	Meta SPC 2 (10.08% sodium hypochlorite)	At 25% v/v: no foam after 1 min. At 50% v/v: no foam after 1 min.	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	CIPAC MT 47.3	Meta SPC 2 (13.125% sodium hypochlorite)	At 0.2% v/v: no foam after 1 min. At 2% v/v: no foam after 1 min. The max. use rate for this product is covered by the 25% v/v concentration tested for the 10.08% sodium hypochlorite, as all products of Meta SPC 2 are dilutions of the active substance solution.	E. Servajean, 2021, report 20-30-047-ES Part 1	Acceptable
	CIPAC MT 47.3	Meta SPC 2 (15.225% sodium hypochlorite)	At 0.167% v/v: no foam after 1 min. At 1.67% v/v: no foam after 1 min The max. use rate for this product is covered by the 25% v/v concentration tested for the 10.08% sodium hypochlorite, as all products of Meta SPC 2 are dilutions of the active substance solution.	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	-	Meta SPC 3 (1.575% sodium hypochlorite)	Not required for a ready to use liquid formulation.	-	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
	CIPAC MT 47.3	Meta SPC 5 (5.145% sodium hypochlorite)	At 1% v/v: 60 mL of foam after 1 min. 50 mL after 12 min. At 4% v/v: 82 mL of foam after 1 min. 60 mL after 12 min. For Meta SPC 5, a use rate of 15% has been claimed. The persistent foaming should have been tested at the max. use rate. As the foam is > 60 mL at 4% v/v, products of Meta SPC 5 are foamig formulations.	E. Servajean, 2021, Amendment to the final report 20-30-019-ES Part 1	Acceptable The mention « foaming products » is proposed.
	CIPAC MT 47.3	Meta SPC 8 (2.73% sodium hypochlorite)	At 1% v/v : 32 mL of foam after 1 min. At 30% v/v: 100 mL of foam after 1 min. 52 mL after 12 min. As the foam is > 60 mL at 30% v/v, products of Meta SPC 8 are foamig formulations.	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable The mention « foaming products » is proposed.
Flowability/Pourability/ Dustability	Waived		Not required for SL nor AL formulations.		Acceptable
Burning rate — smoke generators	Waived		Not required for SL nor AL formulations.		Acceptable
Burning completeness — smoke generators	Waived		Not required for SL nor AL formulations.		Acceptable
Composition of smoke — smoke generators	Waived		Not required for SL nor AL formulations.		Acceptable
Spraying pattern — aerosols	Waived		The products are not aerosols.		Acceptable
Spray characteristics – trigger spray	Priming and discharge rate: FEA 643 Spray pattern: FEA 644	Meta SPC 3 (1.575% sodium hypochlorite)	Priming: Primed on the 6th stroke. Discharge rate = 1.32 g/spray. Spray pattern: Round shape, 20-23 cm diameter.	E. Servajean, 2020, report 20-30-017-ES Part 1	Acceptable
Particle size distribution – trigger spray	CIPAC MT 187	Meta SPC 3 (1.575% sodium hypochlorite)	The percentage of the respirable volume fraction less than 10 µm is 0.081%. The mean results on three assays are the following: Dv(0.1) = 84.73 µm Dv(0.5) = 193.6 µm	P. Padilla, 2021, Intermediary report 20-914015-001	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
			Dv(0.9) = 540.5 µm		
Physical compatibility	Waived		The formulations of the family are not used in combination with other products.		Acceptable
Chemical compatibility	Waived	Meta SPC 1 Meta SPC 3 Meta SPC 8	The formulations of the family are not used in combination with other products.		According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. The mention "EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine)" is proposed by the applicant. Products should not be used in conjunction with acids or ammonia.
		Meta SPC 2	The formulations of the family are not used in combination with other products.		According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
					The mention "EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine)" is proposed by the applicant. Moreover, the mention EUH031 "contact with acids liberates toxic gas" is also proposed by the applicant. Products should not be used in conjunction with acids or ammonia.
		Meta SPC 5	The formulations of the family are not used in combination with other products.		According to the current knowledge, sodium hypochlorite can react with acids to form chlorine gas. The mention "EUH206: Warning! Do not use together with other products. May release

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
					dangerous gases (chlorine)" is proposed by eCA. Moreover, the mention EUH031 "contact with acids liberates toxic gas" is also proposed by eCA in SPC according to ATP13 of CLP regulation. Products should not be used in conjunction with acids or ammonia.
Degree of dissolution and dilution stability	CIPAC MT 41.1	Meta SPC 1 (2.73% sodium hypochlorite)	At 1% v/v: no separated material. At 30% v/v: no separated material.	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable
	CIPAC MT 41.1	Meta SPC 2 (10.08% sodium hypochlorite)	At 25% v/v: no separated material. At 50% v/v: no separated material. For products containing 10.08% sodium hypochlorite, a max. use rate of 17% has been claimed for fungi. This is covered with the 2 tested concentrations.	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	CIPAC MT 41.1	Meta SPC 2 (13.125% sodium hypochlorite)	At 2% v/v: 2mL of flocculated material at the bottom. For products containing 13.125% sodium hypochlorite, a max. use rate of 9% has been claimed for fungi. Considering that all products of Meta SPC 2 are dilutions of the active substance solution, this is covered by the 25% v/v concentration tested for the 10.08% sodium hypochlorite.	E. Servajean, 2021, report 20-30-047-ES Part 1	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
	CIPAC MT 41.1	Meta SPC 2 (15.225% sodium hypochlorite)	At 1.67% v/v: 2mL of flocculated material at the bottom. For products containing 15.225% sodium hypochlorite, a max. use rate of 7.5% has been claimed for fungi. Considering that all products of Meta SPC 2 are dilutions of the active substance solution, this is covered by the 25% v/v concentration tested for the 10.08% sodium hypochlorite.	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	-	Meta SPC 3 (1.575% sodium hypochlorite)	Not required for a ready to use liquid formulation.	-	Acceptable
	CIPAC MT 41.1	Meta SPC 5 (5.145% sodium hypochlorite)	4% v/v: no separated material. For Meta SPC 5, a use rate of 25% has been claimed for fungi. The dilution stability should have been tested at the max. use rate.	E. Servajean, 2021, Amendement to the final report 20-30-019-ES Part 1	Acceptable
	CIPAC MT 41.1	Meta SPC 8 (2.73% sodium hypochlorite)	At 1% v/v: no separated material. At 30% v/v: 3mL of flocculated material at the bottom.	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable
Surface tension	OECD 115	Meta SPC 1 (2.73% sodium hypochlorite)	69.9 mN/m (20°C)	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable
	OECD 115	Meta SPC 2 (10.08% sodium hypochlorite)	66.4 mN/m (20°C)	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	OECD 115	Meta SPC 2 (13.125% sodium hypochlorite)	75.1 mN/m (20°C)	E. Servajean, 2021, report 20-30-047-ES Part 1	Acceptable
	OECD 115	Meta SPC 2 (15.225% sodium hypochlorite)	78.9 mN/m (20°C)	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	OECD 115	Meta SPC 3 (1.575% sodium hypochlorite)	62.5 mN/m (20°C)	E. Servajean, 2020, report	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	eCA assessment
				20-30-017-ES Part 1	
	OECD 115	Meta SPC 5 (5.145% sodium hypochlorite)	32.9 mN/m (20°C) The test item is considered as surface-active.	E. Servajean, 2020, report 20-30-019-ES Part 1	Acceptable
	OECD 115	Meta SPC 8 (2.73% sodium hypochlorite)	31.7 mN/m (20°C) The test item is considered as surface-active.	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable
Viscosity (Kinematic)	OECD 114	Meta SPC 1 (2.73% sodium hypochlorite)	20°C: 1.16 mm²/s 40°C: 0.76 mm²/s	E. Servajean, 2020, report 20-30-009-ES Part 1	Acceptable
	OECD 114	Meta SPC 2 (10.08% sodium hypochlorite)	20°C: 1.77 mm²/s 40°C: 1.14 mm²/s	E. Servajean, 2020, report 20-30-016-ES Part 1	Acceptable
	OECD 114	Meta SPC 2 (13.125% sodium hypochlorite)	20°C: 2.30 mm²/s 40°C: 1.39 mm²/s	E. Servajean, 2021, report 20-30-047-ES Part 1	Acceptable
	OECD 114	Meta SPC 2 (15.225% sodium hypochlorite)	20°C: 2.65 mm²/s 40°C: 1.58 mm²/s	E. Servajean, 2021, report 20-30-042-ES Part 1	Acceptable
	OECD 114	Meta SPC 3 (1.575% sodium hypochlorite)	20°C: 1.09 mm²/s 40°C: 0.71 mm²/s	E. Servajean, 2020, report 20-30-017-ES Part 1	Acceptable
	OECD 114	Meta SPC 5 (5.145% sodium hypochlorite)	20°C: 1.38 mm²/s 40°C: 0.87 mm²/s	E. Servajean, 2020, report 20-30-019-ES Part 1	Acceptable
	OECD 114	Meta SPC 8 (2.73% sodium hypochlorite)	20°C: 1.22 mm²/s 40°C: 0.74 mm²/s	E. Servajean, 2020, report 20-30-021-ES Part 1	Acceptable

- **NA-MIC minor change application (2022)**

The applicant claims longer shelf lives for Meta SPC 1, 3 and 8:

- 18 months for meta SPC 1.
- 24 months for meta SPC 3.
- 18 months for meta SPC 8.

The storage stability studies at ambient temperatures have been finalised for meta SPCs 1, 3 and 8. Their results are summarised in the below table.

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5</td><td>Meta SPC 1 (2.73% sodium hypochlorite) Bath 47-20-097</td><td>The test item was stored in HDPE 1L bottles at 18-22°C protected from light.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 12 MONTHS</th><th>AFTER 18 MONTHS</th><th>AFTER 24 MONTHS</th></tr>
<tr><td>Active chlorine (measured)
IC method validated</td><td>26.7 g/kg</td><td>22.08 g/kg
(82.8% of initial)</td><td>21.91 g/kg
(82.1% of initial)</td><td>21.0 g/kg
(78.6% of initial)</td></tr>
<tr><td>NaOCl equivalent</td><td>28.04 g/kg</td><td>23.2 g/kg</td><td>23.00 g/kg</td><td>22.05 g/kg</td></tr>
<tr><td>Chlorate (measured)
LC-MS method validated</td><td>0.86 g/kg</td><td>2.14 g/kg
(248.6% of initial)</td><td>2.59 g/kg
(301.5% of initial)</td><td>2.83 g/kg
(393.3% of initial)</td></tr>
<tr><td>Sodium Chlorate equivalent</td><td>1.1 g/kg</td><td>2.7 g/kg</td><td>3.3 g/kg</td><td>3.6 g/kg</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
</table></td><td>E. Servajean, 2022, report No. 20-30-009-ES-FR2</td><td>Products of Meta SPC 1 are identical. They are SL formulation and the proposed use rate is 30% v/v.
A shelf life of 18 months is claimed by the applicant.
Loss of active substance content after 18M exceeds 10% of initial content.

Technical properties are acceptable after 24M and they are considered sufficiently representative for the claimed shelf life of 18M. Persistent foaming was not provided. However, according to the composition, such property is not relevant and was not requested in the</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>4.1</td><td>12.3</td><td>15.1</td><td>17.2</td></tr>
<tr><td>pH (neat item)
CIPAC MT 75.3</td><td>12.2</td><td>-</td><td>-</td><td>12.3</td></tr>
<tr><td>pH 1% w/v
CIPAC MT 75.3</td><td>10.3</td><td>-</td><td>-</td><td>10.4</td></tr>
<tr><td>Free alkalinity
CIPAC MT 191</td><td>0.12% w/w as NaOH</td><td>-</td><td>-</td><td>0.13% w/w as NaOH</td></tr>
<tr><td>Dilution stability at 1% v/v
CIPAC MT 41.1</td><td>No separated material</td><td>-</td><td>-</td><td>No separated material</td></tr>
<tr><td>Dilution stability at 30% v/v
CIPAC MT 41.1</td><td>No separated material</td><td>-</td><td>-</td><td>No separated material</td></tr>
</table>
The active substance content decreased by more than 10%. This has been taken into account for the determination of the in-use concentration of the product, and its was found that the active chlorine content was sufficient to guarantee the efficacy up to 18 months of storage.
It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after 12, 18 and 24 months of storage, but this is acceptable as the maximum levels are covered in the risk assessments.
The physicochemical properties of the product were stable.

Therefore, the shelf-life of meta SPC 1 is set at 18 months.
</td><td></td><td>framework of the first authorisation.

The product could be considered stable after 18 months at ambient temperature, providing that efficacy tests are acceptable (see efficacy section).

Moreover, chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after storage. Please refer to human health section regarding conclusion on chlorate content.</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr>
<td></td>
<td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5</td>
<td>Meta SPC 3 (1.575% sodium hypochlorite) Batch 58-20-001B</td>
<td>The test item was stored in HDPE 0.8L bottles with sprayers (TS5 guala) at 18-22°C, protected from light.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 12 MONTHS</th><th>AFTER 18 MONTHS</th><th>AFTER 24 MONTHS</th></tr>
<tr><td>Active chlorine (measured)
IC method validated</td><td>15.5 g/kg</td><td>13.49 g/kg
(87.3% of initial)</td><td>13.73 g/kg
(88.8% of initial)</td><td>11.7 g/kg
(75.8% of initial)</td></tr>
<tr><td>NaOCl equivalent</td><td>16.3 g/kg</td><td>14.2 g/kg</td><td>14.4 g/kg</td><td>12.3 g/kg</td></tr>
<tr><td>Chlorate (measured)
LC-MS method validated</td><td>0.48 g/kg</td><td>0.78 g/kg
(162.1% of initial)</td><td>0.93 g/kg
(193.2% of initial)</td><td>1.09 g/kg
(227.5% of initial)</td></tr>
<tr><td>Sodium Chlorate equivalent</td><td>0.6 g/kg</td><td>0.99 g/kg</td><td>1.18 g/kg</td><td>1.4 g/kg</td></tr>
<tr><td>Sodium chlorate/available chlorine (%)</td><td>3.9</td><td>7.3</td><td>8.6</td><td>11.9</td></tr>
<tr><td>Appearance</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td><td>Light yellow translucent liquid</td></tr>
<tr><td>pH (neat item)
CIPAC MT 75.3</td><td>12.0</td><td>-</td><td>-</td><td>12.1</td></tr>
<tr><td>pH (1% w/v)
CIPAC MT 75.3</td><td>10.1</td><td>-</td><td>-</td><td>9.9</td></tr>
</table>
</td>
<td>E. Servajean, 2022, report No. 20-30-017-ES-FR2</td>
<td>Products of Meta SPC 3 are identical. They are ready to use formulation (spray).
A shelf life of 24 months is claimed by the applicant.
Loss of active substance content after 24M exceeds 10% of initial content.

Technical characteristics after storage were found acceptable. However, it should be noted that the spray particles size distribution after storage is missing (post authorisation data required in the framework of the first authorisation).

Therefore, the product could be considered stable after 24 months at ambient temperature, providing that efficacy tests are acceptable (see efficaciy section)

Chlorate content is higher than the maximum content set</td>
</tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Free alkalinity
CIPAC MT 191</td><td>0.07% w/w as NaOH</td><td>-</td><td>-</td><td>0.07% w/w as NaOH</td></tr>
<tr><td>Number of strokes required for priming
FEA 643</td><td>6</td><td>-</td><td>-</td><td>6</td></tr>
<tr><td>Discharge rate
FEA 643</td><td>1.32 g/spray</td><td>-</td><td>-</td><td>1.33 g/spray</td></tr>
<tr><td>Spray pattern
FEA 643</td><td>Round shape 20-23 cm diameter</td><td></td><td></td><td>Round shape 18-24 cm diameter</td></tr>
</table>
The active substance content decreased by more than 10%. However, efficacy data show that the concentration of active chlorine is still efficacious at the end of the 24-month storage.
It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after 12, 18 months and 24 of storage, but this is acceptable as the maximum levels are covered in the risk assessments.
The physicochemical properties of the product were stable.

Therefore, the shelf-life of meta SPC 3 is set at 24 months.
</td><td></td><td></td></tr>
<tr><td></td><td>GIFAP monograph no.17

Active chlorine: See section 2.2.5

Chlorate: See section 2.2.5</td><td>Meta SPC 8 (2.73% sodium hypochlorite) Batch 54-20-010B (sodium hypochlorite 2.6% + 5% perfumed detergent)</td><td>
The test item was stored in HDPE 1L bottles at 18-22°C protected from light.
<table>
<tr><th>RESULTS</th><th>UPON RECEIPT</th><th>AFTER 12 MONTHS</th><th>AFTER 18 MONTHS</th><th>AFTER 24 MONTHS</th></tr>
<tr><td>Active chlorine (measured)
IC method validated</td><td>27.0 g/kg</td><td>22.49 g/kg
(83.2% of initial)</td><td>22.55 g/kg
(83.44% of initial)</td><td>10.3 g/kg
(38.2% of initial)</td></tr>
</table>
</td><td>E. Servajean, 2022, Report no. 20-30-021-ES-FR2</td><td>Products of Meta SPC 8 are SL formulation and the proposed use rate is 30% v/v.
A shelf life of 18 months is claimed by the applicant.
Loss of active substance content</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results					Reference	eCA assessment
			NaOCl equivalent	28.35 g/kg	23.61 g/kg	23.68 g/kg	10.82 g/kg		after 18M exceeds 10% of initial content Technical characteristics after storage 24M were found acceptable. The products are foaming formulations. However, it was noticed that pH has decreased significantly after 24M. The product appears more stable after 18M than after 24M: content of av.Cl is higher than 2% after 18M, while it fell below 1% after 24%. pH is probably more alkaline after 18M, explaining this better stability. Therefore, the product could be considered stable after 18 months at ambient temperature, providing that efficacy tests are acceptable (see efficacy section). Chlorate content is higher than the maximum content set in the regulation (sodium chlorate:
			Chlorate (measured) LC-MS method validated	0.82 g/kg	2.02 g/kg (246.2% of initial)	2.41 g/kg (293.3 g/kg)	4.08 g/kg (496.5% of initial)		
			Sodium Chlorate equivalent	1 g/kg	2.6 g/kg	3.08 g/kg	5.2 g/kg		
			Sodium chlorate/available chlorine (%)	3.7	11.6	13.7	50.5		
			Appearance	Light yellow transluscent liquid	Light yellow transluscent liquid	Light yellow transluscent liquid	Light yellow transluscent liquid		
			pH (neat item) CIPAC MT 75.3	12.2	-	-	9.5		
			pH (1% w/v) CIPAC MT 75.3						
			Free alkalinity CIPAC MT 191	0.11% w/w as NaOH	-	-	0.05% w/w as NaOH		
			Dilution stability at 1% v/v CIPAC MT 41.1	No separated material	-	-	No separated material		
			Dilution stability at 30% v/v CIPAC MT 41.1	No separated material	-	-	Few flocculated material at the bottom		
			Persistent foaming at 1%	32 mL of foam after 1	-	-	No foam after 1 min		

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>eCA assessment</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>v/v
CIPAC MT 47.3</td><td>min (16%)</td><td></td><td></td><td></td></tr>
<tr><td>Persistent foaming at 30% v/v
CIPAC M 47.3</td><td>100 mL of foam after 1 min (50%)</td><td>-</td><td>-</td><td>45 mL of foam after 1 min (23%)</td></tr>
</table>

The active substance content decreased by more than 10%. The decrease was significant after 24 months.
Efficacy data show that the concentration of active chlorine is still efficacious 18 months of storage.
It should be noted that the content of chlorate is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) after 12 and 18 months of storage, but this is acceptable as the maximum levels are covered in the risk assessments.
Some variations of the physicochemical properties was observed after 24 months, but this will not impact negatively the use of the products or the safety of the user (e.g. the pH becomes more neutral, which means that the aged product is less corrosive while the active chlorine is more efficacious). Those variations are due to the large decrease of active substance content between 18 and 24 months of storage. 18-months old products will therefore present properties that are closer to those of fresh products.

Therefore, the shelf-life of meta SPC 8 is set at 18 months.</td><td></td><td>≤5.4% of available chlorine) after storage. Please refer to human health section regarding conclusion on chlorate content.</td></tr>
</table>

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

The products of the biocidal product family are light yellow or colourless translucent liquids. The pH of the neat formulations ranges from 12 to 13, the alkalinity ranges from 0.07% to 0.42% as NaOH and the relative density ranges from 1.028 to 1.242.

Products of Meta SPC 5 and 8 are surface active and all products have been demonstrated to be stable at low temperatures.
After accelerated storage (54 ° C / 2 weeks), the degradation of the active content was > 10% for all tested products. Therefore, the products should not be stored above 30°C.

Results of the ambient storage stability studies show a significant loss in active substance content and increase in sodium chlorate content for all tested products. Moreover, it should be noted that the chlorate content is higher than the maximum content set in the regulation after storage for all tested products.
The shelf lives of meta SPCs (considering a maximum of 50% degradation of active chlorine) are reported below:

- 9 months for Meta SPC 1.
- 3 months for Meta SPC 2.
- 9 months for Meta SPC 3.
- 8 months for Meta SPC 5.
- 9 months for Meta SPC 8.

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

Products of Meta SPC 5 and 8 are foaming formulations.

The mention EUH206 is applied for all products of the family. Moreover, the mention EUH031 is applied for products of Meta SPC 5 and 2.
All products should not be used in conjunction with acids or ammonia.

For Meta SPC 3, the spray particles size distribution after storage is required in post authorisation.

- **NA-MIC minor change application (2022)**

Final storage studies up to 24 months of storage are available for meta SPCs 1, 3 and 8. The results show that the active chlorine level of the products remains above the validated efficacious threshold after respectively 18, 24 and 18 months, meaning that the in-use dilutions previously authorised do not need to be updated.
New chlorate contents after 18/24/18M for Meta SPC 1/3/8 have been taken into account for risk assessment. Please refer to HH, ENV and residues sections.
The physicochemical properties of the test items after storage show that the products can still be used properly.
In conclusion, the following shelf-lives are set:

- 18 months for meta SPC 1.
- 24 months for meta SPC 3.
- 18 months for meta SPC 8.

2.2.3 Physical hazards and respective characteristics

Most physical hazards have been waived based on the products compositions and on experience in their handling.

Some studies are available to cover the following hazard categories:

- Flammable liquids and auto-ignition temperature

Test on a fictive mixture containing the maximum concentration of active substance that can be in contact with organic matter (formulation reported in confidential annex in the BPF excel file) and the maximum contenant of organic matter in the family. This formulation covers all the products of the family.

- Corrosive to metals

Test on the formulation with the lowest active substance concentration in the family (formulation of Meta SPC 3 containing 1.5% active chlorine - 1.575% sodium hypochlorite). The objective is to confirm that this product needs to be classified as corrosive to metals, and so that all other products also need to be classified.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR Evaluation	Reference
Explosives	statement	Meta SPC 1,2 and 3	The products are dilutions of the active substance therefore read across to the active substance data set is applicable. A sodium hypochlorite aqueous solution with an active chlorine concentration of 15.9% w/w was considered for explosive properties. The active substance is not explosive.	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 of Meta SPC 1 and 3, cross reading is acceptable since data from the CAR are a worst case.	-
		Meta SPC 5 and 8	As no component of the mixtures has been classified for explosive properties, the products are not classified for such hazards, because no reaction/synergy is expected. Besides no chemical group associated with explosive properties is present in the mixtures.	Acceptable	C&L inventory (harmonised classification)
Flammable gases	waived			Not relevant as the products are liquids.	
Flammable aerosols	waived			Not relevant as the products are not aerosols.	
Oxidising gases	waived			Not relevant as the products are liquids.	
Gases under pressure	waived			Not relevant as the products are not gases under pressure.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR Evaluation	Reference
Flammable liquids	EC Method A.9	Fictive mixture containing the maximum concentration of active substance that can be in contact with organic matter (4.9% sodium hypochlorite) and the maximum contenant of organic matter in the family.	No flash point was osbserved up to 100°C. Therefore, it can be concluded that no formulation of the family is flammable.	Acceptable	P. Padilla, 2021, report 20-914015-003
Flammable solids	waived			Not relevant as the products are liquids	
Self-reactive substances and mixtures	statement		According to Guidance on the application of the CLP criteria, "substances and mixtures must be considered for classification in this hazard class 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". For Meta SPCs 1, 2 and 3 containing only active substance and water, a waiving is acceptable. Meta SPCs 5 and 8 contain formulants as surfactants and they do not satisfy the waiver for chemical group associated with self reactive properties. However, in view of very low concentrations of compounds (maximum 0.5%) and the absence of explosive properties, eCa is of opinion that requesting a	Acceptable for Meta SPC 1, 2 and 3 For Meta SPC 5 and 8, DSC tests (performed on one product of each Meta SPC) are required in post registration to confirm the non classification for self-reactive properties of the products.	C&L inventory (harmonised classificaion)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR Evaluation	Reference
			full test is not appropriate. eCA rather proposes to request a DSC test in post registration to confirm the non classification in this hazard class for those meta-SPCs.		
Pyrophoric liquids	statement		Products in the BPF do not contain components that ignite spontaneously on coming into contact with air at normal temperatures. Products are known to be stable at room temperature for prolonged periods of time (months).	Not relevant.	C&L inventory (harmonised classificaion)
Pyrophoric solids	waived		Not relevant; all products in the BPF are liquids.	Not relevant	
Self-heating substances and mixtures	statement		Products in the BPF do not contain components that ignite spontaneously on coming into contact with air at normal temperatures. Products are known to be stable at room temperature for prolonged periods of time (months).	Not relevant due to the composition of the family product.	C&L inventory (harmonised classificaion)
Substances and mixtures which in contact with water emit flammable gases	statement		The products are water-based formulations and are known to form stable mixtures with water.	Acceptable	C&L inventory (harmonised classificaion)
Oxidising liquids	statement		For Meta SPC 1, 2 and 3, cross reading to data of the CAR can be made as products are dilutions of active substance solutions. For Meta SPC 5 and 8, based on the classification of other co-formulants of the biocidal products, none of them were classified as oxidizing. Moreover, the mixtures are very much diluted as products contain more than 80% water. Therefore, they are not classified for oxidising liquids.	According to the CAR (confirmatory data peer reviewed in 2018), solutions of NaClO (25.3%) are not considered as oxidizing liquid. Additionally, other constituents are not classified. Consequently, products of the	C&L inventory (harmonised classificaion)

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>FR Evaluation</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>family do not possess oxidizing properties.</td><td></td></tr>
<tr><td>Oxidising solids</td><td>waived</td><td></td><td></td><td>Not relevant as products are liquids</td><td></td></tr>
<tr><td>Organic peroxides</td><td>waived</td><td></td><td>Not relevant, no organic peroxides present in the products of the BPF.</td><td>Not relevant</td><td></td></tr>
<tr><td>Corrosive to metals</td><td>UN test C.1</td><td>Meta SPC 3 (1.5% sodium hypochlorite)</td><td>2 mm thickness aluminium and steel plates were exposed to the test item i for 7 days at 55 °C ± 1 °C.

<table><tr><th>Specimen</th><th>Loss of mass (%)</th></tr><tr><td>Immersed steel plate</td><td>15.02</td></tr><tr><td>Half way immersed steel plate</td><td>9.51</td></tr><tr><td>Non immersed steel plate</td><td>0.67</td></tr><tr><td>Immersed aluminium plate</td><td>5.60</td></tr><tr><td>Half way immersed aluminium plate</td><td>3.06</td></tr><tr><td>Non immersed aluminium plate</td><td>0.05</td></tr></table>
A mass loss of 15.02% was observed on the completely immersed steel plate after 7 days at 55°C, exceeding the 13.5% threshold.

Therefore, the test item must be classified as Meta Corrosive, category 1 (H290).</td><td>Acceptable

All products of the family are classified as H290.</td><td>P. Padilla, 2021, report 20-914015-002</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	FR Evaluation	Reference
			Also, localised corrosions were observed on steel plates (immerged and half way immerged) but their depths were not measured as the recorded mass loss alone allows to draw the final conclusion. Since all other formulations of the family are more concentrated in active substance, which is corrosive to metals, it can be concluded that all products of the family are classified as H290.		
Auto-ignition temperatures of products (liquids and gases)	EC Method A.15	Fictive mixture containing the maximum concentration of active substance that can be in contact with organic matter (4.9% sodium hypochlorite) and the maximum contenant of organic matter in the family.	No auto-ignition was observed up to 600.0 °C.	Acceptable	P. Padilla, 2021, report 20-914015-003
Relative self-ignition temperature for solids	waived		Not relevant; all products in the BPF are liquids.	Not relevant	
Dust explosion hazard	waived		Not relevant; all products in the BPF are liquids.	Not relevant	

Conclusion on the physical hazards and respective characteristics of the product
The products are neither flammable nor auto-flammable. They have no explosive and no oxidizing properties. All the products of the family are classified as corrosive to metals (H290). For Meta SPC 5 and 8, DSC tests (performed on one product of each Meta SPC) are required in post registration to confirm the non classification for self-reactive properties of the products. Implication concerning labelling: H290 Met Corr. 1

2.2.4 Methods for detection and identification

Analytical methods were developed for the analysis of the active substance active chlorine and its impurity chlorate in the formulations of the family. Both methods were validated (according to the SANCO/3030/99 rev. 5 guideline) on each representative product used in the stability studies.

Method of analysis for active chlorine
When potassium iodide is added to a sample that has active chlorine at an acidic pH, iodine and chloride are released in direct proportion to the amount of active chlorine in the sample.

$OCl^- + 2\ I^- + 2\ H_3O^+ \rightarrow I_2 + Cl^- + 3\ H_2O$

First, aqueous volumes of the test substance are prepared and chloride was quantified by ion chromatography and conductivity detection (native chloride).

IC	Metrohm 761 Compact IC with conductivity detector
Column	Metrosep A SUPP 1 250 mm x 4.6 mm x 7 µm (Metrohm)
Mobile phase	3 mM Na2CO3 in water
Flow	1.0 mL/min
Temperature	Ambient
Injection volume	20 µL
Retention time	Chloride 6 min
Total run time	15 min

Active chlorine is then converted to chloride: the solutions are acidified with 0.1% acetic acid, and then added with 0.5% of a 3.33% w/v Potassium iodide solution (50 µL of KI solution + 10 µL of acetic acid for 10 mL of test substance aqueous solution). Released iodine is then extracted with 10% v/v of n-heptane (1 mL for 10 mL of test substance aqueous solution).

The resulting solutions are then again assessed for chloride concentration (Total chloride).

Active chlorine = 2 * (Total chloride - native chloride)

Method of analysis for chlorate
Chlorate is assessed by LC-MS and external calibration.

HPLC	Agilent 1100 System
MS detector	Agilent G6120B
Column	Jupiter Proteo 250 x 4.6 mm, 4 µm (Phenomenex)
Mobile phase	75% NH4OH 50 mM 25% Acetonitrile
Flow	0.7 mL/min
Temperature	25°C
Injection volume	20 µL

Interface	API-ES in negative ion mode, m/z = 67.0, 69.0, 83.0 and 85.0 Heated nebulizer at 325 °C Drying gas 10.0 L/min Nebulizer pressure 40 psig VCap 3000 V
Retention time	2.5 min
Total run time	5.0 min

Methods validation results

Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 1 (2.73% sodium hypochlorite)									
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		
Active chlorine (active substance)	IC with conductivity detection (see above)	Recovery: Level 1: 1.86% w/w (n=2) Level 2: 2.87% w/w (n=2) Precision: 6 working solutions prepared	The linearity was validated on the range 0.03 – 10 mg/L (n=9) log(chloride, mg/L) = 0.967*log(Area) – 0.895 r^2=99.99%	The method deduces the content of native chloride ions from the total content after transformation of active chlorine into chloride. Hence, only the ions coming from active chlorine are taken into account for active chlorine concentration determination. Chromatograms of a chloride standard, native chloride in the test substance, total chloride in the test substance, blank solvent and blank matrix have been provided.	99.6-100.7 99.9-100.4 25.94-27.21 g/kg	100.2 100.2 26.7 g/kg	0.78 0.35 1.80		E. Servajea 2020, repo 20-30-009 ES Part 1
Chlorate (impurity)	LC-MS (see above)	Recovery: Level 1: 0.41 g/kg (n=2) Level 2: 0.57 g/kg (n=2) Precision: Level 1: 5 mg of test item/L (0.0044 mg chlorate/L) Level 2: 50 mg of test item/L	The linearity was validated on the range 0.003 – 0.70 mg/L (n=8) log(chlorate, mg/L) = 1.027*log(Area) – 5.770 r^2 = 99.97%	Selectivity and specificity were insured by selecting representative ions m/z = 67.0, 69.0, 83.0 and 85.0. The blank matrix was assessed at more than 100x the concentration used for the test substance working solutions. No interfering peak area was observed at the retention time of chlorate. Mass spectrum and chromatograms of a chlorate standard, blank solvent and blank matrix have been provided.	95.2-96.9 97.4-97.5 0.82-0.88 g/kg 0.83-0.88 g/kg	96.1 97.5 0.85 g/kg 0.87 g/kg	1.25 0.073 2.55 2.09	LOQ = 0.003 mg chlorate/L (n=5)	E. Servajea 2020, repo 20-30-009 ES Part 1

		(0.045 mg chlorate/L) Level 3: 500 mg of test item/L (0.45 mg chlorate/L) 6 working solutions prepared			0.85-0.88 g/kg	0.86 g/kg	1.29		

Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 2 (10.08% sodiu hypochlorite)									
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		
Active chlorine (active substance)	IC with conductivity detection (see above)	Recovery: Level 1: 4.98% w/w Level 2: 7.12% w/w Precision: 6 working solutions prepared	The linearity was validated on the range 0.03 – 10 mg/L (n=9) log(chloride, mg/L) = 0.967*log(Area) – 0.895 r^2=99.99%	The method deduces the content of native chloride ions from the total content after transformation of active chlorine into chloride. Hence, only the ions coming from active chlorine are taken into account for active chlorine concentration determination. Chromatograms of a chloride standard, native chloride in the test substance, total chloride in the test substance, blank solvent and blank matrix have been provided.	99.1-101.0 100.3-101.4 97.97-99.93 g/kg	100.1 100.9 98.7 g/kg	1.34 0.77 0.77		E. Servajea 2020, repo 20-30-016 ES Part 1
Chlorate (impurity)	LC-MS (see above)	Recovery: Level 1: 0.34 g/kg (n=2)	The linearity was validated on the range 0.003 – 0.70 mg/L (n=8)	Selectivity and specificity were insured by selecting representative ions m/z = 67.0, 69.0, 83.0 and 85.0. The blank matrix was assessed at more than 100x the concentration	97.7-98.7 96.7-98.1	98.2 97.4	0.72 1.02	LOQ = 0.003 mg chlorate/L (n=5)	E. Servajea 2020, repo 20-30-016 ES Part 1

		Level 2: 0.49 g/kg (n=2) Precision: Level 1: 2.35 mg of test item/L (0.016 mg chlorate/L) Level 2: 23.5 mg of test item/L (0.17 mg chlorate/L) Level 3: 95 mg of test item/L (0.65 mg chlorate/L) 6 working solutions prepared	log(chlorate, mg/L) = 1.027*log(Area) – 5.770 r^2 = 99.97%	used for the test substance working solutions. No interfering peak area was observed at the retention time of chlorate. Mass spectrum and chromatograms of a chlorate standard, blank solvent and blank matrix have been provided.	6.77-7.10 g/kg 7.04-7.42 g/kg 6.84-7.13 g/kg	6.94 g/kg 7.25 g/kg 6.94 g/kg	1.76 1.94 1.50		

Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 2 (13.125% sodiu hypochlorite)									
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		
Active chlorine (active substance)	IC with conductivity detection (see above)	Recovery: Level 1: 2.02% w/w (n=2) Level 2: 2.84% w/w (n=2)	The linearity was validated on the range 0.03 – 20 mg/L (n=10) log(chloride, mg/L) =	The method deduces the content of native chloride ions from the total content after transformation of active chlorine into chloride. Hence, only the ions coming from active chlorine are taken into account for active chlorine concentration determination. Chromatograms of a chloride	100.0-101.0 99.1-101.3	100.5 100.2	0.70 1.56		E. Servajea 2021, repo 20-30-047 ES Part 1

		Precision: 6 working solutions prepared	1.000*log(Area) + 0.680 r^2=99.97%	standard, native chloride in the test substance, total chloride in the test substance, blank solvent and blank matrix have been provided.	122.04-125.03 g/kg	123.5 g/kg	0.86		
Chlorate (impurity)	LC-MS (see above)	Recovery: Level 1: 0.85 g/kg (n=2) Level 2: 1.7 g/kg (n=2) Precision: Level 1: 2.4 mg of test item/L (0.005 mg chlorate/L) Level 2: 12 mg of test item/L (0.025 mg chlorate/L) Level 3: 60 mg of test item/L (0.123 mg chlorate/L) 6 working solutions preparedfor each level	The linearity was validated on the range 0.003 – 0.70 mg/L (n=8) log(chlorate, mg/L) = 1.056*log(Area) – 5.869 r^2 = 99.98%	Selectivity and specificity were insured by selecting representative ions m/z = 67.0, 69.0, 83.0 and 85.0. The blank matrix was assessed at more than 5x the concentration used for the test substance working solutions. No interfering peak area was observed at the retention time of chlorate. Chromatograms of a chlorate standard, blank solvent and blank matrix have been provided.	97.1-101.2 102.3-102.3 1.94-2.06 g/kg 1.94-2.07 g/kg 1.99-2.05 g/kg	99.2 102.3 2.02 g/kg 2.02 g/kg 2.03 g/kg	2.9 0 2.11 2.37 1.18	LOQ = 0.007 mg chlorate/L or 0.6 g/kg (n=5)	E. Servajea 2021, repo 20-30-047 ES Part 1

Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 2 (15.225% sodiu hypochlorite)									
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		
Active chlorine (active substance)	IC with conductivity detection (see above)	Recovery: Level 1: 1.91% w/w (n=2) Level 2: 2.42% w/w (n=2) Precision: 6 working solutions prepared	The linearity was validated on the range 0.03 – 20 mg/L (n=10) log(chloride, mg/L) = 1.000*log(Area) + 0.680 r^2=99.97%	The method deduces the content of native chloride ions from the total content after transformation of active chlorine into chloride. Hence, only the ions coming from active chlorine are taken into account for active chlorine concentration determination. Chromatograms of a chloride standard, native chloride in the test substance, total chloride in the test substance, blank solvent and blank matrix have been provided.	99.9-100.1 100.5-101.3 145.85-149.44 g/kg	100.0 100.9 147.1 g/kg	0.14 0.56 0.88		E. Servajea 2021, repo 20-30-042 ES Part 1
Chlorate (impurity)	LC-MS (see above)	Recovery: Level 1: 0.85 g/kg (n=2) Level 2: 1.7 g/kg (n=2) Precision: Level 1: 2.4 mg of test item/L (0.006 mg chlorate/L) Level 2: 12 mg of test item/L (0.028 mg chlorate/L)	The linearity was validated on the range 0.003 – 0.70 mg/L (n=8) log(chlorate, mg/L) = 1.056*log(Area) – 5.869 r^2 = 99.98%	Selectivity and specificity were insured by selecting representative ions m/z = 67.0, 69.0, 83.0 and 85.0. The blank matrix was assessed at more than 5x the concentration used for the test substance working solutions. No interfering peak area was observed at the retention time of chlorate. Chromatograms of a chlorate standard, blank solvent and blank matrix have been provided.	99.2-100.5 99.9-100.5 2.39-2.49 g/kg 2.33-2.50 g/kg	99.9 100.2 2.43 g/kg 2.41 g/kg	0.92 0.42 1.45 2.95	LOQ = 0.007 mg chlorate/L (n=5)	E. Servajea 2021, repo 20-30-042 ES Part 1

		Level 3: 60 mg of test item/L (0.144 mg chlorate/L) 6 working solutions prepared for each level			2.39-2.54 g/kg	2.45 g/kg	2.16		

Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 3 (1.575% sodiu hypochlorite)									
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		
Active chlorine (active substance)	IC with conductivity detection (see above)	<u>Recovery</u>: Level 1: 1.08% w/w (n=2) Level 2: 1.86% w/w (n=2) <u>Precision</u>: 6 working solutions prepared	The linearity was validated on the range 0.03 – 10 mg/L (n=9) log(chloride, mg/L) = 0.967*log(Area) – 0.895 r^2=99.99%	The method deduces the content of native chloride ions from the total content after transformation of active chlorine into chloride. Hence, only the ions coming from active chlorine are taken into account for active chlorine concentration determination. Chromatograms of a chloride standard, native chloride in the test substance, total chloride in the test substance, blank solvent and blank matrix have been provided.	98.7-101.2 100.6-101 15.2-16.17 g/kg	100.0 100.8 15.5 g/kg	1.77 0.28 2.45		E. Servajea 2020, repo 20-30-017 ES Part 1
Chlorate (impurity)	LC-MS (see above)	<u>Recovery</u>: Level 1: 0.24 g/kg (n=2) Level 2: 0.38 g/kg (n=2)	The linearity was validated on the range 0.003 – 0.70 mg/L (n=8) log(chlorate, mg/L) =	Selectivity and specificity were insured by selecting representative ions m/z = 67.0, 69.0, 83.0 and 85.0. The blank matrix was assessed at more than 100x the concentration used for the test substance	95.2-96.1 102-103.1	95.7 102.6	0.67 0.76	LOQ = 0.003 mg chlorate/L (n=5)	E. Servajea 2020, repo 20-30-017 ES Part 1

		Precision: Level 1: 10 mg of test item/L (0.005 mg chlorate/L) Level 2: 100 mg of test item/L (0.05 mg chlorate/L) Level 3: 1000 mg of test item/L (0.49 mg chlorate/L) 6 working solutions prepared for eache level	1.027*log(Area) – 5.770 r² = 99.97%	working solutions. No interfering peak area was observed at the retention time of chlorate. Mass spectrum and chromatograms of a chlorate standard, blank solvent and blank matrix have been provided.	0.46-0.5 g/kg 0.47-0.51 g/kg 0.47-0.51 g/kg	0.48 g/kg 0.48 g/kg 0.48 g/kg	3.44 2.98 3.37		

Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 5 (5.145% sodiu hypochlorite)									
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		
Active chlorine (active substance)	IC with conductivity detection (see above)	Recovery: Level 1: 4.04% w/w (n=2) Level 2: 5.86% w/w (n=2) Precision:	The linearity was validated on the range 0.03 – 10 mg/L (n=9) log(chloride, mg/L) = 0.967*log(Area) – 0.895	The method deduces the content of native chloride ions from the total content after transformation of active chlorine into chloride. Hence, only the ions coming from active chlorine are taken into account for active chlorine concentration determination. Chromatograms of a chloride standard, native chloride in the	99-100.3 98.7-101.1 47.02-49.76 g/kg	99.7 99.9 48.2 g/kg	0.92 1.63 1.98		E. Servajea 2020, repo 20-30-019 ES Part 1

		6 working solutions prepared	r^2=99.99%	test substance, total chloride in the test substance, blank solvent and blank matrix have been provided.					
Chlorate (impurity)	LC-MS (see above)	Recovery: Level 1: 0.37 g/kg (n=2) Level 2: 0.54 g/kg (n=2) Precision: Level 1: 3.25 mg of test item/L (0.008 mg chlorate/L) Level 2: 32.5 mg of test item/L (0.082 mg chlorate/L) Level 3: 162.5 mg of test item/L (0.4 mg chlorate/L) 6 working solutions prepared for each level	The linearity was validated on the range 0.003 – 0.70 mg/L (n=8) log(chlorate, mg/L) = 1.027*log(Area) – 5.770 r^2 = 99.97%	Selectivity and specificity were insured by selecting representative ions m/z = 67.0, 69.0, 83.0 and 85.0. The blank matrix was assessed at more than 100x the concentration used for the test substance working solutions. No interfering peak area was observed at the retention time of chlorate. Mass spectrum and chromatograms of a chlorate standard, blank solvent and blank matrix have been provided.	97.9-98.0 97.4-97.7 2.41-2.47 g/kg 2.45-2.65 g/kg 2.42-2.57 g/kg	98.0 97.6 2.45 g/kg 2.52 g/kg 2.47 g/kg	0.072 0.22 1.01 2.98 2.24	LOQ = 0.003 mg chlorate/L (=5)	E. Servajea 2020, repo 20-30-019 ES Part 1

Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 8 (2.73% sodium hypochlorite)									
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		
Active chlorine (active substance)	IC with conductivity detection (see above)	Recovery: Level 1: 1.86% w/w (n=2) Level 2: 2.87% w/w (n=2) Precision: 6 working solutions prepared	The linearity was validated on the range 0.03 – 10 mg/L (n=9) log(chloride, mg/L) = 0.967*log(Area) – 0.895 r^2=99.99%	The method deduces the content of native chloride ions from the total content after transformation of active chlorine into chloride. Hence, only the ions coming from active chlorine are taken into account for active chlorine concentration determination. Chromatograms of a chloride standard, native chloride in the test substance, total chloride in the test substance, blank solvent and blank matrix have been provided.	98.4-101.5 101.2-101.3 26.6-27.82 g/kg	100.0 101.3 27.0 g/kg	2.19 0.07 1.56		E. Servajea 2020, repo 20-30-021 ES Part 1
Chlorate (impurity)	LC-MS (see above)	Recovery: Level 1: 0.41 g/kg (n=2) Level 2: 0.61 g/kg (n=2) Precision: Level 1: 5 mg of test item/L (0.004 mg chlorate/L) Level 2: 50 mg of test item/L (0.044 mg chlorate/L)	The linearity was validated on the range 0.003 – 0.70 mg/L (n=8) log(chlorate, mg/L) = 1.027*log(Area) – 5.770 r^2 = 99.97%	Selectivity and specificity were insured by selecting representative ions m/z = 67.0, 69.0, 83.0 and 85.0. The blank matrix was assessed at more than 100x the concentration used for the test substance working solutions. No interfering peak area was observed at the retention time of chlorate. Mass spectrum and chromatograms of a chlorate standard, blank solvent and blank matrix have been provided.	105.1-105.5 105.3-105.5 0.76-0.81 g/kg 0.82-0.87 g/kg	105.3 105.4 0.78 g/kg 0.84 g/kg	0.27 0.13 2.68 2.59	LOQ = 0.003 mg chlorate/L (n=5)	E. Servajea 2020, repo 20-30-021 ES Part 1

		Level 3: 500 mg of test item/L (0.44 mg chlorate/L) 6 working solutions prepared for eache level			0.82-0.85 g/kg	0.84 g/kg	1.46		

Analytical methods for soil
Residue definition: HClO/ClO^- Not required. For none of the intended uses, soil is the first receiving compartment. Environmental exposure is expected via the facility drain into the STP or via the treated effluent directly into the surface water. Active chlorine (HClO/ClO—) can reach the soil compartment only indirectly, via sewage sludge: rapid degradation occurs already with organic matter therein. In the event of contamination of soil, e.g. due to direct application of chlorinated water, hypochlorous acid/hypochlorite anion would react rapidly with organic matter in soil, anyway.

Analytical methods for air
Residue definition: Cl_2/HClO/ClO^- Hypochlorite is a non-volatile species. Hypochlorous acid is volatile, but according to literature data, the Henry's Law constant is ≈ 0.1 Pa m^3 mol^{-1}, i.e. volatilization from the aqueous phase is expected to be slow. Furthermore, there are indications that the half-life is only a few hours, i.e. much shorter than the value derived by Atkinson calculation. So occurrence in air is not probable for this species, either. In PT2, no spray applications are envisaged. In PT4, spray applications are envisaged, but the spraying is performed at low pressure, in the form of foam or sticky gel. At the in-use pH values for PT2 and PT4, exposure to gaseous chlorine is not expected, but throughaccidental events (chlorine can be formed and released when the active chlorine equilibrium is shifted to low pHs by strong acids, e.g. by mixing hypochlorite-based solutions with acidic cleaning agents). In case of an accidental release of chlorine, two analytical methods ([3], [4]) for the monitoring of chlorine in workplace air are available in the CAR, which allow the determination of chlorine in workplace air in the range 0.3-7.0 mg Cl_2/m^3. In principle, the range can be expanded. Though not validated, the two available methods are published methods, so they can still be concluded to be acceptable for the purpose (determination of chlorine in workplace air).

Analytical methods for drinking water
Residue definition: HClO/ClO^- and relevant metabolite chlorate ClO_3^- The analytical methods for active chlorine (HClO/ClO^-) as available in the original Euro Chlor dossier are not acceptable, since the validation is not in accordance with the Additional Guidance on TNsG on analytical methods. Therefore, a fully-validated analytical method for active chlorine residues in drinking water is requested. A fully validated analytical method is also requested for the relevant metabolite chlorate (ClO_3^-).
Analytical methods for residues in surface water
Residue definition: HClO/ClO^- Not required. Environmental exposure is expected *via* the facility drain into the STP or *via* the treated effluent directly into the surface water, but rapid degradation occurs with organic matter therein. Rapid degradation occurs also with the organic matter in surface water ($DT50_{surface\ water}$ = 56 min at environmental temperature).

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

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

Analytical methods for animal and human body fluids and tissues
Residue definition: $HClO/ClO^-$ Not required. Hypochlorous acid/ hypochlorite anion are oxidizing agents and degrade rapidly with organic matter. Besides, due to corrosive properties, systemic toxicity would be secondary to local effects. Nevertheless, in case of an accidental release of chlorine, the analytical methods available for the monitoring of chlorine in workplace air are meaningful for monitoring human exposure.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Residue definition: $HClO/ClO^-$ and relevant metabolite chlorate ClO_3^- Under PT4, fully-validated analytical methods for residues of both active chlorine ($HClO/ClO^-$) and the relevant metabolite chlorate (ClO_3^-) are requested for monitoring purposes in various matrices and for the estimation of human and animal exposure. Nevertheless, active chlorine degrades rapidly in contact with food matrices, hence the request for analytical methods for their residues in food/feeding stuff cannot be met, but for chlorate only.

Conclusion on the methods for detection and identification of the product
Analytical methods for the detection and identification of the active substance active chlorine and its relevant impurity chlorate have been validated on several formulations of the family. Analytical methods for monitoring in soil, air, water, body fluids/tissues and food/feed of plant/animal origin are active substance data. The applicant has letters of access to the active substance dossiers.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 01: Disinfectants
PT2: Disinfectants and algaecides not intended for direct application to humans or animals.
PT4: Food and feed area.

The biocidal products family consists of 8 meta-SPCs intended to be used by professional and non-professional users by wiping or spraying, depending on the META SPC.

The biocidal products family is intended to be used as disinfectant for use in Product Type (PT) 2, and 4 for the following applications:

1. Disinfection of surfaces by spraying (without mechanical action) PT2 and PT4 – Meta SPC 1, 2, 3, 5 and 8
2. Disinfection of surfaces by wiping with mop/cloth and bucket (without mechanical action) PT2 and PT4 – Meta SPC 1, 2, 5 and 8

- **NA-MIC minor change application (2022)**

The biocidal products family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE (Meta SPC 1, 2, 3, 5 and 8) was initially authorized for disinfection of surfaces by spraying and wiping against bacteria, yeast and fungi (except for Meta SPC 2 and Meta SPC 5) under clean conditions only.

In the frame of the minor change application, the applicant claimed:

- A modification of the conditions of uses: disinfection in dirty conditions (without cleaning of the surfaces prior application)
- An increase of the validated shelf-life for Meta SPC 1 (from 9 to 18 months), Meta SPC 3 (from 9 to 24 months) and Meta SPC 8 (from 9 to 18 months).

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

The biocidal products are intended to be used for disinfection of hard surfaces against bacteria, yeasts and fungi.

The appliquant claimed also an efficacy against smell generating organisms.

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

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products are intended to produce a reduction in the number of viable bacterial cells (bactericidal activity), yeasts (yeasticidal activity) and fungi (fungicidal activity) of relevant test organisms under defined conditions.

2.2.5.4 Mode of action, including time delay

The active substance released from sodium hypochlorite in aqueous solutions is available chlorine.

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

Hypochlorite reacts actively by chlorination of nitrogen with compounds like amino acids. The disinfecting efficiency of hypochlorite aqueous solution is dependent on the available chlorine concentration and decreases with an increase in pH. It is irrelevant whether available chlorine is generated from chlorine gas, calcium hypochlorite or sodium hypochlorite.

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

The mode of action of available chlorine released from sodium hypochlorite is non-specific. Microorganisms are inactivated by chlorination and oxidative reactions attacking multiple molecular sites on the cell surface as well as the cell interior.

2.2.5.5 Efficacy data

First Application (2022)

- **Tested products:**

The biocidal product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE consists of products containing the active substance Sodium Hypochlorite in the range of 1.575 to 15.225 % w/w.

Efficacy studies provided based on EN norms were performed with 3 differents products:
- Product with 2.6% w/v available chlorine (no perfume and no detergent) from Meta-SPC1
- Product with 2.6% w/v available chlorine (with detergent, no perfume) from Meta-SPC8
- Product with 2.6% w/v available chlorine (with detergent and perfume) from Meta SPC8

Perfumes are not expected to influence efficacy. Detergents are expected to increase disinfection efficacy of products in soiled conditions.

Please note that the exact compositions of the tested products are presented in the confidential section of the PAR.
ECA agree with the approach proposed by the applicant to consider the products tested as representative of the family. Indeed, variations of coformulants present in the products are not considered to have a biocidal activity or an influence on the efficacy of the biocidal product family (please refer to the detailed conclusions for each Meta SPC).

- Tested aged-products

All the efficacy tests have been carried out with fresh representative products.

However, active substance concentration loss between before and after shelf life is expected to be higher than 10% for all products of all meta-SPCs.

According to the Technical Agreements for Biocides (TAB, point 12):
- Efficacy shelf life test should preferably be performed with aged products that have been stored for the complete claimed shelf life.
- In some cases, it is also acceptable when efficacy shelf life tests are performed with fresh product with an active substance concentration comparable to the concentration measured in a stored product after the claimed shelf life. In those cases, a robust justification and/or a clear indication from the physico-chemical assessment is required which explains why age-related changes in co-formulants would not have an effect on efficacy of the aged product, and why reduction in the quantity of active substance would be the only issue to be addressed.

In order to justify the efficacy of all the products within this family at the end of the shelf-life, it was chosen by the applicant to test (P2S2 test) also a sodium hypochlorite solution with a concentration of 1.3% available chlorine, corresponding to the quantity of active substance contained in an artificially aged product when it contained 2.6% of available chlorine at the time of manufacture and after it lost 50% of its active substance content. The tests are performed under dirty conditions against bacteria, yeasts and fungi.

However no robust justification and/or a clear indication from the physico-chemical assessment which explains why age-related changes in co-formulants would not have an effect on efficacy of the aged product. Nevertheless, considering the claimed compositions for each Meta SPC and the kind as well as the % of the co-formulants claimed, we consider that the approach proposed by the applicant is acceptable (please refer to the conclusion of each meta SPC, below for more details on the validated shelf-life).

- **Table of the experimental 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**
Disinfection	Hard surfaces - PT2-4	Product with 2.6% available chlorine (no perfume and no detergent) – Meta SPC 1 Product with 2.6% available chlorine (with detergent, no perfume) – Meta SPC 8 Product with 2.6% available chlorine (with detergent and perfume) – Meta SPC 8	**Bacteria:** *P. aeruginosa,* *E. coli,* *S. aureus,* *E. hirae*	EN 1276	Phase 2 step 1 test (suspension test) Dilution: 0.001% and 1% Temperature: 20°C Clean condition: 0,3 g/L bovine serum albumin Contact time: 5 min 3 replicats/product/test organism Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 1 % v/v for all products.	BioPreserv (2020). 19BP280 - EN 1276. Revision on 30/04/2020 (to correct some deviations from the method: N, Nv/Nv0, A, B,C) R.I.: 2
Disinfection	Hard surfaces - PT2-4	Product with 2.6% available chlorine (with detergent, no perfume) – Meta SPC 8 Product with 2.6% available chlorine (with	**Yeasts:** *C. albicans* **Fungi:** *A. brasiliensis*	EN 1650	Phase 2 step 1 test (suspension test) Dilution: 0.001% and 1% Temperature: 20°C Clean condition: 0,3 g/L bovine serum albumin	Yeasticidal and fungicidal activity demonstrated at 1 % v/v for all products.	BioPreserv (2020). 19BP280 - EN 1650. Revision on 30/04/2020 (to correct some deviations from the

		detergent and perfume) – Meta SPC 8			Contact time: 15 min 3 replicats/product/test organism Criteria: at least a 4 log reduction		method: A, B,C) R.I.: 2
Disinfection	Hard surfaces - PT2-4- PT2	Product with 2.6% available chlorine (no perfume and no detergent) – Meta SPC 1	**Yeasts:** *C. albicans* **Fungi:** *A. brasiliensis*	EN 1650	Phase 2 step 1 test (suspension test) Dilution: 0.001% and 1% Temperature: 20°C Clean conditions: 0,3 g/L bovine serum albumin Contact time: 15 min 3 replicats/product/test organism Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 1 % v/v Fungicidal activity demonstrated at 1 % v/v even if one of the replicats has only 3.8 log reduction.	BioPreserv (2020). 19BP280 - EN 1650. Revision on 30/04/2020 (to correct some deviations from the method: A, B,C) R.I.: 2
Disinfection	Hard surfaces - PT2-4	Product with 2.6% available chlorine (no perfume and no detergent) – Meta SPC 1 Product with 2.6% available	**Bacteria:** *P. aeruginosa,* *E. coli,* *S. aureus,* *E. hirae.* **Fungi:** *A. brasiliensis*	EN 13697	Phase 2 step 2 test (surface test) Dilution: 0.001% and 1% Temperature: 20°C	Bactericidal and yeasticidal activity demonstrated at 1 % v/v 3 log reduction is not achieved for *A. brasiliensis.*	BioPreserv (2020). 19BP280 - EN 13697. Revision on 30/04/2020 (to correct some

		chlorine (with detergent, no perfume) – Meta SPC 8 Product with 2.6% available chlorine (with detergent and perfume) – Meta SPC 8	**Yeasts:** *C. albicans*		Clean condition: 0,3 g/L bovine serum albumin Contact time: 5 min for bacteria and 15 min for yeast and fungi Criteria: at least a 3 log reduction for yeast and fungi and 4 log reduction for bacteria	Therefore, fungicidal activity has not been demonstrated.	deviations from the method: N, Nts) R.I.: 2
Bactericide Yeasticide	Hard surfaces - PT2-4	Solution Hypochlorite de sodium Available chlorine: 1.3% Batch: 58-20-001D	**Bacteria:** *P. aeruginosa,* *E. coli,* *S. aureus,* *E. hirae.* **Yeasts:** *C. albicans*	EN 13697	Phase 2 step 2 test (surface test) Dilutions tested: - Bacteria: 0.1, 5, 8, 12 and 15% - Yeasts: 0.1, 5, 8 and 12% Temperature: 20°C Dirty condition: 3 g/L bovine serum albumin Contact time: 5 min Criteria: at least a 3 log reduction for yeast and fungi and 4 log reduction for bacteria.	Yeasticidal activity demonstrated at 8 % v/v. Bactericidal efficacy is not demonstrated as 4 log reduction as not reached (*E. hirae*) or deviations are observed for *P. aeruginosa* ("NC-Nc is not greater than ± 0.3 lg" and "NT-Nc is not greater than ± 0.3 lg "not validated) and for *E. coli* (not sufficient recovery rate from coupons to reach 4 log reduction).	Actalia (2020) SMI.2020.338.2 R.I.: 2
Bactericide	Hard surfaces - PT2-4	Solution hypochlorite de sodium	**Bacteria:** *E. coli,* *E. hirae*	EN 13697+A1: 2019	Phase 2 step 2 test (surface test)	Activity against *E. coli* and *E. hirae* demonstrated at 30 % v/v.	Au C., 2020 No LMM 2021001L

		Available chlorine: 1.3% w/w Batch: 58-20-001F			Contact time: 20 minutes Temperature: 20°C Soiling: dirty conditions (bovine albumin 3 g/L) Surface: stainless steel Concentrations tested: 0.1, 30 and 50 % v/v Criteria: at least a 4 log reduction		R.I.: 2 (data are missing for *P. aeruginosa*, and *S. aureus*)
Fungicide	Hard surfaces - PT2-4	Solution Hypochlorite de sodium Available chlorine: 1.3% w/w Batch: 58-20-001A	**Fungi** *A. brasiliensis*	EN 13697+A1: 2019	Phase 2 step 2 test (surface test) Contact time: 20 minutes Temperature: 20°C Soiling: dirty conditions (bovine albumin 3 g/L) Surface: stainless steel Concentrations tested: 0.1, 30 and 50 % v/v Criteria: at least a 3 log reduction	Fungicidal efficacy demonstrated at 50 % v/v.	Au C. 2021 No LMM 2021002L R.I.: 1

- **Meta SPC 1, META-SPC 2 and META-SPC 3**

META-SPC 1 consists of products to be diluted to 30 % v/v (surface disinfection), containing available chlorine at 2.6 % w/v.
META-SPC 2 consists of products to be diluted between 5 and 7.5% v/v (surface disinfection), containing available chlorine in the range of 9.6 to 16 % w/v.
META-SPC 3 consists of ready-to-use products containing available chlorine at 1.5 % w/v.

The product tested (2.6% w/v available chlorine - no perfume and no detergent) is then considered as representative of the claimed composition of the products of the META-SPC 1 (no variations in the claimed compositions) and META-SPC 2 (worst case regarding the claimed composition of the products of the META-SPC 2 (2.6% instead of 9.6% available substance).

For META-SPC 3, concentration of available chlorine (1.5 % w/v) is lesser than the representative product tested. Besides, considering that there is no other coformulants present in the composition and products are used without dilution, eCA agree to consider the results obtained with product with 2.6% w/v available chlorine (no perfume and no detergent) acceptable for META-SPC3 products.

Based on the efficacy data provided:
- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1 % v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v.
- fungicidal activity is demonstrated in phase 2, step 1 test (EN 1650), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v. Nevertheless, efficacy is not demonstrated int phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA).

Please note that efficacy tests with a product which contains available chlorine at 1.3% w/w have also been submitted, in order to support the shelf life claimed by the applicant (loss of 50% of its active substance content):
- yeasticidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 8 % v/v.
- fungicidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 20 minutes with dirty conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 50 % v/v.

However, no bactericidal efficacy has been demonstrated as efficacy against all the mandatory strains (i.e. *P. aeruginosa*) has not been demonstrated with the product Hypochlorite de sodium at 1.3% w/w available chlorine.

Therefore, as bacteria is a mandatory target organism for the uses claimed, these studies could not be used to support the efficacy at the claimed shelf-life and the efficacy under dirty conditions (without cleaning prior application).

Moreover P2S1 tests with dirty conditions are also missing to support the efficacy without cleaning prior application. Therefore, efficacy under dirty conditions (without cleaning prior application) is not demontrated based on the efficacy data provided.

Note that since the EN 13697 study against fungi is valid and supports the efficacy of available chlorine at 1.3% v/v at 50% v/v, eCA considers that efficacy of the products 2.6% w/v against fungi is demonstrated at the in-use concentration of 25 % v/v (TC: 20 minutes), at 20°C in clean conditions (0.3 g/L BSA), based on P2S1 and P2S2 tests (worst case) provided.

Regarding the claimed shelf-life for Meta SPC 1 and 3:
- Bactericidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) is not demonstrated.
- But bactericidal efficacy with a product at 2.6% available chlorine is demonstrated at 1% v/v (i.e 0.026% active chlorine) which is lower that the claimed in use application rate (after dilution) for Meta SPC 1 (i.e 0.78% active chlorine) and Meta SPC 3 (i.e 1.55% active chlorine). See detailed explanations in the confidential section of the PAR.
- Fungicidal and yeasticidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) are demonstrated in P2S2 tests at an in use application rate lower than claimed.

Therefore, we consider that efficacy data provided are sufficient to support the efficacy after 9 months for Meta SPC1 and Meta SPC 3 which are the maximum shelf life acceptable based on the APCP data provided.

Regarding the claimed shelf-life for Meta SPC 2:
- Bactericidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) is not demonstrated.
- But bactericidal efficacy with a product at 2.6% available chlorine is demonstrated at 1% v/v (i.e 0.026% active chlorine) which is lower that the claimed in use application rate (after dilution) for Meta SPC 2 (i.e 0.74% active chlorine). See detailed explanations in the confidential section of the PAR.
- Yeasticidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) is demonstrated in P2S2 tests at an in use application rate lower than claimed.

However, the coresponding in use active chlorine after 3 months of storage (i.e 0.525% and 0.580% active chlorine) are lower for fungi than the effective concentration demonstrated in the efficacy studies (i.e. 0.650% active chlorine). Therefore, the efficacy against fungi is not demonstrated after 3 months for Meta SPC 2 and only efficacy against bacteria and yeasts are demonstrated with a shelf-life of 3 months for Meta SPC 2.

- **Meta SPC 5**

META-SPC 5 consists of products to be diluted to 15 % v/v (surface disinfection) containing available chlorine at 4.9 % w/v, with a detergent.
The representative product tested with 2.6% w/v available chlorine (no perfume and detergent) is considered as a worst case regarding the claimed composition of the products of the META-SPC 5.

Based on the efficacy data provided:

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1 % v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v.
  fungicidal activity is demonstrated in phase 2, steps 1 test (EN 1650), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v. Nevertheless, efficacy is not demonstrated int phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA).

Please note that efficacy tests with a product which contains available chlorine at 1.3% w/w have also been submitted, in order to support the shelf life claimed by the applicant (loss of 50% of its active substance content):

- yeasticidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 8 % v/v.
- fungicidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 20 minutes with dirty conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 50 % v/v.

However, no bactericidal efficacy has been demonstrated as efficacy against all the mandatory strains (i.e. *P. aeruginosa*) has not been demonstrated with the product Hypochlorite de sodium at 1.3% w/w available chlorine.

Therefore, as bacteria is a mandatory target organism for the uses claimed, these studies could not be used to support the efficacy at the claimed shelf-life and the efficacy under dirty conditions (without cleaning prior application). Moreover P2S1 tests with dirty conditions are also missing to support the efficacy without cleaning prior application. Therefore, efficacy under dirty conditions (without cleaning prior application) is not demontrated based on the efficacy data provided.

Note that since the EN 13697 study against fungi is valid and supports the efficacy of available chlorine at 1.3% w/w at 50% v/v, eCA considers that efficacy of the products 2.6% v/v against fungi is demonstrated at the in-use concentration of 25 % v/v (TC: 20 minutes), at 20°C in clean conditions (0.3 g/L BSA), based on P2S1 and P2S2 tests (worst case) provided.

Regarding the claimed shelf-life:
- Bactericidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) is not demonstrated.
- But bactericidal efficacy with a product at 2.6% available chlorine is demonstrated at 1% v/v (i.e 0.026% active chlorine) which is lower that the claimed in use application rate (after dilution) for Meta SPC 5 (i.e 0.723% active chlorine). See detailed explanations in the confidential section of the PAR.
- Yeasticidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) is demonstrated in P2S2 tests at an in use application rate lower than claimed.

However, the corresponding in use active chlorine after 8 months of storage (i.e 0.518% active chlorine) is lower for fungi than the effective concentration demonstrated in the efficacy studies (i.e. 0.650% active chlorine). Therefore, the efficacy against fungi is not demonstrated after 8 months for Meta SPC 5 and only efficacy against bacteria and yeasts are demonstrated with a shelf-life of 8 months for Meta SPC 5.

- **Meta SPC 8**

META-SPC 8 consists of products to be diluted to 30 % v/v (surface disinfection), containing available chlorine at 2.6 % w/v.

Considering the composition of META-SP8, eCA agreed that the products with 2.6% w/v available chlorine (perfume and detergent) and with 2.6% w/v sodium hypochlorite (no perfume and no detergent) are considered as representative regarding the claimed composition of the products of the META-SPC 8.

Based on the efficacy data provided:

- bactericidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1276 and EN 13697), at 20°C, with a contact time of 5 minutes with clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 1 % v/v.
- yeasticidal activity is demonstrated both in phase 2, steps 1 and 2 tests (EN 1650 and EN 13697), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v.
- fungicidal activity is demonstrated in phase 2, steps 1 test (EN 1650), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 1 % v/v. Nevertheless, efficacy is not demonstrated int phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 15 minutes with clean conditions (0.3 g/L BSA).

Please note that efficacy tests with a product which contains available chlorine at 1.3% w/w have also been submitted, in order to support the shelf life claimed by the applicant (loss of 50% of its active substance content):

- yeasticidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 5 minutes with dirty conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 8 % v/v.
- fungicidal activity is demonstrated in phase 2, step 2 test (EN 13697), at 20°C, with a contact time of 20 minutes with dirty conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 50 % v/v.

However, no bactericidal efficacy has been demonstrated as efficacy against all the mandatory strains (i.e. *P. aeruginosa*) has not been demonstrated with the product Hypochlorite de sodium at 1.3% w/w available chlorine.

Therefore, as bacteria is a mandatory target organism for the uses claimed, these studies could not be used to support the efficacy at the claimed shelf-life and the efficacy under dirty conditions (without cleaning prior application). Moreover P2S1 tests with dirty conditions are also missing to support the efficacy without cleaning prior application. Therefore, efficacy under dirty conditions (without cleaning prior application) is not demontrated based on the efficacy data provided.

Note that since the EN 13697 study against fungi is valid and supports the efficacy of available chlorine at 1.3% w/w at 50% v/v, eCA considers that efficacy of the products 2.6% w/v against fungi is demonstrated at the in-use concentration of 25 % v/v (TC: 20 minutes), at 20°C in clean conditions (0.3 g/L BSA), based on P2S1 and P2S2 tests (worst case) provided.

Regarding the claimed shelf-life:
- Bactericidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) is not demonstrated.
- But bactericidal efficacy with a product at 2.6% available chlorine is demonstrated at 1% v/v (i.e 0.026% active chlorine) which is lower that the claimed in use application rate (after dilution) for Meta SPC 8 (i.e 0.81% active chlorine). See detailed explanations in the confidential section of the PAR.
- Fugicidal and yeasticidal efficacy with a product at 1.3% available chlorine (loss of 50% of its active substance content) are demonstrated in P2S2 tests are demonstrated in P2S2 tests at an in use application rate lower than claimed.

Therefore, we consider that efficacy data provided are sufficient to support the efficacy after 9 months for Meta SPC8 which is the maximum shelf life acceptable based on the APCP data provided.

Conclusion on the efficacy of the product

The product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE has shown a sufficient efficacy, in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy Parts B+C, for the following uses, at the claimed application rate:

META SPC 1

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30% v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket included (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

META SPC 2

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 0.525% w/w active chlorine, 15 min, 20 °C

    Efficacy against fungi is not demonstrated for a shelf-life of 3 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.

- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 0.525% w/w active chlorine, 15 min, 20 °C

    Efficacy against fungi is not demonstrated for a shelf-life of 3 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.

META SPC 3

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 100% v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 100% v/v, 20 min, 20 °C

META SPC 5

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 15 % v/v, 15 min, 20 °C

    Efficacy against fungi is not demonstrated for a shelf-life of 8 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.

- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 15 % v/v, 15 min, 20 °C

    Efficacy against fungi is not demonstrated for a shelf-life of 8 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.

META SPC 8

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

  Efficacy under dirty conditions has not been demonstrated.

- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

It has to be noted that following efficacy tests submitted, pre-cleaning has been added and contact time for bacteria, yeasts and fungi have been increased.

Moreover, the applicant claimed also an efficacy against smell generating organisms. The argumentation provided by the applicant was: "Smell generating organisms are bacteria and fungi. As the products have been reported efficient for these organisms, the claim for desodorising is considered relevant".
Nevertheless, as no efficacy data according to the requirements of the Efficacy guidance Vol II Part B/C, section 5.4.0.5.4 were provided, eCA considers that this claim has not been demonstrated.

- **NA-MIC minor change application (2022)**

To support the efficacy under dirty conditions and proposed extensions of the shelf-life, new efficacy studies carried out with products with 2.6% w/v available chlorine (with and without detergent) and products with 1.3% w/w available chlorine were submitted by the applicant. The compositions of all tested products are presented in the confidential part of the PAR.

All efficacy studies results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

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**
Disinfection	Hard surfaces - PT2-4 **Bridging tests**	Product with 2.6% w/v available chlorine (no perfume and no detergent) Batch: 47-23-006	**Bacteria:** *P. aeruginosa,* *E. coli,* *S. aureus,* *E. hirae*	EN 1276:2019	Phase 2 step 1 test (suspension test) Dilution: 1%, 3% and 5% v/v Temperature: 20°C Dirty condition: 3 g/L bovine serum albumin Contact time: 20 min Criteria: at least a 5 log reduction	*P. aeruginosa*: No efficacy demonstrated for all tested concentration: - 4.56 log reduction is observed at 3% v/v. - 4.94 log reduction is observed at 5% v/v. *E. coli:* Efficacy demonstrated at 1% v/v. *S. aureus*: Efficacy demonstrated at 3% v/v. *E. hirae*: Efficacy demonstrated at 1% v/v. Based on this study, it can be determined that the worst case organism is *P. aeruginosa.*	LMM, Report n° LMM 2023007 L R.I. = 1
Disinfection	Hard surfaces - PT2-4 **Bridging tests**	Product with 2.6% w/v available chlorine + detergent Batch: 52-23-001A	**Bacteria:** *P. aeruginosa*	EN 1276:2019	Phase 2 step 1 test (suspension test) Dilution: 0.1%, 3% and 5% v/v Temperature: 20°C	*P. aeruginosa* : Efficacy demonstrated at 3% and 5% v/v. Based on the results obtained of the product without detergent	LMM, Report n° LMM 2023029 L R.I. = 2

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>Dirty condition: 3 g/L bovine serum albumin

Contact time: 20 min

Criteria: at least a 5 log reduction</td><td>compared to the product with detergent (please refer to the efficacy study above) :
<table><tr><td></td><td>3%</td><td>5%</td></tr><tr><td>Product (no perfume and detergent)</td><td>4.56</td><td>4.94</td></tr><tr><td>Product + detergent</td><td>>5.16</td><td>>5.16</td></tr></table>
It can be assumed that that the presence of detergent in the formulation has at least no negative impact on the efficacy of the product.</td><td></td></tr>
<tr><td>Disinfection</td><td>Hard surfaces - PT2-4

Bridging tests</td><td>Product with 2.6% w/v available chlorine (no perfume and no detergent)

Batch: 47-23-006</td><td>Yeast :
Candida albicans

Fungi:
Aspergillus brasiliensis</td><td>EN 1650:2019</td><td>Phase 2 step 1 test (suspension test)

Dilution:
C. albicans: 0.1%, 0.2% and 1% v/v
A. brasilensis: 0.1%, 0.2% and 5% v/v

Temperature: 20°C

Dirty condition: 3 g/L bovine serum albumin

Contact time: 20 min</td><td>C. albicans:
No efficacy demonstrated for all tested concentrations.
At 1% v/v, the log reduction was 3.13.

A. brasiliensis:
No efficacy demonstrated for all tested concentrations.
At 5% v/v, the log reduction was 3.71.</td><td>LMM, Report n° LMM 2023031 L

R.I. = 1</td></tr>
</table>

<table>
<tr><th colspan="8">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td>Criteria: at least a 4 log reduction</td><td></td><td></td></tr>
<tr><td>Disinfection</td><td>Hard surfaces - PT2-4

Bridging tests</td><td>Product with 2.6% w/v available chlorine + detergent

Batch: 52-23-001A</td><td>Yeast :
Candida albicans

Fungi:
Aspergillus brasiliensis</td><td>EN 1650:2019</td><td>Phase 2 step 1 test (suspension test)

Dilution:
C. albicans: 0.1%, 0.2% and 1% v/v
A. brasilensis: 0.1%, 0.2% and 5% v/v

Temperature: 20°C

Dirty condition: 3 g/L bovine serum albumin

Contact time: 20 min

Criteria: at least a 4 log reduction</td><td>C.albicans:

No efficacy has been demonstrated for all tested concentrations.
At 1% v/v, the log reduction was 3.04.

A.brasiliensis:

No efficacy demonstrated for all tested concentrations.
At 5% v/v, the log reduction was 3.48.

Based on the results obtained of the product without detergent compared to the product detergent (performed at the same time, please refer to the efficacy study above):
<table><tr><td></td><td>C. albicans (1%)</td><td>A. brasiliensis (5%)</td></tr><tr><td>Product (no pefume and detergent)</td><td>3.13</td><td>3.71</td></tr></table></td><td>LMM, Report n° LMM 2023032 L

R.I. = 1</td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organism(s)							
						Product + detergent: 3.04 / 3.48 Difference: 0.09 log / 0.23 log Therefore, as the difference is < 1log, according to the guidance Harmonized approach to determine a worst-case (or a representative) test product to be taken into account for efficacy core assessment for a disinfectant BPF (Dec 2020, BPC 37), it can be considered that the detergent has no impact on the efficacy of the product for yeasts and fungi.	

- **Representative tested products:**

During the first authorisation of the product family, in order to support the efficacy and to justify the impact of coformulants on the efficacy, efficacy tests have been carried out with 3 different products with 2.6% w/v available chlorine (one with no perfume and no detergent, one with detergent and no perfume, and one with detergent and perfume) and with products with 1.3% w/w available chlorine under clean conditions only. Under these conditions it was considered that these representative products were acceptable to cover the efficacy of the product family.

In the frame this minor change application, in order to justify the worst case test product according to the requirement of the BPC document "Harmonized approach to determine a worst-case (or a representative) test product to be taken into account for efficacy core assessment for a disinfectant BPF » (Dec 2020, BPC-37)" in force, phase 2 step 1 bridging studies should be performed under the hardest conditions claimed in the application (i.e. highest soiling claimed: dirty conditions).

Therefore, the applicant has provided new P2S1 tests in dirty conditions with the products containing 2.6% w/v available chlorine (without and with detergent) to support the non-influence of the coformulants (detergent) on the efficacy under dirty conditions.

Based on the results of these studies, it can be considered that the detergent has no impact on the efficacy of the product also under dirty conditions.
Therefore, efficacy studies carried out with a representative product without detergent are considered as acceptable to support the efficacy for Meta SPC 1, 2, 3, 5 and Meta SPC 8 under dirty conditions. Moreover to take into account the AS loss during shelf life, efficacy studies have been performed with 1.3% w/w available chlorine based product (50% loss).

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**
Disinfection	Hard surfaces - PT2-4	Solution Hypochlorite de sodium Available chlorine: 1.3% w/w Batch: 58-22-001A	**Bacteria:** *P. aeruginosa,* *E. coli,* *S. aureus,* *E. hirae*	EN 1276:2019	Phase 2 step 1 test (suspension test) Dilution: 0.1%, 1%, 15% and 30% v/v Temperature: 20°C Dirty condition: 3 g/L bovine serum albumin Contact time: 20 min Criteria: at least a 5 log reduction	Bactericidal activity demonstrated at 15 % v/v.	Au C., 2022 Report No. LMM 2022004 L R.I.: 1
Disinfection	Hard surfaces - PT2-4	Solution Hypochlorite de sodium Available chlorine: 1.3% w/w Batch: 58-22-001A	**Yeasts:** *C. albicans* **Fungi:** *A. brasiliensis*	EN 1650:2019	Phase 2 step 1 test (suspension test) Dilution: Yeast: 1%, 4% and 8% v/v Fungi: 1%, 25% and 50% v/v Temperature: 20°C Dirty condition: 3 g/L bovine serum albumin Contact time: 20 min Criteria: at least a 4 log reduction	Yeasticidal activity demonstrated at 4 % v/v. Fungicidal activity demonstrated at 25 % v/v.	Au C., 2022 Report No. LMM 2022005 L R.I.: 1 See first application for P2S2 test (SMI.2020.338.2)

Experimental data on the efficacy of the biocidal product against target organism(s)							
Bactericide	Hard surfaces - PT2-4	Solution hypochlorite de sodium Available chlorine: 1.3% v/v Batch: 58-21-002A	**Bacteria:** *P. aeruginosa*	EN 13697+A1: 2019	Phase 2 step 2 test (surface test) Contact time: 5 minutes Temperature: 20°C Soiling: dirty conditions (bovine albumin 3 g/L) Surface: stainless steel Concentrations tested: 0.1, 8 and 12% v/v Criteria: at least a 4 log reduction	Not acceptable to support the efficacy as the criterion of the EN13697 method "NT-Nc is not greater than ± 0.3 lg" is not validated." (other mandatory strains have been tested in the tests SMI.2020.338.2 (*S.aureus*) and LMM 2021001L (*E.hirae* and *E.coli*), submitted in the frame of the first application)	Actalia (2021) No SMI.2020.338.2 R.I.: 3

- **Efficacy in dirty conditions:**

Based on the new efficacy data provided, with the representative product at 1.3% w/w available chlorine (without detergent):

- bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), at 20°C, with a contact time of 20 minutes with dirty conditions (3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 15 % v/v. Phase 2 step 2 tests have been submitted during the first authorisation but efficacy has not been demonstrated on *P.aeruginosa*, since basic limit "NT-Nc is not greater than ± 0.3 lg" was not fulfilled.
- Yeasticidal and fungicidal activities are demonstrated both in phase 2, step 1 and step 2 tests (EN 1650 and in the frame of first application EN 13697), at 20°C, with a contact time of 20 minutes with dirty conditions (3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 8% v/v and fungicidal activity is shown at the in-use condition of 50% v/v.

In the frame of the minor change, the applicant has once again provided the test according to EN 13697 on *P.aeruginosa* alone, where the criterion ""NT-Nc is not greater than ± 0.3 lg" is not validated (i.e. 6.19-5.87=0.32).

The applicant has provided the following justifications: "As requested by the EN 13697 standard, NT and Nc values have been rounded to two significant figures. The difference between NT and Nc (NT-Nc) was calculated from these values and rounded to one significant figure to enable the comparison to the limit value of ±0.3 lg given with one significant figure. Then NT-Nc equals to 0.3 lg which complies with the EN 13697 requirements".

ECA does not agree with the justifications provided by the applicant. Indeed, as indicated in the standard, the values must be rounded to two significant figures. Therefore, we consider that this rule is also applicable for criteria and then the criterion should be considered as "NT-Nc is not greater than ± 0.**30** lg".

Therefore, eCA still considers that this study is not acceptable to support the efficacy against *P. aeruginosa* under dirty conditions and should be rejected.

As there is no other efficacy studies (P2S2 tests) provided or already included in the dossier to support the efficacy against *P. aeruginosa* (mandatory strain), the bactericidal efficacy under dirty conditions (without cleaning prior application) is not demonstrated.

- **Regarding claims for extended shelf-life**

Based on the efficacy data provided and the minimum application rate demonstrated in the efficacy studies, eCA considers that efficacy under clean conditions is demonstrated until 18 months (Meta SPC1 and 8) and 24 months (Meta SPC5) of storage according to the APCP data provided.

Please refer to the detailed explanations in the confidential section of the PAR.

Conclusion on the efficacy of the product
The elements presented in the dossier are not sufficient to demonstrate the efficacy of the product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE under dirty conditions, in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy Parts B+C as no acceptable P2S2 test against

bacteria under dirty conditions has been provided. Efficacy assessment supports the shelf-life.

2.2.5.6 Occurrence of resistance and resistance management

According to the Assessment Report of Active chlorine released from sodium hypochlorite (January 2017), 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.

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

First authorisation (2022)

French competent authorities (FR CA) assessed that product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE 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), Version 3.0, April 2018 and EN 14885:2015 standard for the following uses:

META SPC 1

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30% v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket included (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C

- Other target organisms:
  - Fungi: 30% v/v, 20 min, 20 °C

META SPC 2

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 0.525% w/w active chlorine, 15 min, 20 °C

    Efficacy against fungi is not demonstrated for a shelf-life of 3 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.
- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 0.525% w/w active chlorine, 15 min, 20 °C

  Efficacy against fungi is not demonstrated for a shelf-life of 3 months (maximum shelf life acceptable based on the APCP assessment) at the claimed in use application rate.

META SPC 3

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 100% v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 100% v/v, 20 min, 20 °C

META SPC 5

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 15 % v/v, 15 min, 20 °C

  Efficacy against fungi is not demonstrated for a shelf-life of 8 months (maximum shelf life acceptable based on the APCP data provided) at the claimed in use application rate.

- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 15 % v/v, 15 min, 20 °C

  Efficacy against fungi is not demonstrated for a shelf-life of 8 months (maximum shelf life acceptable based on the APCP data provided) at the claimed in use application rate.

META SPC 8

- Use 1: Disinfection of surfaces by spraying (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:

- Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
- Other target organisms:
  - Fungi: 30% v/v, 20 min, 20 °C

- Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT 2 and PT 4) under clean conditions:
  - Mandatory target organisms:
    - Bacteria and yeasts: 30 % v/v, 15 min, 20 °C
  - Other target organisms:
    - Fungi: 30% v/v, 20 min, 20 °C

It has to be noted that following efficacy tests submitted, pre-cleaning has been added and contact time for bacteria, yeasts and fungi have been increased.

Moreover, the appliquant claimed also an efficacy against smell generating organisms. The argumentation provided by the applicant was: "Smell generating organisms are bacteria and fungi. As the products have been reported efficient for these organisms, the claim for desodorising is considered relevant.". Nevertheless, as no efficacy data according to the requirements of the Efficacy guidance Vol II Part B/C, section 5.4.0.5.4 were provided, eCA consider that this claim has not been demonstrated.

- **NA-MIC minor change application (2022)**

Refer to first application (in the frame of MIC, efficacy in dirty conditions have not been validated).

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

none

2.2.6 Risk assessment for human health

The Assessment Reports for Active Chlorine released from sodium hypochlorite (PT2 and PT4, Italy, January 2017) state that sodium hypochlorite dissociates in water to form the sodium cation (Na^+) and hypochlorite anion (ClO^-), which is characterised by its well-known irritating/corrosive effects. Hypochlorite is in equilibrium of hypochlorous acid (HClO) and chlorine (Cl_2). The remaining sodium cation is a physiologically essential element and required in intermediary metabolism. During BPC TO-WGIII-2016, the members agreed that human health effects are primarily due to the local mode of action of sodium hypochlorite and potential systemic effects are secondary to its direct irritating reactivity.

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 (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.
Moreover the presence of chlorate should also be taken into account 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 addressed at the renewal of the active substance.

2.2.6.1 Assessment of effects on Human Health

With the exception of *in-vitro* skin corrosion test conducted with "Afise Javel 2.6" covering products of meta-SPC 1 and 3, no data are available on the products.
Classification is addressed based on available information on the active substance and co-formulants, according to the guidance of the CLP Regulation (EC No 1272/2008).

Skin corrosion and irritation

Meta-SPC 1 and 3

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 Membrane Barrier Test Method for Skin Corrosion,	Test item name : "AFISE JAVEL 2.6" (Batch	Performed according to the Corrositex® Method	The test was performed following 3 steps. <u>Step 1 – Compatibility test</u>: confirmed by a color change (from yellow to	A deviation (Dev 120/14) has been recorded in order to define	Faccioli F. (2014) Final report : S-2014-

Summary table of in vitro studies on skin corrosion/irritation					
OECD Guideline 435 (July 2015), GLP compliance, Reliability : 1	LAB2014-14) 4 replicates – 500µl of test item Negative control: Citric acid 10% Positive control: sodium hydroxide 50% and sulfuric acid 10%		purple) <u>Step 2 – Timescale Category test</u>: First trial: not conclusive Confirmation test: liquid turned into a slight grey coloration → assignment to Category 2 <u>Step 3 – Measurement of membrane barrier penetration:</u> **No disruption** of the membrane before 60 min (4 replicates) Negative control: no disruption of the membrane before 1 hour Positive control: disruption of the membrane after 11 min 40 sec and 13 min 35 sec <u>Conclusion:</u> According to the OECD 435 guideline and GHS criteria, the test item is **not corrosive** to skin.	a new preparation of bio-barrier because the negative control was reacted within 60 minutes, and the step 3 of experimentation was repeated → deviation not critical	01731 AMi

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Irritating to skin
Justification for the value/conclusion	The *in-vitro* skin corrosion (CORROSITEX®) assay performed on the product "Afise Javel 2.6" confirmed that the product is not corrosive to skin. The active substance content in this product is between 1 and 5% in the mixture. Therefore, a classification as Category 2 Skin Irritant is required for this product, according to the specific concentration limit of the active substance and CLP Regulation. Products of meta-SPC 1 and 3 are water-based formulations with the active substance at maximum 2.6% w/w as the only component. Therefore the product "Afise Javel 2.6" tested for the assay is representative of the products of meta-SPC 1 and 3 and the results of the test can be extrapolated to them.

Classification of the product according to CLP	The meta-SPC 1 anc 3 are classified as Skin Irritant 2; H315, according to the CLP criteria.

Meta-SPC 2, 5 and 8

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Corrosive to skin
Justification for the value/conclusion	Taking into account the extreme pH of the formulations (> 11.5), products from meta-SPC 2, 5 and 8 are considered corrosive to the skin according to the CLP criteria.
Classification of the product according to CLP	The meta-SPC 2, 5 and 8 are classified as Skin Corrosive 1; H314.

Eye irritation

No *in-vitro* data or *in-vivo* data on eye damage/irritation is available for the biocidal products in the BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE. Classification of the products from the BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE is performed according to the calculation rules laid down in the CLP regulation.

Meta-SPC 1 and 3

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes eye irritation
Justification for the value/conclusion	The products of meta-SPC 1 and 3 are classified Skin Irritant Cat 2 (H315) following an *in vitro* skin corrosion test (CORROSITEX®). This classification no longer involve an automatic classification as Eye damaging (H318), as it is the case when the products are classified Skin corrosive (H314). Therefore, the classification for eye damage/irritation for the products of meta-SPC 1 and 3 is determined using the Specific Concentration Limits established for this substance. These SPC prevail over a classification using the pH, as pH has already been taken into consideration when the SPC have been derived for the active substance into water. The products of meta-SPC 1 and 3 contain only the active substance into water, at a concentration between 1 and 3%, which leads to a classification as Category 2 Eye Irritant (H319).
Classification of the product according to CLP	The products of meta-SPC 1 and 3 are classified Eye Irrit. 2; H319, according to the CLP criteria.

Meta-SPC 2, 5 and 8

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes eye damage

Justification for the value/conclusion	The pH is above 11.5 for the products of meta-SPC 2, 5 and 8 and therefore these products are proposed to be classified Category 1 Eye Damaging, according to the CLP Regulation.
Classification of the product according to CLP	The products of meta-SPC 2, 5 and 8 are classified Eye Dam 1; H318, according to the CLP criteria.

Respiratory tract irritation

Meta-SPC 1 and 3

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. However, products of meta-SPC 1 and 3 are not classified as Skin corrosive and therefore they are not considered as Respiratory tract irritant.
Classification of the product according to CLP	No classification required.

Meta-SPC 2, 5 and 8

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 Critaria, a classification for corrosivity is considered to implicitly cover the potential to cause respiratory tract irritation. Additional classification for Respiratory tract irritation is not required. However, as products of meta-SPC 2, 5 and 8 are classified as Skin corrosive (H314) and used for spraying application, the mention EUH071: corrosive to the respiratory tract is required and a qualitative risk assessment is performed.
Classification of the product according to CLP	No classification required but the mention EUH071: corrosive to the respiratory tract is required.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing to the skin
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products in the BPF BIOCIDAL PRODUCT FAMILY BASED ON

	SODIUM HYPOCHLORITE, none of the components is classified for skin sensitizing properties.
Classification of the product according to CLP	No classification required

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitizing to the respiratory tract
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products in the BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE. None of the components is classified for respiratory sensitizing properties.
Classification of the product according to CLP	No classification required

Acute toxicity

No data on acute toxicity by oral, dermal and inhalation route is available for the biocidal products in the BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE. The classification of the products has been performed according to the calculation rules laid down in the CLP regulation.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	No acutely toxic via the oral route
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products in the BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE. For details on the calculations, please refer to the confidential PAR.
Classification of the product according to CLP	No classification required

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No acutely toxic via the inhalation route
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products in the BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE. None of the components is classified for acute inhalation toxicity properties.
Classification of the product according to CLP	No classification required

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via dermal route
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products in the BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE. None of the components is classified for acute dermal toxicity properties.
Classification of the product according to CLP	No classification required

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Sodium hypochlorite
Value(s)*	Not relevant
Justification for the selected value(s)	Local mode of action: skin corrosion/irritation and oxidization at the site of first contact

Data waiving	
Information requirement	Annex III of Regulation 5EC) No. 528/2012 (BPR), point 8.6 "Dermal absorption"
Justification	With respect to the biocidal products in BPF BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE, dermal absorption is not considered relevant. Toxicity of the biocidal products is characterised by active substance releaser sodium hypochlorite, which acts by a local mode of action due to direct chemical reactivity.

	In the absence of clear systemic effects, dermal absorption values were not deemed necessary; a default value of 100% was set in the "Active chlorine released from sodium hypochlorite Assessment Report" (Sodium hypochlorite in PT2-5, Italy, 2017).

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

Other

- **NA-MIC minor change application (2022**)

The minor change regarding the extension of the shelf-life for Meta-SPCs 1, 3 and 8 induces an increase of the sodium chlorate concentration at final time in these Meta-SPCs.
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.
These new concentrations and ATE have been used to perform the classification according to the classification rules (see Confidential annex).
These changes have no impact on the classification of the meta-SPCs and the identification of substances of concern.

2.2.6.2 Exposure assessment and risk characterisation

The biocidal product family BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE contains five Meta SPC described here below:

- Meta SPC 1 with products that contain 2.6% avCl. All disinfectants products of Meta SPC 1 are liquid formulations to be diluted.
- Meta SPC 2 with products that contain max 14.5% avCl. All disinfectants products of Meta SPC 2 are liquid formulations to be diluted.
- Meta SPC 3 with products that contain max 1.5% avCl. All disinfectants products of Meta SPC 3 are ready to use liquid formulations.
- Meta-SPC 5 with products that contain max 4.9% avCl. All disinfectants products of Meta SPC 5 are liquid formulations to be diluted.
- Meta-SPC 8 with products that contain max 2.6% avCl. All disinfectants products of Meta SPC 8 are liquid formulations to be diluted.

These products are intended for professional and non-professional users.

All the uses of the biocidal product family are summarized for each Meta SPC in the table below.

Table 1: Uses and scenarios summary developed in the exposure assessment

Product type	Uses	Scenarios	Meta SPC
PT02 PT04	Use 1: Disinfection of surface by spraying indoor	Application by spraying	Meta SPC 1, 2, 3, 5 and 8
	Use 2: Disinfection of surfaces by wiping with mop / cloth and bucket indoor	Application by wiping with mop / cloth and bucket	Meta SPC 1, 2, 5 and 8

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 (2017) any systemic effects observed in toxicity studies were considered as secondary effects. Consequently, a local risk assessment is performed for the products of BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE family.

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

In water, sodium hypochlorite (NaOCl) 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 NaOCl (as avCl) is considered relevant. The minor fraction of volatile hypochlorous acid (HClO) is considered negligible.

All the product of the family are products with a pH higher than 10. Therefore only exposure to aerosols of NaOCl (as avCl) is considered relevant.

Considering this:
- A quantitative local risk assessment is performed for inhalation exposure to NaOCl (as avCl) aerosols;
- A qualitative local risk assessment is performed for dermal exposure to NaOCl (as avCl).

Secondary exposure to NaOCl upon dermal contact with dry treated surfaces is considered to be non-relevant, as described in the AR (2017): 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.
Secondary exposure to NaOCl upon dermal contact with wet treated surfaces during contact time is considered relevant for assessment for bystander and general public. Inhalation exposure after application of NaOCl is also considered relevant for the assessment of secondary exposure.

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	nr	Yes	Yes	nr	Yes	Yes	No
Dermal	nr	Yes	Yes	nr	Yes	Yes	No
Oral	nr	No	Yes	nr	No	No	Yes

[Please indicate the main paths of human exposure by stating "yes","no" or "n.a." (not applicable) for each cell.]

List of scenarios

Summary table: exposure scenarios		
Scenario and task number	**Description of scenario and tasks**	**Exposed group**
Primary exposure		
Scenario 1	***Disinfection of surfaces by spraying***	
Task [1.1]	*Mixing and loading*	Professionals
Task [1.2]	*Application by spraying with a trigger spray*	Professionals
Task [1.3]	*Post-application – Rinsing with a cloth*	Professionals
Scenario 2	***Disinfection of surfaces by wiping with a mop/cloth and bucket***	
Task [2.1]	*Mixing and loading*	Professionals
Task [2.2]	*Application of the product by mopping and wiping*	Professionals
Task [2.3.a]	*Post-application – Rinsing with a mop*	Professionals
Task [2.3.b]	*Post-application – Rinsing with a cloth*	Professionals
Scenario 3	**Disinfection of surfaces by spraying**	
Task [3.1]	*Mixing and loading manual*	Non professionals
Task [3.2]	*Application by spraying with a trigger spray*	Non professionals
Task [3.3]	*Post-application – Rinsing with a cloth*	Non professionals
Scenario 4	***Disinfection of surfaces by wiping with a mop/cloth and bucket***	
Task [4.1]	*Mixing and loading manual*	Non professionals
Task [4.2]	*Application of the diluted product by mopping or wiping*	Non professionals
Task [4.3]	*Post-application – Rinsing with a mop or cloth*	Non professionals
Secondary exposure		
Scenario [5]	*Presence of bystanders*	General public / bystanders
Scenario [6]	*Contact with wet treated surface and oral exposure due to hand-to-mouth transfer*	General public

Reference values to be used in Risk Characterisation

Substance	Exposure route	Reference value
Sodium hypochlorite [1]	Oral	$NOAEC_{oral}$ = 0.1 % avCl
	Dermal	$NOAEC_{dermal}$ = 1.0 % avCl
	Inhalation	AEC_{inhal} = 0.5 mg/m³ avCl
	ARfD = 36 µg/kg bw/d	
	ADI = 3 µg/kg bw/d	

[1] according to the Assessment report for Active chlorine released from sodium hypochlorite, Italy, January 2017

Industrial exposure

Not relevant

Professional exposure

Primary exposure

Use 1: Disinfection of surfaces by spraying (PT2 and 4)

Products of meta-SPC 1, 2, 5 and 8 have to be diluted before use. The dilution rate and content of available chlorine in the dilution are reported below:

- **Meta-SPC1**: 300mL/L of product, taking into account the content of avCl in the meta-SPC 1 (2.6% w/w) and the density of 1.052, content of avCl in the dilution is **0.82% w/w** for meta-SPC 1.
- **Meta-SPC2**: 50-75mL/L of product, taking into account the content of avCl in the meta-SPC 2 (9.6-14.5% w/w) and the density of 1.18, content of avCl in the dilution is **0.85-0.86% w/w** for meta-SPC 2.
- **Meta-SPC5**: 150mL/L of product, taking into account the content of avCl in the meta-SPC 5 (4.9% w/w) and the density of 1.091, content of avCl in the dilution is **0.80% w/w** for meta-SPC 5.
- **Meta-SPC8**: 300mL/L of product, taking into account the content of avCl in the meta-SPC 8 (2.6% w/w) and the density of 1.051, content of avCl in the dilution is **0.82% w/w** for meta-SPC 8.

Products of **meta-SPC 3** are ready to use, the content of available chlorine in the product is **1.5% w/w**.

The professional user applies the dilution or the RTU product by spraying using a trigger spray. After a contact time of minimum 5 min, the product is rinsed with clean water (PT2) or potable water (PT4).

Exposure during the cleaning of the equipment (bucket, trigger spray) is covered by the exposure during application.

Dermal and inhalation exposure is expected during the spray application and only dermal exposure is expected during the mixing & loading and rinsing.

Scenario 1: Disinfection of surfaces by spraying

Task [1.1]: Mixing and loading (meta-SPC 1, 2, 5 and 8)

Description of Task [1.1]: Mixing and loading (meta-SPC 1, 2, 5 and 8)
Before use, products of meta-SPC 1, 2, 5 and 8 are diluted in water accoding to the claimed doses. The dilution step is either done manually if the packaging is less than 20L, or (semi-)automatically if the packaging is more than 20L. As pH >10 for the products of the meta-SPC 1, 2, 5 and 8, inhalation of vapours of HClO is negligible. Exposure to aerosols is also considered negligible for manual loading due to small quantities and for semi-automated loading as no exposure is expected. Content of available chlorine in the products of meta-SPC 1, 2, 5 and 8 ranges between 2.6% w/w and 14.5% w/w. As a worst-case approach, calculation for the dermal exposure is made with 2.6% w/w which covers all the meta-SPC (1, 2, 5 and 8).

Tier	**Parameters**	**Value**	**Source**
Tier 1	Maximum sodium hypochlorite concentration (%w/w avCl)	2.6% (Meta-SPC 1 and 8) 14.5% (Meta-SPC 2) 4.9% (Meta-SPC 5)	Applicant's data

Calculations for Task [1.1]

Summary table: estimated exposure concentration from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [1.1]	1 / No PPE	negligeable	2.6

Task [1.2]: Application of the product by trigger spray (meta-SPC 1, 2, 3, 5 and 8)

Description of Task [1.2]: Application of the product by trigger spray (meta-SPC 1, 2, 3, 5 and 8)
The professional user applies the diluted product (meta-SPC 1, 2, 5 and 8) or the RTU product (meta-SPC3) on surfaces using a trigger spray. Dermal and inhalation exposure is expected during the spray application. As pH > 10 for the dilutions and for RTU products of the meta-SPC 3, only exposure to aerosols of sodium hypochlorite is expected. To assess inhalation exposure during the spray application, the **Consumer product spraying and dusting model 2 (hand-held trigger spray)** from BHHEM (p.244), is used. The exposure value from the model is as follows: • 10.5 mg/m3 (inhalation)

Description of Task [1.2]: Application of the product by trigger spray (meta-SPC 1, 2, 3, 5 and 8)			
Content of available chlorine in the dilution for meta-SPC 1, 2, 5 and 8 ranges between 0.80% w/w and 0.86% w/w. The maximum concentration of 0.86% w/w of available chlorine in the diluted product is used for meta-SPC 1, 2, 5 and 8. The concentration of available chlorine is 1.5% w/w in the RTU products for meta-SPC 3.			
Tier	**Parameters**	**Value**	**Source**
Tier 1	Maximum sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data
	Sodium hypochlorite concentration in RTU product (%w/w avCl)	1.5% (Meta-SPC 3)	Applicant's data
	Inhalation exposure value (mg/m3)	10.5 mg/m3	Consumer product spraying and dusting model 2

Calculations for Task [1.2]

Summary table: estimated exposure concentration from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [1.2]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	9.03×10^{-2}	0.86
	Meta-SPC 3		
	1 / No PPE	1.58×10^{-1}	1.5

Task [1.3]: Post-application – Rinsing with a cloth (meta-SPC 1, 2, 3, 5 and 8)

Description of Task [1.3]: Post-application – Rinsing with a cloth (meta-SPC 1, 2, 3, 5 and 8)
After a contact time of minimum 5 min, the dilution or RTU product applied with a trigger spray is rinsed off with a wet cloth by the professional user. After application on surfaces, the active substance is expected to quickly react with the organic surface matter during the claimed contact time. Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order and the pH is assumed to remain above 10. Considering this, exposure through inhalation to vapours during this task is considered negligible. Dermal exposure during rinsing is covered by the application of the dilution or the RTU product. As a worst case, the professional user will be exposed at a concentration not higher than the concentration of available chlorine in the dilution or RTU product.

Description of Task [1.3]: Post-application – Rinsing with a cloth (meta-SPC 1, 2, 3, 5 and 8)			
The maximum concentration of available chlorine in the diluted product is 0.86% w/w for meta-SPC 1, 2, 5 and 8. The concentration of available chlorine is 1.5% w/w in the RTU products for meta-SPC 3.			
Tier	**Parameters[1]**	**Value**	**Source**
Tier 1	Maximum sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data
	Sodium hypochlorite concentration in RTU product (%w/w avCl)	1.5% (Meta-SPC 3)	Applicant's data

Calculations for Task [1.3]

Summary table: estimated exposure concentration from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [1.3]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	negligeable	0.86
	Meta-SPC 3		
	1 / No PPE	negligeable	1.5

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/m_3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

Risk characterisation

- Quantitative risk assessment (inhalation exposure)

Meta-SPC 1, 2, 5 and 8

Task/ Scenario	Tier	AEC (mg/m3)	Estimated inhalation concentration (mg/m3)	Estimated uptake/ AEC (%)
Mixing and loading (manual or semi-automated)				
Task [1.1]	1/ No PPE	0.5	negligeable	nr
Application by trigger spray				
Task [1.2]	1/ No PPE	0.5	$9.03x10^{-2}$	18%
Post-application				
Task [1.3]	1/ No PPE	0.5	negligeable	nr

For meta-SPC 1, 2, 5 and 8, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all scenarios.

Meta-SPC 3 (RTU)

Task/ Scenario	Tier	AEC (mg/m3)	Estimated inhalation concentration (mg/m3)	Estimated uptake/ AEC (%)
Application by trigger spray				
Task [1.2]	1/ No PPE	0.5	$1.58x10^{-1}$	32%
Post-application				
Task [1.3]	1/ No PPE	0.5	negligeable	nr

For meta-SPC 3, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all scenarios.

- Qualitative risk assessment (dermal exposure)

The product of meta-SPC 2, 5 and 8 are classified Skin corrosive category 1 (H314) and severe eye damage (H318), as well as the diluted products of meta-SPC 5 and 8 (see Confidential annex), and the product of meta-SPC 1 and 3 are classified Skin irritant (H315) and eye irritant (H319). All the products are intended to be applied by professionals. Considering that, a qualitative risk assessment is performed.

The professional is using the product for the mixing & loading task for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products classified H315 are used in the same conditions (frequency, duration of exposure) as the products classified H314. Hence, the same PPE are required for the use of all these products (gloves, skin coverage and chemical goggles).
Please refer to the tables below.

For the application of the diluted products of meta-SPC 1 and 2, the dilution are not classified, leading to no unacceptable risk.

Products of meta-SPC 2, 5 and 8 are classified Skin corrosive category 1 (H314) and they are applied by spraying. Therefore, the mention EUH071 is required. However, the products of meta-SPC 2 are diluted and the dilution, which is sprayed, is not classified H314 anymore and therefore qualitative risk assessment is not necessary.
Diluted products of meta-SPC 5 and 8 are classified H314 and therefore a qualitative risk assessment is performed. The diluted products are sprayed for a low duration and with PPE. Considering this, the risk is deemed acceptable.

Outcome of qualitative local risk assessment for disinfection of surfaces by spraying by professional users: Products from meta-SPC 2, 5 and 8, and diluted products of meta-SPC 5 and 8 are skin corrosive and eye damaging.

Hazard		**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Mixing and loading Post-application (Meta-SPC 5 and 8)	Skin	Frequency: once a day, everyday Duration: Mixing and loading = 10 min Rinsing = 10 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (2.6 to 14.5% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few min per day) (↑) High frequency
HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (2.6 to 14.5% avCl)	Chemical goggles			

Hazard		Exposure information							Risk	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Application (Meta-SPC 5 and 8)	Skin	Frequency: once a day, everyday Duration: Application by spraying = 30 min	Dermal contact (0.80 to 0.82% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few min per day) (↑) High frequency (↑) Spray application
HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (0.80 to 0.82% avCl)	Chemical goggles			
HIGH	EUH071			Inhalation		Inhalation exposure (0.80 to 0.82% avCl)	Respiratory protective equipment			

Outcome of qualitative local risk assessment for disinfection of surfaces by spraying by professional users: Products from meta-SPC 1 and 3 are skin and eye irritant.

Hazard		**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
LOW	Skin Irrit. Cat 2 (H315)	2 and 4	Mixing and loading (Meta-SPC 1) Post-application (Meta-SPC 3)	Skin	Frequency: once a day, everyday Duration: Mixing and loading = 10 min Rinsing = 10 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (2.6% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (less than few hours per day) (↑) High frequency
LOW	Eye Irrit. Cat 2 (H319)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (2.6% avCl)	Chemical goggles			

Hazard		**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
LOW	Skin Irrit. Cat 2 (H315)	2 and 4	Application (Meta-SPC 3)	Skin	Frequency: once a day, everyday Duration: Mixing and loading = 10 min Application by spraying = 30 min	Dermal contact (1.5% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (less than few hours per day) (↑) High frequency (↑) Spray application
LOW	Eye Irrit. Cat 2 (H319)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (1.5% avCl)	Chemical goggles			

Conclusion for Use 1 – Disinfection of surfaces by spraying (Meta-SPC 1, 2, 3, 5 and 8):

For products pertaining to **Meta-SPC 1 and 2,** the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

- For mixing and loading task: gloves, body protection and chemical goggles.

For products pertaining to **Meta-SPC 3**, the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

- For application by spraying and post-application task: gloves, body protection and chemical goggles.

For products pertaining to **Meta-SPC 5 and 8**, the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

- For mixing and loading and post-application tasks: gloves, body protection and chemical goggles.
- For application by spraying: gloves, body protection, chemical goggles and respiratory protective equipment.

Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT2 and 4)

Products of meta-SPC 1, 2, 5 and 8 have to be diluted before use.
The dilution rate and content of available chlorine in the dilution are reported below:

- **Meta-SPC1**: 300mL/L of product, taking into account the content of avCl in the meta-SPC 1 (2.6% w/w) and the density of 1.052, content of avCl in the dilution is **0.82% w/w** for meta-SPC 1.
- **Meta-SPC2**: 50-75mL/L of product, taking into account the content of avCl in the meta-SPC 2 (9.6-14.5% w/w) and the density of 1.18, content of avCl in the dilution is **0.85-0.86% w/w** for meta-SPC 2.
- **Meta-SPC5**: 150mL/L of product, taking into account the content of avCl in the meta-SPC 5 (4.9% w/w) and the density of 1.091, content of avCl in the dilution is **0.80% w/w** for meta-SPC 5.
- **Meta-SPC8**: 300mL/L of product, taking into account the content of avCl in the meta-SPC 8 (2.6% w/w) and the density of 1.051, content of avCl in the dilution is **0.82% w/w** for meta-SPC 8.

The professional user applies the dilution by mopping or wiping with a cloth.
After a contact time of minimum 5 min, the product is rinsed with clean water (PT2) or potable water (PT4).

Exposure during the cleaning of the equipment (bucket, mop, cloth) is covered by the exposure during application.

Dermal and inhalation exposure is expected during the application and only dermal exposure is expected during the post-application tasks.

Scenario 2: Disinfection of surfaces by wiping with a mop/cloth and bucket

Task [2.1]: Mixing and loading (meta-SPC 1, 2, 5 and 8)

Description of Task [2.1]: Mixing and loading (meta-SPC 1, 2, 5 and 8)
Before use, products of meta-SPC 1, 2, 5 and 8 are diluted in water accoding to the claimed doses. The dilution step is either done manually if the packaging is less than 20L, or (semi-)automatically if the packaging is more than 20L. This task is similar to the Mixing and Loading before spraying. Refer to Task [1.1].

Task [2.2]: Application of the product mopping and wiping (meta-SPC 1, 2, 5 and 8)

Description of Task [2.2]: Application of the product by mopping and wiping (meta-SPC 1, 2, 5 and 8)
The professional user applies the dilution (meta-SPC 1, 2, 5 and 8) on surfaces by wiping using a mop or a cloth and bucket.

Description of Task [2.2]: Application of the product by mopping and wiping (meta-SPC 1, 2, 5 and 8)
Exposure by inhalation to vapours of sodium hypochlorite is not expected, as pH for the dilution is > 10 for these meta-SPC. According to HEEG Opinion 8 "Defaults and appropriate models to assess human exposure for dipping processes (PT 8)", the Dipping model 1 (p. 26 of Userguidance and p. 308 of BHHEM) is appropriate to assess exposure during manual dipping. In this model, no inhalation exposure is expected during the task consisting in the dipping of wooden articles in open tanks. It is assumed that the inhalation exposure during the dipping of wooden articles is similar to the exposure during the dipping of a mop or a cloth in a bucket. Therefore, exposure to aerosols during mopping or wiping activities (including dipping of a cloth into a bucket) is considered negligible. Content of available chlorine in the dilution for meta-SPC 1, 2, 5 and 8 ranges between 0.80% w/w and 0.86% w/w. The maximum concentration of 0.86% w/w of available chlorine in the diluted product is used for calculation.

Tier	**Parameters**	**Value**	**Source**
Tier 1	Maximum sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (meta-SPC 1, 2, 5 and 8)	Applicant's data

Calculations for Task [2.2]

Summary table: estimated exposure concentration from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [2.2]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	negligible	0.86

Task [2.3.a]: Post-application – Rinsing with a mop (meta-SPC 1, 2, 5 and 8)

Description of Task [2.3.a]: Post-application –Rinsing with a mop (meta-SPC 1, 2, 5 and 8)
After a contact time of minimum 5 min, the diluted product applied by mopping is rinsed off with water using a mop. This task is similar to the rinsing with a cloth after spraying. Refer to Task [1.3].

Tier	**Parameters**[1]	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data

Calculations for Task [2.3.a]

Summary table: estimated exposure concentration from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [2.3.a]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	negligible	0.86

Task [2.3.b]: Post-application – Rinsing with a cloth (meta-SPC 1, 2, 5 and 8)

Description of Task [2.3.b]: Post-application – Rinsing with a cloth (meta-SPC 1, 2, 5 and 8)			
After a contact time of minimum 5 min, the dilution product applied by moping or wiping can also be rinsed off with a wet cloth by the professional user.This task is similar to the rinsing with a cloth after spraying. Refer to Task [1.3].			
Tier	**Parameters[1]**	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data

Calculations for Task [2.3.b]

Summary table: estimated exposure concentration from professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [2.3.b]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	negligible	0.86

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 and post-application/ maintenance) is not relevant.

Risk characterisation

Local effect (sodium hypochlorite)

- Quantitative risk assessment (inhalation exposure)

Meta-SPC 1, 2, 5 and 8

For all tasks of scenario 2 for meta-SPC 1, 2, 5 and 8, the estimated inhalation concentration is considered negligible and therefore below the AEC of sodium hypochlorite.

- Qualitative risk assessment (dermal exposure)

The products of meta-SPC 2, 5 and 8 are classified Skin corrosive category 1 (H314) and severe eye damage (H318), as well as the diluted products of meta-SPC 5 and 8 (see Confidential annex), and the products of meta-SPC 1 are classified Skin irritant (H315) and eye irritant (H319). The products are intended to be applied by professionals. Considering that, a qualitative risk assessment is performed.

The professional is using the product for the mixing & loading task for a low duration per day and with PPE. Considering this, the risk is deemed acceptable. Products classified H315 are used in the same conditions (frequency, duration of exposure) as the products classified H314. Hence, the same PPE are required for the use of all these products (gloves, skin coverage and chemical goggles).

For the application by wiping of diluted products classified H314 and H318 (meta-SPC 5 and 8), the professional user is directly exposed to corrosive product for a high duration when using a cloth or a mop without a handle. Indeed, the user is exposed during the entire duration of the task to corrosive product on the mop or the cloth and in the bucket during the dipping. Considering this, the risk is not considered acceptable. However, if a mop with a handle is used for the application, the risk is deemed acceptable, as exposure to the corrosive product is limited.
Please refer to the tables below.

Outcome of qualitative local risk assessment for disinfection of surfaces by mopping or wiping by professional users:
Products from meta-SPC 2, 5 and 8 and diluted products from meta-SPC 5 and 8 are skin corrosive and eye damaging.

Hazard		**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Mixing and loading Post-application (meta-SPC 5 and 8)	Skin	Frequency: once a day, everyday Duration: Mixing and loading = 10 min Rinsing = 10 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (2.6 to 14.5% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (few min per day) (↑) High frequency
HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (2.6 to 14.5% avCl)	Chemical goggles			

Outcome of qualitative local risk assessment for disinfection of surfaces by mopping or wiping by professional users:
Diluted products from meta-SPC 5 and 8 are skin corrosive and eye damaging.

Hazard		**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Application using a mop with a handle	Skin	Frequency: once a day, everyday Duration: Mopping/ wiping = 120 min	Dermal contact (0.8 and 0.82% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals RMM: - Do not dip your hands in the bucket - Apply the product only with a mop with a handle	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration as exposure is limited by the handle (↑) High frequency
HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (0.8 and 0.82% avCl)	Chemical goggles			

Hazard		**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Application by wiping with a cloth or a mop without a handle	Skin	Frequency: once a day, everyday Duration: Mopping/ wiping = 120 min	Dermal contact (0.8 and 0.82% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals RMM: - Do not dip your hands in the bucket - Apply the product only with a mop with a handle	**Not acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↑) Exposure to corrosive product (↑) High exposure duration (↑) High frequency
HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (0.8 and 0.82% avCl)	Chemical goggles			

Outcome of qualitative local risk assessment for disinfection of surfaces by mopping or wiping by professional users:
Products from meta-SPC 1 are skin and eye irritant.

Hazard		**Exposure information**							**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE**	**Relevant RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
LOW	Skin Irrit. Cat 2 (H315)	2 and 4	Mixing and loading	Skin	Frequency: once a day, everyday Duration: Mixing and loading = 10 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (2.6% avCl)	Gloves Skin coverage Eye protection Optional face shield	<u>Labelling:</u> - Labelling according to CLP <u>Trained personnel</u>: - Professional workers - Instructions for use minimizing exposure for professionals	**Acceptable**	(↓) Professionals following instructions for use and RMM on the label (↓) Professionals using PPE (↓) Low exposure duration (less than few hours per day) (↑) High frequency
LOW	Eye Irrit. Cat 2 (H319)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer during task (2.6% avCl)	Chemical goggles			

Conclusion for Use 2 – Disinfection of surfaces by wiping with a mop/cloth and bucket (Meta-SPC 1, 2, 5 and 8):

For products pertaining to **Meta-SPC 1 and 2**, the risk is considered acceptable taking into account the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

- For mixing and loading task: gloves, body protection and chemical goggles.
- For application by mopping or wiping and post-application task (**Meta-SPC 5 and 8**): gloves, body protection and chemical goggles.

For products pertaining to **Meta-SPC 5 and 8**, the risk is considered unacceptable **for wiping with a cloth or a mop without a handle** taking into account the qualitative risk assessment for local effects.
However, for products of **Meta-SPC 5 and 8**, the risk is considered acceptable for **wiping with a mop with a handle**, taking into account the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM) and personal protective equipment (PPE) listed below:

- For mixing and loading task: gloves, body protection and chemical goggles.
- For application by mopping or wiping and post-application task: gloves, body protection and chemical goggles.
- Do not dip your hands in the bucket.
- Apply the product only with a mop with a handle.

- **NA-MIC minor change application (2022)**

The minor changes have no impact on the human health risk assessment.

Non-professional exposure

Primary exposure

Use 1: Disinfection of surfaces by spraying (PT2 and 4)

Products of meta-SPC 1, 2, 5 and 8 have to be diluted before use. The dilution rate and content of avCl in the dilution are reported below:

- **Meta-SPC1**: 300mL/L of product, taking into account the content of avCl in the meta-SPC 1 (2.6% w/w) and the density of 1.052, content of avCl in the dilution is **0.82% w/w** for meta-SPC 1.
- **Meta-SPC2**: 50-75mL/L of product, taking into account the content of avCl in the meta-SPC 2 (9.6-14.5% w/w) and the density of 1.18, content of avCl in the dilution is **0.85-0.86% w/w** for meta-SPC 2.
- **Meta-SPC5**: 150mL/L of product, taking into account the content of avCl in the meta-SPC 5 (4.9% w/w) and the density of 1.091, content of avCl in the dilution is **0.80% w/w** for meta-SPC 5.
- **Meta-SPC8**: 300mL/L of product, taking into account the content of avCl in the meta-SPC 8 (2.6% w/w) and the density of 1.051, content of avCl in the dilution is **0.82%** w/w for meta-SPC 8.

Products of **meta-SPC 3** are ready to use. The content of avCl in the product is **1.5% w/w.**

The non-professional user applies the dilution or the RTU product by spraying using a trigger spray. After a contact time of minimum 5 min, the product is rinsed with clean water (PT2) or potable water (PT4).

Exposure during the cleaning of the equipment (bucket, trigger spray) is covered by the exposure during application.

Dermal and inhalation exposure is expected during the spray application and only dermal exposure is expected during the mixing&loading and rinsing.

Scenario 3: Disinfection of surfaces by spraying

Task [3.1]: Mixing and loading manual (meta-SPC 1, 2, 5 and 8)

Description of Task [3.1]: Mixing and loading manual (meta-SPC 1, 2, 5 and 8)			
According to the ConsExpo Disinfectant Products Factsheet, during the mixing and loading of a liquid, dermal exposure can occur. Exposure by inhalation is considered negligible as no vapour is expected. Indeed, as pH > 10 for the products of the meta-SPC 1, 2, 5 and 8, vapours of HClO are negligeable. Content of avCl in the products of meta-SPC 1, 2, 5 and 8 ranges between 2.6% w/w and 14.5% w/w. Calculation for the dermal exposure is made with 2.48% w/w, which covers all the meta-SPC (1, 2, 5 and 8).			
Tier	**Parameters**	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration (%w/w avCl)	2.6% (Meta-SPC 1 and 8) 14.5% (Meta-SPC 2) 4.9% (Meta-SPC 5)	Applicant's data

Calculations for Task [3.1]

Summary table: estimated exposure concentration from non-professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [3.1]	1 / No PPE	negligible	2.6

Task [3.2]: Application of the product by trigger spray (meta-SPC 1, 2, 3, 5 and 8)

Description of Task [3.2]: Application of the product by trigger spray (meta-SPC 1, 2, 3, 5 and 8)
The non professional user applies the diluted product or RTU product on surfaces using a trigger spray. Dermal and inhalation exposure is expected during the spray application. As pH > 10 for the dilution and for RTU products of the meta-SPC 3, only exposure to aerosols of sodium hypochlorite is expected.

Description of Task [3.2]: Application of the product by trigger spray (meta-SPC 1, 2, 3, 5 and 8)

To assess inhalation exposure during the spray application, the **Consumer product spraying and dusting model 2 (hand-held trigger spray)** from BHHEM (p.244), is used.

The exposure value from the model is:

- 10.5 mg/m3 (inhalation)

Content of avCl in the dilution for meta-SPC 1, 2, 5 and 8 ranges between 0.80% w/w and 0.86% w/w. The maximum concentration of 0.86% w/w of available chlorine in the diluted product is used for meta-SPC 1, 2, 5 and 8. The concentration of available chlorine is 1.5% w/w in the RTU products for meta-SPC 3.

Tier	Parameters	Value	Source
Tier 1	Max sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data
	Sodium hypochlorite concentration in RTU product (%w/w avCl)	1.5% (Meta-SPC 3)	Applicant's data

Calculations for Task [3.2]

Summary table: estimated exposure concentration from non-professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [3.2]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	9.03×10^{-2}	0.86
	Meta-SPC 3		
	1 / No PPE	1.58×10^{-1}	1.5

Task [3.3]: Post-application – Rinsing with a cloth (meta-SPC 1, 2, 3, 5 and 8)

Description of Task [3.3]: Post-application –Rinsing with a cloth (meta-SPC 1, 2, 3, 5 and 8)

After a contact time of minimum 5 min, the dilution or RTU product applied with a trigger spray is rinsed off with a wet cloth by the non-professional user.

After application on surfaces, the active substance is expected to quickly react with the organic surface matter during the claimed contact time. Moreover, due to the fast drying time, the decrease of the pH induced by flushing with water during the rinsing step of the treated surfaces is assumed to be of low order and the pH is assumed to remain above 10. Considering this, exposure through inhalation to vapours during this task is considered negligible.

According to the ConsExpo Disinfectant Products Factsheet (4.2.2.3), during rinsing, dermal exposure can occur.

Description of Task [3.3]: Post-application –Rinsing with a cloth (meta-SPC 1, 2, 3, 5 and 8)			
Dermal exposure during rinsing is covered by the application of the dilution / RTU product. As a worst case, the non-professional 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 0.86% w/w for meta-SPC 1, 2, 5 and 8. The concentration of available chlorine is 1.5% w/w in the RTU products for meta-SPC 3.			
Tier	**Parameters**	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data
	Sodium hypochlorite concentration in RTU product (%w/w avCl)	1.5% (Meta-SPC 3)	Applicant's data

Calculations for Task [3.3]

Summary table: estimated exposure concentration from non-professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [3.3]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	negligible	0.86
	Meta-SPC 3		
	1 / No PPE	negligible	1.5

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/m^3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

Risk characterisation

Use 1: Disinfection of surfaces by spraying (PT2 and 4)

- Quantitative risk assessment (inhalation exposure)

Meta-SPC 1, 2, 5 and 8

- Inhalation exposure

Task/ Scenario	Tier	AEC (mg/m3)	Estimated concentration (mg/m3)	Estimated concentration / AEC (%)
M&L				
Task [3.1]	Negligible			n.r.
Application by trigger spray				
Task [3.2]	1/ No PPE	0.5	$9.03x10^{-2}$	18%
Post application				
Task [3.3]	Negligible			n.r.

For meta-SPC 1, 2, 5 and 8, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all scenarios.

Meta-SPC 3

- Inhalation exposure

Task/ Scenario	Tier	AEC (mg/m3)	Estimated concentration (mg/m3)	Estimated concentration / AEC (%)
Application by trigger spray				
Task [3.2]	1/ No PPE	0.5	$1.58x10^{-1}$	32%
Post application				
Task [3.3]	Negligible			n.r.

For meta-SPC 3, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all scenarios.

- Qualitative risk assessment (dermal exposure)

The products of meta-SPC 2, 5 and 8 are classified Skin corrosive category 1 (H314) and severe eye damage (H318), as well as diluted products of meta-SPC 5 and 8 (see Confidential annex), and the products for meta-SPC 1 and 3 are classified skin irritant (H315) and eye irritant (H319). All the products are intended to be applied by non-professional. Considering that, a qualitative risk assessment is performed. Please refer to the tables below.

For products of META SPC 2, 5 and 8, considering the absence of a protection offered by the packaging to limit exposure, risk is not considered acceptable for non-professional.
For the products of META SPC 1, the non-professional is using the product for a moderate frequency and for a low duration per day. Considering this and the additional RMM "washing on hands after use", the risk is deemed acceptable.

For application of meta-SPC 3 applied by spraying, the non-professional is expected using the product for a moderate frequency and for a duration lower than 1 hour per day. Considering this and the additional RMM "washing on hands after use" and the product has to be sprayed downward, the risk is deemed acceptable.

For the application of the diluted products of meta-SPC 1 and 2, the dilution are not classified, leading to no unacceptable risk.
Diluted products of meta-SPC 5 and 8 are classified H314 and therefore a qualitative risk assessment is performed. The corrosive diluted products are sprayed for 30min continuously by non professional user leading to high exposure of corrosive product. Considering this, the risk is not acceptable.

- Qualitative risk assessment (inhalation exposure)

Products of meta-SPC 2, 5 and 8 are classified Skin corrosive category 1 (H314) and they are applied by spraying. Therefore, the mention EUH071 is required. However, the products of meta-SPC 2 are diluted and the dilution, which is sprayed, is not classified H314 anymore and therefore qualitative risk assessment is not necessary.
Diluted products of meta-SPC 5 and 8 are classified H314 and therefore a qualitative risk assessment is performed. The corrosive diluted products are sprayed for 30min continuously by non professional user leading to high exposure of corrosive product. Considering this, the risk is not acceptable.

Outcome of qualitative local risk assessment for disinfection of surfaces by spraying by non-professional users: Products from meta-SPC 1 and 3 are skin and eye irritant.

Hazard		**Exposure information**						**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE and RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
LOW	Skin Irrit. Cat 2 (H315)	2 and 4	Mixing and loading (meta-SPC 1) Rinsing (meta-SPC 3)	Skin	Frequency: no data Duration: Mixing and loading = 1.33 min Rinsing = 10 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (1.5 to 2.6% avCl)	<u>No PPE</u> <u>Labelling:</u> - Labelling according to CLP - Instructions for use and storage - "Washing on hands after use" <u>Packaging:</u> - Child-proof closure	**Acceptable**	(↓) instruction of use and RMM on the label (washing on hands after use) (↓) Low exposure duration (less than one hour per day) (↑) moderate frequency (↑) Formulation (liquid formulation to be diluted, no viscious formulation limitating splashes) (↓) child-proof closure
LOW	Eye Irrit. Cat 2 (H319)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer (1.5 to 2.6% avCl)			

Hazard		**Exposure information**						**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE and RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
LOW	Skin Irrit. Cat 2 (H315)	2 and 4	Application (meta-SPC 3)	Skin	Frequency: no data Duration: Spraying application = 30 min	Dermal contact (1.5% avCl)	<u>No PPE</u> <u>Labelling:</u> - Labelling according to CLP - Instructions for use and storage - "Washing on hands after use" - "The product has to be sprayed downward" <u>Packaging:</u> - Child-proof closure	**Acceptable**	(↓) instruction of use and RMM on the label (washing on hands after use, the product should be sprayed downward) (↑) Exposure by spraying (↓) Low exposure duration (less than one hours per day) (↑) moderate frequency (↓) child-proof closure (↓) no children or infant exposure
LOW	Eye Irrit. Cat 2 (H319)			Eyes		Eye exposure through potential spraying or hand-to-eye transfer (1.5% avCl)			

Outcome of qualitative local risk assessment for disinfection of surfaces by spraying by non-professional users: Products from Meta-SPC 2, 5 and 8 and diluted products from meta-SPC 5 and 8 are skin corrosive and eye damage

Hazard		Exposure information						Risk	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE and RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Mixing and loading	Skin	Frequency: no data Duration: Mixing and loading = 1.33 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (2.6 to 14.5% avCl)	None	**Not acceptable**	(↓) instruction of use and RMM on the label (washing on hands after use) (↓) Low exposure duration (less than few minutes per day) (↑) Formulation (liquid formulation to be diluted, no

HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer (2.6 to 14.5% avCl)			viscious formulation limitating splashes) (↑) moderate frequency (equal to or less than once per week cannot be ensure) (↑) Exposure to corrosive substance (↑) Mode of application (the product should be loaded undiluted a first time for measurement and then in a bucket leading to an increase of potential dermal exposure through spills and splashes) (↓) child-proof closure (↓) no children or infant exposure The uncertainties that may decrease the risk are the following: (↓) Modification of the formulation to avoid the M&L task (diluted solution

								with no classification) and/or to reduce splashes; (↓) Other packaging; (↓) Restriction of the use frequency

Application (meta-SPC 5 and 8)

Hazard		**Exposure information**						**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE and RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Application	Skin	Frequency: no data Duration: Spraying application = 30min	Dermal contact (0.8 and 0.82% avCl)	<u>None</u>	**Not Acceptable**	(↓) instruction of use and RMM on the label (washing on hands after use, the product should be sprayed downward) (↑) Exposure by spraying (↑) Exposure to corrosive substance (↑) Moderate exposure duration (↑) moderate frequency (equal to or less than once per week cannot be ensure) (↓) child-proof closure (↓) no children or infant exposure
HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer (0.8 and 0.82% avCl)			

<FR>	<BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE>	<PT 2, 4>

Conclusion for Use 1: Disinfection of surfaces by spraying (Meta-SPC 1, 2, 3, 5 and 8)

For products pertaining to **Meta-SPC 1**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

- Washing on hands after use

For products pertaining to **Meta-SPC 3**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

- Washing on hands after use
- The product has to be sprayed downward

For products pertaining to **Meta-SPC 2, 5 and 8**, risk is not acceptable considering the qualitative risk assessment for local effects.

Use 2: Disinfection of surface by wiping with mop / cloth and bucket (PT2 and 4)

As for use 1, products of meta-SPC 1, 2, 5 and 8 have to be diluted before use. The dilution rate and content of avCl in the dilution are the same as for the use 1:

- **Meta-SPC1**: 300mL/L of product, equivalent to **0.82% w/w** of avCl in the dilution.
- **Meta-SPC2**: 50-75mL/L of product, equivalent to **0.85-0.86% w/w** of avCl in the dilution.
- **Meta-SPC5**: 150mL/L of product, equivalent to **0.80% w/w** of avCl in the dilution.
- **Meta-SPC8**: 300mL/L of product, equivalent to **0.82% w/w** of avCl in the dilution.

The non-professional user applies the dilution by mopping or wiping with cloth. After a contact time of minimum 5 min, the product is rinsed with clean water (PT2) or potable water (PT4).

Exposure during the cleaning of the equipment (bucket, mop, cloth) is covered by the exposure during application.

Only dermal exposure is expected during the mixing&loading, application and rinsing.

Scenario 4: Disinfection of surface by wiping with mop/cloth and bucket

Task [4.1]: Mixing and loading manual (meta-SPC 1, 2, 5 and 8)

Description of Task [4.1]: Mixing and loading manual (meta-SPC 1, 2, 5 and 8)			
According to the ConsExpo Disinfectant Products Factsheet, during the mixing and loading of a liquid, dermal exposure can occur. Exposure by inhalation is considered negligible as no vapour is expected. Indeed, as pH > 10 for the products of the meta-SPC 1, 2, 5 and 8, vapours of HClO are negligeable. Content of avCl in the products of meta-SPC 1, 2, 5 and 8 ranges between 2.6% w/w and 14.5% w/w. Calculation for the dermal exposure is made with 2.6% w/w which covers all the meta-SPC (1, 2, 5 and 8).			
Tier	**Parameters**	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration (%w/w avCl)	2.6% (Meta-SPC 1 and 8) 14.5% (Meta-SPC 2) 4.9% (Meta-SPC 5)	Applicant's data

Calculations for Task [4.1]

Summary table: estimated exposure concentration from non-professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [4.1]	1 / No PPE	negligeable	2.6

Task [4.2]: Application of the product by mopping or wiping (meta-SPC 1, 2, 5 and 8)

Description of Task [4.2]: Application of the product by mopping or wiping (meta-SPC 1, 2, 5 and 8)
The non-professional user applies the diluted product on surfaces using a mop or a cloth. Dermal exposure is expected during the application. According to the ConsExpo Disinfectant Products Factsheet, during application, dermal exposure can occur. Exposure by inhalation is considered negligeable as no vapour is expected. Indeed, as pH > 10 for the dilution, vapours of HClO are negligeable. Content of avCl in the dilution for meta-SPC 1, 2, 5 and 8 ranges between 0.80% w/w and 0.86% w/w. The maximum concentration of 0.86% w/w of available chlorine in the diluted product is used for meta-SPC 1, 2, 5 and 8.

Tier	**Parameters**	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data

Calculations for Task [4.2]

Summary table: estimated exposure concentration from non-professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [4.2]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	negligeable	0.86

Task [4.3]: Post-application – Rinsing with a cloth (meta-SPC 1, 2, 3, 5 and 8)

Description of Task [4.3]: Post-application –Rinsing with a cloth (meta-SPC 1, 2, 5 and 8)
After a contact time of minimum 5 min, the dilution applied with a mop or cloth is rinsed off with a wet mop or cloth by the non-professional user. This task is similar to the rinsing with a cloth after spraying. Refer to Task [3.3]. Normally no rinsing is required after mopping according to the ConsExpo Disinfectant Products Factsheet.

Tier	**Parameters**	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data

Calculations for Task [4.3]

Summary table: estimated exposure concentration from non-professional uses			
Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg/m3)**	**Estimated dermal concentration (% avCl)**
Task [4.3]	Meta-SPC 1, 2, 5 and 8		
	1 / No PPE	negligeable	0.86

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/m_3) is relevant for risk characterisation and the addition of exposure levels and the calculation of a combined exposure during the different tasks (e.g. M&L, application and post-application/ maintenance) is not relevant.

Risk characterisation

Use 2: Disinfection of surfaces by wiping with mop/cloth and bucket (PT2 and 4)

- Quantitative risk assessment (inhalation exposure)

For all tasks and all scenari, exposure by inhalation is negligeable for meta-SPC 1, 2, 5 and 8.

- Qualitative risk assessment (dermal exposure)

The products of meta-SPC 2, 5 and 8 are classified Skin corrosive (H314) and severe eye damage (H318), as well as the diluted products of meta-SPC 5 and 8 (see Confidential annex), and the products for meta-SPC 1 are classified skin irritant (H315) and eye irritant (H319). All the products are intended to be applied by non-professional. Considering that, a qualitative risk assessment is performed. Please refer to the tables below.

For products of META SPC 2, 5 and 8, considering the absence of a protection offered by the packaging to limit exposure, risk is not considered acceptable for non-professional.
For the products of META SPC 1, the non-professional is using the product for a moderate frequency and for a low duration per day. Considering this and the additional RMM "washing on hands after use", the risk is deemed acceptable.

For the application of the diluted products of meta-SPC 1 and 2, the dilution are not classified, leading to no unacceptable risk.

Diluted products of meta-SPC 5 and 8 are classified H314 and therefore a qualitative risk assessment is performed. The corrosive diluted products are expected to be used more than few minute per day. Moreover high exposure of corrosive product is expected with the use of a mop and a bucket and even with a mop with a handle. Considering this, the risk is not acceptable.

Outcome of qualitative local risk assessment for disinfection of surfaces by mopping or wiping by non-professional users: Products from meta-SPC 1 are skin and eye irritant.

Hazard		**Exposure information**						**Risk**	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE and RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
LOW	Skin Irrit. Cat 2 (H315)	2 and 4	Mixing and loading	Skin	Frequency: no data Duration: Mixing and loading = 1.33 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (2.6% avCl)	<u>No PPE</u> <u>Labelling:</u> - Labelling according to CLP - Instructions for use and storage - "Washing on hands after use" <u>Packaging:</u> - Child-proof closure	**Acceptable**	(↓) instruction of use and RMM on the label (washing on hands after use) (↓) Low exposure duration (less than one hour per day) (↓) Practically no exposure (↑) moderate frequency (↑) Formulation (liquid formulation to be diluted, no viscious formulation limitating splashes) (↓) child-proof closure (↓) no children or infant exposure
LOW	Eye Irrit. Cat 2 (H319)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer (2.6% avCl)			

<FR>	<BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE>	<PT 2, 4>

Outcome of qualitative local risk assessment for disinfection of surfaces by mopping or wiping by non-professional users: Products from Meta-SPC 2, 5 and 8 and diluted products of meta-SPC 5 and 8 are skin corrosive and eye damage

Hazard		Exposure information						Risk	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE and RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Mixing and loading	Skin	Frequency: no data Duration: Mixing and loading = 1.33 min	Skin exposure through potential liquid spills around the opening of the bottle and/or due to splashes of the liquid concentrate (2.6 to 14.5% avCl)	None	**Not acceptable**	(↓) instruction of use and RMM on the label (washing on hands after use) (↓) Low exposure duration (less than few minutes per day) (↑) Formulation (liquid formulation to be diluted, no

HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer (2.6 to 14.5% avCl)			viscious formulation limitating splashes) (↑) moderate frequency (equal to or less than once per week cannot be ensure) (↑) Exposure to corrosive substance (↑) Mode of application (the product should be loaded undiluted a first time for measurement and then in a bucket leading to an increase of potential dermal exposure through spills and splashes) (↓) child-proof closure (↓) no children or infant exposure The uncertainties that may decrease the risk are the following: (↓) Modification of the formulation to avoid the M&L task (diluted solution with no classification) and/or to reduce splashes;

									(↓) Other packaging; (↓) Restriction of the use frequency

Application (meta-SPC 5 and 8)

Hazard		Exposure information						Risk	
Hazard category	**Effects in terms of C&L**	**PT**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant PPE and RMMs**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓)**
HIGH	Skin Corr. Cat 1 (H314)	2 and 4	Application	Skin	Frequency: no data Duration: Application no data	Dermal contact (0.8 and 0.82% avCl)	None	**Not acceptable**	(↓) instruction of use and RMM on the label (washing on hands after use) (↑) Moderate exposure duration (less than few minutes per day cannot be ensure)

HIGH	Eye Dam. Cat 1 (H318)			Eyes		Eye exposure through potential splashed or hand-to-eye transfer (0.8 and 0.82% avCl)			(↑) moderate frequency (equal to or less than once per week cannot be ensure) (↑) Exposure to corrosive substance (↑) Mode of application (the user is in direct contact with the diluted product) (↓) child-proof closure (↓) no children or infant exposure

Conclusion for Use 2: Disinfection of surfaces by wiping with a mop / cloth and bucket (Meta-SPC 1, 2, 5 and 8)

For products pertaining to **Meta-SPC 1**, risk is acceptable considering the qualitative risk assessment for local effects with the application of risk mitigation measures (RMM):

- Washing on hands after use

For products pertaining to **Meta-SPC 2, 5 and 8**, risk is not acceptable considering the qualitative risk assessment for local effects.

- **NA-MIC minor change application (2022)**

The minor changes have no impact on the human health risk assessment.

Secondary exposure – Exposure of the general public

Scenario [5]: Inhalation exposure of the bystander

Description of Scenario [5]
Bystander present during the mixing and loading, application or rinsing step can be exposed by inhalation. This exposure phase is considered covered by inhalation exposure during application since greater exposure is not expected for bystander.

Scenario [6]: Dermal exposure of the general public to the wet product and oral exposure due to hand-to-mouth transfer

Description of Scenario [6]: Dermal exposure of the general public to the wet product and oral exposure due to hand-to-mouth transfer			
General public can touch the wet surface during the contact time of the dilution for meta SPC 1, 2, 5 and 8 or RTU product for meta-SPC 3. Infant after touching the wet surface can be exposed orally to avCl after hand to mouth transfer. Content of avCl in the dilution for meta-SPC 1, 2, 5 and 8 ranges between 0.80% w/w and 0.86% w/w. The maximum concentration of 0.86% w/w of available chlorine in the diluted product is used for meta-SPC 1, 2, 5 and 8. The concentration of available chlorine is 1.5% w/w in the RTU products for meta-SPC 3.			
Tier	**Parameters**	**Value**	**Source**
Tier 1	Max sodium hypochlorite concentration in dilution (%w/w avCl)	0.86% (Meta-SPC 1, 2, 5 and 8)	Applicant's data
	Sodium hypochlorite concentration in RTU product (%w/w avCl)	1.5% (Meta-SPC 3)	Applicant's data

Risk characterisation

Bystander / General public

Local effects (sodium hypochlorite)

- Quantitative risk assessment – Inhalation exposure

All Meta-SPC

Inhalation exposure of the bystander is the same as the inhalation exposure of the user (see primary exposure).

For all meta-SPC, the estimated inhalation concentration is below the AEC of sodium hypochlorite for all scenarios.

- Qualitative risk assessment (dermal and oral exposure)

Products of Meta-SPC 2, 5 and 8 are classified skin corrosive (H314) and severe eye damage (H318), as well as diluted products of meta-SPC 5 and 8, and products of meta-SPC 1 and 3 are classified skin irritant (H315) and eye irritant (H319). Therefore the following risk mitigation measures are required:

- Do not touch the surface until it is totally dried;
- Children should not be present during disinfection

Disinfection by-products exposure

DBP can be formed during the different uses. However no data is available regarding the identity and content of these DBP and no guidance is available for these uses. In this context non risk assessment can be performed.

Monitoring data

[Please add any information on surveys or studies with the actual product or with a surrogate.]

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, residues in food or feed are not expected.

Sodium hypochlorite is widely used for disinfection of surfaces and equipment in food and feed processing areas as well as for disinfection of drinking water, and thus, chlorate residues can be carried-over into food and feed during cleaning, washing and processing steps. Hence a dietary exposure assessment is presented below.

Residue definitions

Nature of residue:

Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly (decomposition to physiological sodium and chloride). Hence, residue formation is assumed to be negligible for aqueous solutions of Na(OCl). Finally, no systemic assessment is required for substances such as Na(OCl) which act by a local mode of action only.
The BPC TOX-WG-IV-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage. Thus, chlorate may represent a worst-case for Na(OCl).
Furthermore, at EU level (WG TOX III-2016) it was finally discussed that only **chlorates** (ClO_3^-) is relevant for the dietary risk assessment. This relevant residue can be present in the BP as impurity and can be generated as Disinfection By Products (DBP) or degradation of the active ingredient in the biocidal product upon storage. Consequently, chlorates is a relevant compound to assess for food, feed and drinking water.

List of scenarios

Please note that the applicant has developed an approach to estimate the risk for consumer via drinking water consumption. This approach have been considered as not relevant by eCA. This assessment is presented in Annex Residue §3.4 as informative data.

Summary table: scenarios				
Scenario number	**Scenario** (e.g. mixing/ loading)	**Use**	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
DRA-1	Professional PT 4 use - Indirect exposure via food	-Disinfection of surfaces by spraying: hard surface (utensils, equipment and furniture) - Disinfection of surfaces (floors, utensils, equipment and furniture) by wiping with mop/cloth and bucket	Secondary Exposure to food in contact with treated surfaces	General public
DRA-2	Non Professional PT 4 use - Indirect exposure via food	-Disinfection of surfaces by spraying: hard surface (utensils, equipment and furniture) - Disinfection of surfaces (floors, utensils, equipment and furniture) by wiping with mop/cloth and bucket	Secondary Exposure to food in contact with treated surfaces	General public

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	Disinfectant – in irrigation water applied by watering tree – indoor use for mushroom crop.	ADI: 0.15 mg/kg bw/d ARfD: not applicable

Summary table of other (non-biocidal) uses			
		Not approved as a PPP active substance.	Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005.

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)

Scenario DRA-1:

With regards to professional intended PT 4 use, dietary exposure to available chlorine and chlorate in food was assessed and considered acceptable in the CAR[5]. This refers to the EFSA Scientific Opinion of the EFSA CONTAM Panel on "*Risks for public health related to the presence of chlorate in food*" (EFSA Journal 2015;13(6):4135) which includes a comprehensive dietary exposure and risk assessment for chlorate residues in food and drinking water based on occurrence data. The conclusion of this assessment remains valid for intended professional PT 4 uses:

"Potential chlorate residues from the application of chlorine and hypochlorite in PTs 4 and 5 are considered to be included in the measured chlorate residue values, and the conclusions drawn by the EFSA CONTAM Panel on chlorate residues cover thus also the dietary risk arising from PT4 and PT5 uses of chlorine and hypochlorite. Since the EFSA Scientific Opinion on chlorate residues provides actual measured data for chlorate residues in food and an exhaustive exposure and risk assessment based on consumption data, the conclusions drawn in the EFSA Scientific Opinion are superior to any dietary risk assessment based on exposure models."
Consequently, no dietary risk assessment is deemed necessary for the intended PT 4 professional uses.

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

Scenario DRA-2:
After non professional PT 4 use, general public may be exposed to chlorate residue by consumption of food that could have been in contact with treated surfaces.

[5] Assessment report, January 2017 – Active chlorine released from sodium hypochlorite. Italy

Dietary exposure assessment has been performed according to ECHA guidance document[6] for adults only. Indeed, as detailed in ECHA guidance document[7], default value of 0.2 m^2 for parameter "area in contact with food" is "*derived for adults; flexibility can be applied in regard to the value to be used for toddlers to allow for different or lower food consumption*". Therefore, detailed scenario exposure is not representative of toddler food intake.

A rinsing step was considered, and indirect exposure via food was performed for two tiers:

- Tier-I (without rinsing of treated surfaces);
- Tier-II (with rinsing of the treated surfaces).

In the absence of measured residue data, the assumption was made that 10% (Tier-IIa) or 1% (Tier-IIb) of chlorate residues remain on the treated surface after rinsing, while 90% or 99%, respectively, of chlorate residues are flushed. This is considered realistic, as chlorate is highly soluble in water: for sodium chlorate, a solubility of 960-1000 g/L is described (EFSA CONTAM Panel, 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13:4135).

It is noticed that chlorate residue formation may depend on the formulation of the products as well as on the storage conditions of the product.
Table below summarizes final chlorate concentration in diluted biocidal product among all intended meta SPC for PT4 use disinfection of surfaces in contact with food for non professional.

Table: final chlorate concentration in diluted biocidal product among all intended meta SPC for PT4 use disinfection of surfaces in contact with food for non professional use

	Non professional - Disinfection of surfaces in contact with food by spraying						
	Meta SPC						
	1	**2**	**2**	**2**	**3**	**5**	**8**
Available chlorine eq Cl_2 (%w/w)	2.6	9.6	12.5	14.5	1.5	4.9	2.6
Chlorate (%w/w) after storage	0.139	1.31	1.61	2.22	0.062	0.493	0.136
Dilution of biocidal product	0.3	0.075	0.055	0.05	1	0.15	0.3
Density	1.052	1.18	1.218	1.242	1.028	1.091	1.051
Chlorate final concentration (%)	0.0439	0.1159	0.1079	0.1379	0.0637	0.0807	0.0429
Chlorate final concentration (mg/L)	438.68	1159.35	1078.54	**1378.62**	637.36	806.79	428.81

[6] Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017

[7] Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017

	Non professional - Disinfection of surfaces in contact with food by wipping/mopping					
	Meta SPC					
	1	**2**	**2**	**2**	**5**	**8**
Available chlorine eq Cl_2 (%w/w)	2.6	9.6	12.5	14.5	4.9	2.6
Chlorate (%w/w) after storage	0.139	1.31	1.61	2.22	0.493	0.136
Dilution of biocidal product	0.3	0.075	0.055	0.05	0.15	0.3
Density	1.052	1.18	1.218	1.242	1.091	1.051
Chlorate final concentration (%)	0.0439	0.1159	0.1079	0.1379	0.0807	0.0429
Chlorate final concentration (mg/L)	438.68	1159.35	1078.54	**1378.62**	806.79	428.81

The highest chlorate concentration is used for indirect exposure via food calculation presented below.

Table: Parameters and input values for scenario DRA-2

Description of Scenario [DRA-2]			
	Parameters	**Value**	**Reference/remarks**
Tier I	In-use concentration chlorate (C)	1378.62 mg/L	BIOCIDAL PRODUCT FAMILY intended uses
	Water film thickness on treated surfaces	0.002 cm	Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017) (1)
	Volume expected considering the water film thickness on treated surfaces (V)	0.02 L/m²	
	Biocide residues on surface (Rsurface)	27.57 mg/m²	Rsurface = CxV
	Area in contact with food (A food contact)	0.2 m^2	Guidance on the BPR : volume III P art B+C, Version 4.0 December 2017 - Default value for surface treatment, acute/ chronic exposure
	Dietary Intake Fraction: Acute/chronic exposure (D)	1 / 0.5	Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017
	Default Body weight (kg) adults (bw)	60 kg	Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017
	Mass transfer efficiency (TF)	1	Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 - Default value (worst case)
	Remaining residues on treated surfaces after a rinsing step Tier I (RF)	100%	Default rinsing factor
Tier IIa/IIb	Remaining residues on treated surfaces after a rinsing step Tier IIa/ Tier IIb (RF)	10% / 1%	Default rinsing factor

(1) Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses - Version 4.0 December 2017

Calculations for Scenario [DRA-2]

Following equation has been used to estimate adult, chronic/acute consumer exposure in both Tier I and Tier IIa/Tier IIb:

$Exp_{cons} = R_{surface} \times A_{food\ contact} \times TF \times D \times RF \div bw$

Table: Estimation of consumer exposure via food for scenario DRA-2

Exposure scenario	Tier	Exposure	Adult
Scenario [DRA-2]	Tier I	Estimation of consumer exposure via food (acute exposure) (mg/kg bw)	0.0919
		Estimation of consumer exposure via food (chronic exposure) (mg/kg bw)	0.0460
	Tier IIa	Estimation of consumer exposure via food (acute exposure) (mg/kg bw)	0.0092
		Estimation of consumer exposure via food (chronic exposure) (mg/kg bw)	0.0046
	Tier IIb	Estimation of consumer exposure via food (acute exposure) (mg/kg bw)	0.0009
		Estimation of consumer exposure via food (chronic exposure) (mg/kg bw)	0.0005

Conclusion

For non-professional PT 4 uses, dietary exposure assessment has been performed according ECHA guidance document[8] for adults only.

Risk for consumers via residues in food

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
Drinking water limit – chlorate	WHO, 2005 WHO/SDE/WSH/05.08/869	Drinking water	0.7 mg/L

[8] Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017

[9] 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

	Water Directive Proposed limit (EC 2020[10])	Drinking water with disinfection method	
Drinking water limit – chlorate	Water Directive Proposed limit (EC 2020[11])	Drinking water except for disinfection method	0.25 mg/L
MRL chlorate - Reg. (EU) 2020/749	MRL fixed based on monitoring data and target sampling on Food commodities	Raw food commodities plant matrices	From 0.05 to 0.7 mg/kg
	MRL fixed based on monitoring data and target sampling on Food commodities	Raw food commodities animal matrices	Muscle: 0.05 mg/kg Fat: 0.1* mg/kg Liver: 0.05 mg/kg Kidney:0.05 mg/kg Edible offals: 0.05 mg/kg Milk: 0.1 mg/kg Eggs: 0.05 mg/kg

The applicant should inform professional users of the product of the existence of MRLs for chlorates. They may be held liable if these MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a product from the BIOCIDAL PRODUCT FAMILY.

Risk for consumers via residues in food

For intended PT 4 non professional use, dietary risk assessment has been performed according ECHA guidance document[12] for adults only and results are detailed below:

[10] EC, 2020: Directive (EU) 2020/2184 of the european parliament and of the council of 16 December 2020 on the quality of water intended for human consumption.

[11] EC, 2020: Directive (EU) 2020/2184 of the european parliament and of the council of 16 December 2020 on the quality of water intended for human consumption.

[12] Guidance on the Biocidal Products Regulation - Volume III Human Health - Assessment & Evaluation -(Parts B+C) - 5. Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses -Version 4.0 December 2017

Table: risk calculation for intended PT4 use "Disinfection of surfaces in contact with food" for non professional use

	Risk for consumers via residues in food					
	Scenario DRA 2: Non professional PT 4 use					
	Dietary exposure (mg/kg bw/d)			**Dietary Risk % of ADI (0.003 mg/kg b.w./d) or ARfD (0.036 mg/kg b.w.)**		
	Tier I	**Tier IIa**	**Tier IIb**	**Tier I**	**Tier IIa**	**Tier IIb**
Adult (chronic)	0.0460	0.0046	0.0005	1531.8	153.2	15.3
Adult (acute)	0.0919	0.0092	0.0009	255.3	25.5	2.6

Conclusion

For non-professional PT 4 uses:

- in Tier I: Indirect exposure via food is above toxicological reference values
- in Tier IIa: Indirect exposure via food is above ADI
- in Tier IIb: Indirect exposure via food is below toxicological reference values

As a conclusion, no concern for general public from indirect exposure to either available chlorine or chlorate in food is observed when a rinsing of treated surfaces occurs.

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

[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several active substances or substances of concern within a product]

2.2.7 Risk assessment for animal health

The risk for animal health is covered by the risk for the general public and therefore is considered acceptable.

2.2.8 Risk assessment for the environment

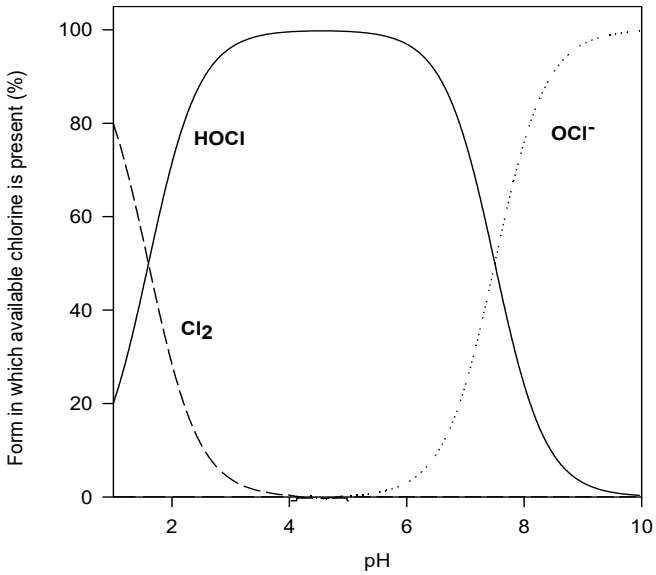
Products of the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE are PT2 and 4 disinfectants. They are applied for:

- PT2/4 Disinfection of surfaces by spraying: hard surface (ustensils, equipment, furniture): The products are applied to surfaces by spraying (Meta SPC 1, 2, 3, 5, 8). Product emissions occur to the STP.

- PT2/4 Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket.: The products are used wiping (Meta SPC 1, 2, 3, 5, 8). Product emissions occur to the STP.

Active substance

The active substance within the product family is active chlorine released from sodium hypochlorite (CAS: 7681-52-9). According to the active substance's assessment report (2017), hypochlorous acid (HClO) is in equilibrium with the hypochlorite ion (ClO-) and chlorine (Cl2). The equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is predominant, and at pH values higher than 10, the only species present is the hypochlorite ion, see figure below.



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

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

One substance of concern has been identified for the environment: Dodecanetrile (CAS n° 2437-25-4) and a complete risk assessment has been performed (see confidential annex for further details on the identification). This substance of concern is relevant for meta-SPC 8 only.

Chlorate formation during storage

The maximal sodium chlorate content at the end of storage exceeds the reference specification for the Meta-SPC 1, 2, 3, 5 & 8 (ranging from 6.04 to 76.76% w/w between

the different Meta-SPC, while the limit is 5.4% w/w (refer to section 2.2.2). Consequently, a risk assessment of chlorate formed during storage is needed for these Meta-SPC.

No harmonized endpoints are actually 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 of concern in relation to human health. 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. A summary of the evaluation is given in Annex 3.7. The risk assessment is still under development and will be amended as agreement on PNEC values and exposure concentrations of DBPs are 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.

2.2.8.1 Effects assessment on the environment

According to the active substance's assessment report (2017), short and long term toxicity data from literature are available for fish, invertebrates, algae and micro-organisms, resulting from flow-through or static tests. Most tests with a static test design result in a factor of 100-500 higher end-points (NOEC, 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 new environmental studies have been conducted on the products. All agreed endpoints have been taken from the final Assessment Report Active substance released from sodium hypochlorite in water (2017). The predicted no effect concentration values (PNEC) are summarised in the table below:

PNEC	Lowest endpoint	AF	PNEC	Test/species
Free available chlorine (FAC)				
STP	NOEC: 41.1 mg/L	10	4.11 mg FAC/L	Respiration inhibition test
fresh water	NOEC: 2.1 µg/L	50	0.042 FAC µg/L	Algae
sediment	-	-	0.045 µg FAC/kg wwt	Equilibrium partitioning from aquatic data using a theoretical K_{oc} of 13.22 L/kg. Calculated
soil	-	-	0.015 µg FAC/kg wwt	

				according to the Guidance part B, vol. IV.
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 non-volatile 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.			

Concerning the assessment of the substance of concern identified for the environment (Dodecanenitrile; CAS n° 2437-25-4), the PNECS have been taken from the REACH registration dossier:
https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/20698

PNEC	Lowest endpoint	AF	PNEC	Test/species
Dodecanenitrile				
STP	0.013 mg/L	10	1.30E-03 mg/L	Toxicity to micro-organisms study was conducted on*Tetrahymena pyriformis*strain GL for 40 hrs. AF for EC50 from a ciliate growth inhibition test
freshwater	0.059 mg/L	1000	5.90E-05 mg/L	A chronic study was available for algae, but not for fish and invertebrate, in which only QSAR were available. Therefore, according to the Volume IV, Part B+C, a factor 1000 is applied to the lowest L(E)C50 (in our case invertebrates : EC50=0.059mg/L) to calculate the PNEC.
sediment	-	-	0.0452 mg/kg wwt (not used as risk is covered by freshwater asssessment)	Equilibrium partitioning calculated according to the Guidance part B, vol. IV.
soil	-	-	0.0362 mg/kg wwt	
groundwater	Reference value for groundwater = 0.1 µg/L			
atmosphere	Air is not an environmental compartment of concern.			
birds	Primary and secondary poisoning are not assessed, as no data are available			

In absence of other data available, these PNECs are taken into account for the environmental risk assessment.

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

All relevant data can be extrapolated from the active substance Active chlorine released from sodium hypochlorite (AR, 2017). Testing of the product is not required.

The products contains classified ingredients other than the active substance (active chlorine released from sodium hypochlorite). However, the classification of the co-formulants included in the different META-SPC does not lead to additional classification (refer to the confidential PAR for detail).

Thus, the environmental hazard classification of the products is driven by the active substance classified as **Aquatic Acute 1, H400 (M=10), Aquatic chronic 1, H410 (M=1)** according to the Regulation (EC) No 1272/2008 (CLP). The classification **H400, H411** applies to all the META-SPC within the family considering a concentration of the active substance in products between 25 and 2.5%, except for meta-SPC 3 which is classified **H412** (concentration of the active substance = 1.5%).

Further Ecotoxicological studies

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

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

No new data is available for BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

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

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

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

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

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

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

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

See Fate and distribution in exposed environmental compartments.

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

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

Leaching behaviour (ADS)

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

Testing for distribution and dissipation in soil (ADS)

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

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

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

Testing for distribution and dissipation in air (ADS)

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

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

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

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

No new data is available for the BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 2
Assessed scenarios	• Scenario 1 – Disinfection in institutional areas • Scenario 2 – Disinfection in industrial areas
ESD(s) used	• Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), P. van der Poel, 2001. • ESD for PT 2: Emission Scenarios for private and public health area disinfectants and other biocidal products (RIVM, 2001) • TAB ENV v2 ENV-55
Approach	• Scenario 1: Average consumption • Scenario 2: Average consumption
Distribution in the environment	Estimated according to : • Guidance on the Biocidal Products Regulation, Vol. IV. Env, Parts B+C, Version 2.0 (October 2017). • Assessment report: Active chlorine released from sodium hypochlorite, Product-type 2, January 2017. • Technical Agreements for Biocides, 2021.
Groundwater simulation	No
Confidential Annexes	Yes
Life cycle steps assessed	Product use
Remarks	-
Assessed PT	PT 4
Assessed scenarios	• Scenario 1 - Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries (2006) • Scenario 2 - Assessment of private use of disinfectants used in food and feed areas
ESD(s) used	ESD for PT 4: Emission scenarios for Disinfectants used in food and feed areas (JRC Scientific and Technical Reports, 2011)
Approach	• Scenario 1: Average consumption • Scenario 2: Average consumption
Distribution in the environment	Estimated according to : • Guidance on the Biocidal Products Regulation, Vol. IV. Env, Parts B+C, Version 2.0 (October 2017). • Assessment report: Active chlorine released from sodium hypochlorite, Product-type 2, January 2017. • Technical Agreements for Biocides, 2021.
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Product use

Remarks	-

Emission estimation

The calculated daily emission of active chlorine to the sewage treatment plant does not take into account a degradation of the active substance in the sewer system. Standard biodegradability testing in the STP is not applicable to inorganic substances such as NaClO. However, the active substance assessment reports indicates that "Active chlorine is highly reactive: it reacts rapidly with organic matter in the sewer, STP, surface water, and soil. Where organic and nitrogenous materials are present, it acts as a highly reactive oxidizing agent. After reaction with organic matter, most (≈99%) of the active chlorine is converted to inorganic chloride. The kinetic model of Vandepitte and Schowanek shows that hypochlorite is eliminated during transport in the sewer within the first minutes. The abundance of reaction partners allows a very quick reaction. The [free chlorine] concentration estimated at the end of the sewer drops below 1 x 10^{-32} µg/L.

Degradation of hypochlorite in the sewer system was therefore 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.
This degradation is taken into account in all relevant uses.

In order to make a worst case risk assessment covering all the relevant META-SPC, a comparison of the different parameters has been done in the table below:

Table 1: Concentrations of substances in the Meta-SPCs

	Substance	Concentration of substance (% w/w)	Dilution factor (worst case)	Density	Concentration in working solution (g/L)
Meta SPC 1	Active chlorine	2.6	0.3	1.052	8.206
	Chlorate	0.139			0.439
Meta SPC 2	Active chlorine	14.5	0.05*	1.242	9.005
	Chlorate	2.22			**1.379**
Meta SPC 3	Active chlorine	1.5	1 (RTU)	1.028	**15.42**
	Chlorate	0.062			0.637

Meta SPC 5	Active chlorine	4.9	0.15	1.091	8.019
	Chlorate	0.493			0.807
Meta SPC 8	Active chlorine	2.6	0.3	1.051	8.198
	Chlorate	0.136			0.429

*Considering an application rate: 5% to 7.5% v/v dilution in water in function of the active chlorine concentration in each product of Meta-SPC 2 as follows:

- 75 mL of product for 925 mL of water (for the products containing 9.60% w/w of active chlorine),
- 55 mL of product for 945 mL of water (for the products containing 12.50% w/w of active chlorine),
- 50 mL of product for 950 mL of water (for the products containing 14.50% w/w of active chlorine),

the dilution of 5 % of the most concentrated product represents the worst case.

The products of Meta-SPC 3 are used pure. Therefore this Meta-SPC is considered as the worst-case and will be used for the calculations for the active substance and the meta-SPC 2 is considered as the worst-case for chlorates.

Dose for the SoC:

The substance of concern is only present in Meta-SPC 8 at 0.05% and thus its dose can be estimated: 0.05 %*0.3*1.051 g/L = 0.158 g/L (considering the worst dilution and density of the Meta-SPC 8 products).

PT2 scenarios

- PT2 - Scenario 1: Disinfection of institutional areas (Meta-SPC 1, 2, 3, 5, 8)

Local emission due to disinfection of lavatory and surfaces were calculated using ESD for PT2 Disinfection in institutional areas (RIVM, 2011). This scenario covers the use Disinfection of hard surfaces (non-professional applications). This assessment covers spraying and wipping. Only the consumption approach is presented as it is considered more relevant than tonnage approach. In fact the tonnage scenarios are not the worst case as they report only the active substance and not chlorates and substances of concern.

The average consumption is presented below:

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1 – Average consumption, Emission scenario for calculating the releases of disinfectants used for sanitary purposes based on average consumption (ESD PT2, 2001, p.10)			

Number of inhabitants feeding one STP [*Nlocal*]	10 000	-	Default value (ESD PT2, 2001)
Fraction released to waste water [*Fwater*]	1	-	Default value (ESD PT2, 2001)
Substance in product [*Cproduct*] Active chlorine Chlorate SoC	 1.54E+01 1.38E+00 1.58E-01	g/l	See Table 1
Consumption per capita [*Qproduct*]:	0.007	l/cap. d	Default value for general purposes+Lavatory(ESD PT2, 2001)
Penetration factor of disinfectant [*Fpenetr*]	0.5	-	Default value (TAB, 2017)

Output				
Calculation: Elocalwater = Nlocal * Qproduct * Cproduct * Fpenetr * Fwater				
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	5.40E-01	As Active chlorine eq Cl2
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	4.83E-02	As Chlorate
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	5.52E-03	As SoC

Calculation after degradation of active chlorine in sewer before the STP:

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 = 44.56 h^{-1}, calculated from the DT_{50} at 12°C: $ln2/DT_{50}$) t 1 = time [h] (= 1 h)	$Elocal_{water}$ = 2.40E-20 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.

- PT2 - Scenario 2: Disinfection of industrial premises (Meta-SPC 1, 2, 3, 5, 8)

Local emission due to disinfection of industrial areas were calculated using ESD for PT2 Disinfection in industrial premises (RIVM, 2011). This scenario applies to disinfection of a wide range of surfaces: small surfaces such as furniture and bigger surfaces such as rooms, walls or floors. Industrial premises are considered as local emission sources which release their wastewater to a local STP.

This scenario covers the use "Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket." and "Disinfection of surfaces by spraying: hard surface (ustensils, equipment, furniture)" by professionnals.

The scenario is based on the concentration of the active substance and volume applied on a surface: an application rate of 0.1 L/m² (based on Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019, in case of absence of more specific information) was considered for the assessment. A surface area of 1000 m² was assessed as it represents a worst-case according to the ESD.

Input parameters for the emission scenario - Disinfection of surfaces, walls, floors, tools, instruments, equipment and other objects in industrial areas by professionals

Variable/parameter	**Unit**	**Symbol**	**S/D/O/P**	**Value**	**Remark**
Application rate of biocidal product	l/m²	Vform	S	0.1	
Concentration of : Active chlorine Chlorate SoC	g/l	Cform	S	1.54E+01 1.38E+00 1.58E-01	See Table 1
Surface area to be disinfected	m²	$AREA_{surface}$	D	1000	
Number of applications per day	d^{-1}	Nappl	D	1	
Fraction of substance disintegrated during or after application (before release to the sewage system)	[-]	F_{dis}	D	0	
Fraction released to wastewater	[-]	F_{water}	D	1	

Output:

Calculations: $Elocal_{water} = V_{form} * C_{form} * AREA_{surface} * N_{appl} * (1-F_{dis}) * F_{water} / 1000$				
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	1.54E+00	As Active chlorine eq Cl2
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	1.38E-01	As Chlorate
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	1.58E-02	As SoC

Calculation after degradation of active chlorine in sewer before the STP:

Calculation: $M_{t1} = M_{t0} * EXP^{(-k * t1)}$	$Elocal_{water}$ = 6.85E-20 kg av Cl/d

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 = 44.56 h^{-1}, calculated from the DT_{50} at 12°C: $ln2/DT_{50}$) t 1 = time [h] (= 1 h)	

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.

PT4 scenario

- PT4 - Scenario 1: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries (Meta-SPC 1, 2, 3, 5, 8)

This scenario covers the use "Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket." and "Disinfection of surfaces by spraying: hard surface (ustensils, equipment, furniture)" for both professionnals and non-professionnals. The local emission is based on the application rate of disinfectant per m^2 (0.1 L/m2 by default) and the area of the treated surface. The main fraction of residues is released to the sewer system.

Elocal calculation for Scenario 1

The local release to wastewater was calculated according to the following equation:

$$Elocal_{water} = Q_{a.i.appl} \bullet AREA_{surface} \bullet Nappl \bullet (1 - F_{dis}) \bullet (1 - F_{elim}) \bullet F_{water} / 1000$$

By default, one application per day is considered as a reasonable worst-case value.

Input parameters for the emission scenario - Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries:

Input	Nomenclature	Value			Unit	Remarks
		Active chlorine	Chlorate	SoC		
Application rate of biocidal product	Vform	0.1	0.1	0.1	l/m²	
Concentration of in-use product	Cform	15.42	1.38	0.16	g/l	See table 1
Application rate of the active substance	$Q_{a.i.appl}$	1.54E+00	1.38E-01	1.58E-02	g/m^2	See above
Surface area to be disinfected for slaughterhouses	$AREA_{surface}$	10 000			m^2	Default
Surface area to be disinfected for kitchens & canteens	$AREA_{surface}$	2 000			m^2	Default

Number of applications per day	Nappl	1	d^{-1}	
Fraction of substance disintegrated during or after application, before release to the sewer system	F_{dis}	0	-	Default
Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water	F_{elim}	0	-	Default
Fraction released to wastewater	F_{water}	1	-	Default

Output:

Calculations:
$Elocal_{water} = Qa.i._{appl} * AREA_{surface} * N_{appl} * (1-F_{dis}) * (1-F_{elim}) * F_{water}/1000$

			Catering kitchens	
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	3.08E+00	As Active chlorine eq Cl2
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	2.76E-01	As Chlorate
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	3.15E-02	As SoC
			Slaughterhouse	
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	1.54E+01	As Active chlorine eq Cl2
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	1.38E+00	As Chlorate
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	1.58E-01	As SoC

Calculation after degradation of active chlorine in sewer before the STP:

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 = 44.56 h^{-1}, calculated from the DT_{50} at 12°C: $ln2/DT_{50}$)	Catering kitchens: $Elocal_{water}$ = 1.37E-19 kg av Cl/d Slaughterhouse: $Elocal_{water}$ = 6.86E-19 kg av Cl/d

t 1 = time [h] (= 1 h)	

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.

- PT4 - Scenario 2: Assessment of private use of disinfectants used in food and feed areas (Meta-SPC 1, 2, 3, 5, 8)

This scenario covers the use "Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth." and "Disinfection of surfaces by spraying: hard surface (ustensils, equipment, furniture)" for private use by non-professionnals only.
The local emission is based on the application rate of disinfectant per m^2 and the area of the treated surface. The main fraction of residues is released to the sewer system. The scenario is based on TAB v2.1, ENV70.

Input	**Nomenclature**	**Value**			**Unit**	**Remarks**
		Active chlorine	**Chlorate**	**SoC**		
Application rate of biocidal product	Vform	0.1	0.1	0.1	l/m²	
Concentration of in-use product	Cform	15.42	1.38	0.16	g/l	See Table 1
Application rate of the active substance	$Q_{a.i.appl}$	1.54E+00	1.38E-01	1.58E-02	g/m²	See above
Number of households feeding one STP	Nhouses	4000				
Fraction of households using product	F_{house}	0.1			-	
Disinfected surface area of a private kitchen	$AREA_{surface}$	2			m^2	Default
Number of applications per day	Nappl	1			d^{-1}	
Fraction released to wastewater	F_{water}	1			-	Default
Fraction released to air	F_{air}	0			-	Default
Penetration factor of disinfectant	F_{penetr}	0.5			-	Default

Output:

Calculations: $Elocal_{water} = Qa.i._{appl} * AREA_{surface} * N_{appl} * F_{penetr} * F_{water} * F_{house} * N_{houses}/1000$				
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	6.16E-01	As Active chlorine eq Cl2

Emission rate to wastewater (standard STP)	kg/d	Elocalwater	5.52E-02	As Chlorate
Emission rate to wastewater (standard STP)	kg/d	Elocalwater	6.32E-03	As SoC

Calculation after degradation of active chlorine in sewer before the STP:

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 = 44.56 h^{-1}, calculated from the DT_{50} at 12°C: $ln2/DT_{50}$) t 1 = time [h] (= 1 h)	$Elocal_{water}$ = 2.74E-20 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.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway – Av Cl					
Representative scenario	**STP**	**Freshwater incl. sediment**	**Marine**	**Soil incl. groundwater**	**Air**
PT2					
Scenario 1: Disinfection in institutional areas	Q	Q	Q	Q	Q
Scenario 2: Disinfection in industrial premises	Q	Q	Q	Q	Q
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with food - large scale catering kitchens, canteens, slaughterhouse	Q	Q	Q	Q	Q
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	Q	Q	Q	Q	Q

Q: Qualitative assessment considering negligible emissions

Identification of relevant receiving compartments based on the exposure pathway – Chlorate					
Representative scenario	**STP**	**Freshwater incl. sediment**	**Marine**	**Soil incl. groundwater**	**Air**
PT2					
Scenario 1: Disinfection in institutional areas	a	SQ	a	a	a
Scenario 2: Disinfection in industrial premises	a	SQ	a	a	a
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with food - large scale catering kitchens, canteens, slaughterhouse	a	SQ	a	a	a
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	a	SQ	a	a	a

SQ: Semi Qualitative assessment; a: covered by the active substance assessment

Identification of relevant receiving compartments based on the exposure pathway – SoC					
Representative scenario	**STP**	**Freshwater incl. sediment**	**Marine**	**Soil incl. groundwater**	**Air**
PT2					
Scenario 1: Disinfection in institutional areas	++	+	n.r.	+	n.r.
Scenario 2: Disinfection in industrial premises	++	+	n.r.	+	n.r.
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with food - large scale catering kitchens, canteens, slaughterhouse	++	+	n.r.	+	n.r.
Scenario 2:	++	+	n.r.	+	n.r.

Identification of relevant receiving compartments based on the exposure pathway – SoC					
Representative scenario	**STP**	**Freshwater incl. sediment**	**Marine**	**Soil incl. groundwater**	**Air**
Assessment of private use of disinfectants used in food and feed areas					

n.r.: not relevant

Input parameters for calculating the fate and distribution of chlorate in the environment are summarised below using different tools and sources:

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)	3.50E-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/m3/mol	Estimated
Biodegradability	Not applicable to inorganic substances	[-]	Not readily biodegradable
DT50 for degradation in soil	1E+06	d (at 12ºC)	Not Readily biodegradable
Rate constant for soil biodegradation	6.93E-07	d-1 (at 12ºC)	

The inputs for Dodecanenitrile (CAS n° 2437-25-4) come from the REACH registration dossier of the substance:

https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/20698

Input parameters (only set values) for calculating the fate and distribution in the environment – SoC			
Input	*Value*	*Unit*	*Remarks*
Molecular weight	181.32	g/mol	-
Vapour pressure (at 20°C)	3.39	Pa	-
Water solubility (at 20°C)	2.34	mg/L	-
Organic carbon/water partition coefficient (Koc)	1887	L/kg	-
Log Kow	4.77	-	-

Biodegradability	Readily biodegradable	[-]	Meeting the 10-day window
DT50 for degradation in soil	30	d (at 12ºC)	Default value
k total for agricultural soil (depth 0.2 m)	2.98E-02	d-1	kbio + kvolat + kleach

The distribution of chlorate and SoC within STP has been estimated using the SimpleTreat 4.0 Model:

Chlorate

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

Dodecanenitrile

Compartment	Percentage [%]	Remarks
Air	20.45	-
Water	4.69	-
Sludge	13.84	-
Degraded in STP	61.02	-

Calculated PEC values

Summary table on calculated PEC values – Active chlorine					
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
PT2					
Scenario 1: Disinfection in institutional areas	Q	Q	Q	Q	Q
Scenario 2: Disinfection in industrial premises	Q	Q	Q	Q	Q
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with	Q	Q	Q	Q	Q

food – large scale catering kitchens, canteens, slaughterhouse					
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	Q	Q	Q	Q	Q

Q: Qualitative assessment considering negligible emissions

Summary table on calculated PEC values – Chlorate					
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
PT2					
Scenario 1: Disinfection in institutional areas	a	2.40E-03	a	5.23	n.r.
Scenario 2: Disinfection in industrial premises	a	6.87E-03	a	14.9	n.r.
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with food – large scale catering kitchens, canteens	a	1.37E-02	a	29.9	n.r.
Scenario 1: Disinfection of hard surfaces, in contact with food – slaughterhouse	a	6.87E-02	a	149	n.r.
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	a	2.75E-03	a	5.99	n.r.

a: covered by the active substance assessment

n.r.: not relevant

Summary table on calculated PEC values – SoC					
	PEC_{STP}	**PEC_{water}**	**PEC_{soil}***	**PEC_{GW}****	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
PT2					
Scenario 1: Disinfection in institutional areas	1.29E-04	1.29E-05	9.40E-04	7.89E-03	n.r.
Scenario 2: Disinfection in industrial premises	3.70E-04	3.69E-05	2.68E-03	2.25E-02	n.r.
PT4					

Scenario 1: Disinfection of hard surfaces, in contact with food – large scale catering kitchens, canteens	7.39E-04	7.37E-05	5.37E-03	4.51E-02	n.r.
Scenario 1: Disinfection of hard surfaces, in contact with food – slaughterhouse	3.70E-03	3.69E-04	2.68E-02	2.25E-01	n.r.
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	1.48E-04	1.48E-05	1.08E-03	9.03E-03	n.r.

*twa over 30 days

** Based on PECsoil twa over 180 days

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not likely to occur as the products of the family are intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for active chlorine as it does not bioaccumulate nor bioconcentrate due to its high water solubility and rapid degradation in the environment.

No secondary poisoning is expected for chlorate as it does not bioaccumulate, as can be seen from its low Log(Kow)< 3.

No secondary poisoning is assessed for SoC as no data is available.

2.2.8.3 Risk characterisation

A qualitative risk characterization 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. Therefore, a semi-qualitative risk assessment is proposed for groundwater and surface water intented for the abstraction of drinking water, with a comparsion with the WHO value of 700 µg/L.

A quantitative assessment is presented for the substance of concern for all the environmental compartments

The PECs calculated for the air compartment are considered negligible.

Active chlorine

Risk characterisation of the active substance is summarized in the following table for each environmental compartment. Results are presented for the three emission scenarios, with degradation of the active substance in the sewer system as it represents the most realistic case in view of the active substance properties.

Summary table on calculated PEC/PNEC values – Active chlorine					
	PEC/PNEC$_{STP}$	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{soil}$**	**PEC/Limit$_{GW}$**	**PEC$_{air}$**
PT2					
Scenario 1: Disinfection in institutional areas –	negligible	negligible	negligible	negligible	negligible
Scenario 2: Disinfection in industrial premises	negligible	negligible	negligible	negligible	negligible
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with food – large scale catering kitchens, canteens, slaughterhouse	negligible	negligible	negligible	negligible	negligible
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	negligible	negligible	negligible	negligible	negligible

Summary table on calculated PEC/PNEC values – Chlorate					
	PEC/PNEC$_{STP}$	**PEC$_{surface\ water\ intented\ for\ the\ abstraction\ of\ drinking\ water}$ /Limit$_{GW*}$**	**PEC/PNEC$_{soil}$**	**PEC$_{GW}$/ Limit$_{GW*}$**	**PEC$_{air}$**
PT2					
Scenario 1: Disinfection in institutional areas –	a	3.43E-03	a	7.47E-03	n.r.
Scenario 2: Disinfection in industrial premises	a	9.81E-03	a	2.14E-02	n.r.
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with food – large scale catering kitchens, canteens	a	1.96E-02	a	4.27E-02	n.r.
Scenario 1: Disinfection of hard surfaces, in contact with food – slaughterhouse	a	9.81E-02	a	2.14E-01	n.r.
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	a	3.93E-03	a	8.55E-03	n.r.

a: covered by the active substance assessment

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

n.r.: not relevant

Summary table on calculated PEC/PNEC values – SoC					
	PEC/PNEC$_{STP}$	**PEC/PNEC water covering sediment as EPM**	**PEC/PNEC soil twa**	**PEC$_{GW}$ [µg/L]**	**PEC$_{air}$**
PT2					
Scenario 1: Disinfection in institutional areas –	9.95E-02	2.19E-01	2.59E-02	7.89E-03	n.r.
Scenario 2: Disinfection in industrial premises	2.84E-01	6.25E-01	7.41E-02	2.25E-02	n.r.
PT4					
Scenario 1: Disinfection of hard surfaces, in contact with food – large scale catering kitchens, canteens	5.69E-01	**1.25E+00**	1.48E-01	4.51E-02	n.r.
Scenario 1: Disinfection of hard surfaces, in contact with food – slaughterhouse	2.84E+00	**6.25E+00**	7.41E-01	2.25E-01	n.r.
Scenario 2: Assessment of private use of disinfectants used in food and feed areas	1.14E-01	2.50E-01	2.97E-02	9.03E-03	n.r.

Conclusions:

In PT02, the risks are acceptable for all the scenarios.

In PT04, unacceptable risks in surface water and STP are foreseen for disinfection of hard surfaces in contact with food for the SoC in the scenario 1 (large scale catering kitchen and canteens, slaughterhouse). Risks are acceptable for the disinfection in private areas by non-professionals.

This restriction will be indicated in the SPC for the PT04 uses of META-SPC 8 (for which the SoC is relevant): **'The disinfection of hard surfaces in contact with food is restricted to domestic areas'.**

Primary and secondary poisoning

Primary poisoning is not likely to occur as the products are intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for active chlorine as it does not bioaccumulate nor bioconcentrate due to its high water solubility and rapid degradation in the environment.

No secondary poisoning is expected for chlorate as it does not bioaccumulate, as can be seen from its low Log(Kow)< 3.

No secondary poisoning is assessed for SoC as no data is available.

Mixture toxicity

A quantitative assessment has been performed only on the SoC and thus a mixture toxicity assessment is not relevant in the case of this dossier.

Aggregated exposure (combined for relevant emmission sources)

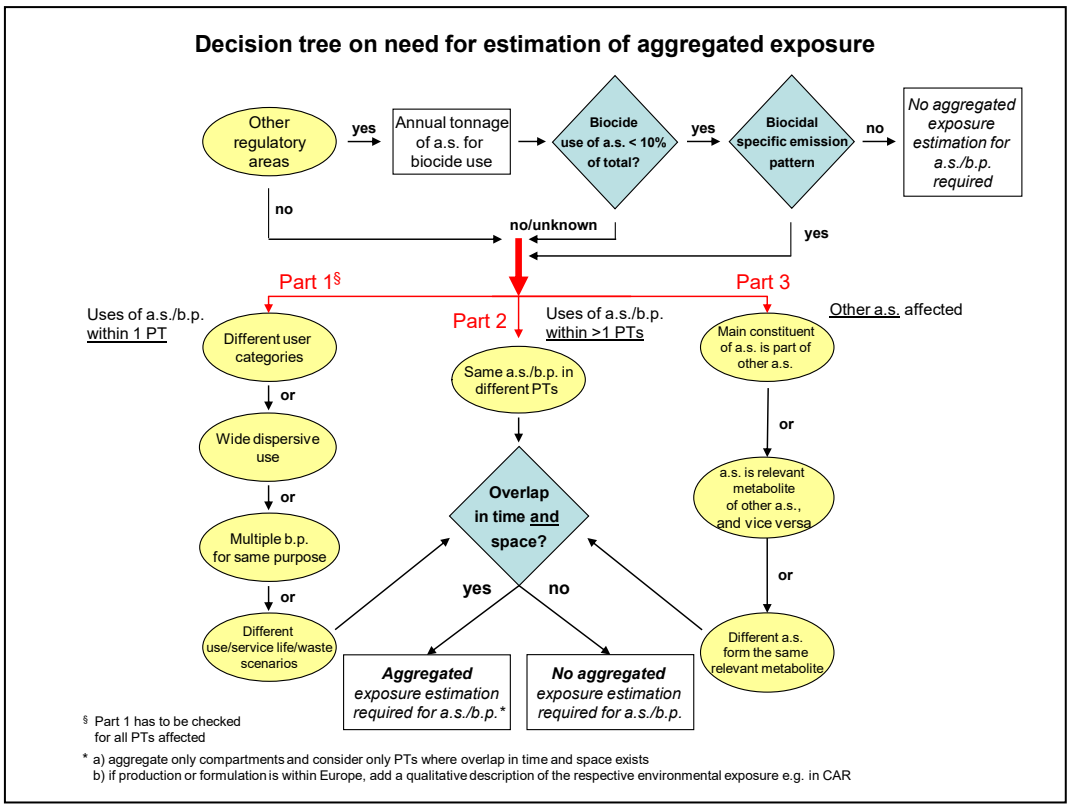


Figure 1: Decision tree on the need for estimation of aggregated exposure

The aggregate risks assessment presented below sums up the SoC risk ratios from all uses and the chlorates assessment for groundwater and surface water intended for drinking water, in case of release to STP. The scenarios taken into account in the calculations are PT2: Scenario 1+2 and PT4: Scenario 2, as PT4: Scenario1 presents unacceptable risks for the environnement.

Summary table on calculated ΣPEC/PNEC values - Chlorates

	ΣPEC/PNEC$_{STP}$	**ΣPEC/PNEC$_{water\ intented\ for\ the\ abstraction\ of\ drinking\ water*}$**	**ΣPEC/PNEC$_{soil}$**	**ΣPEC$_{GW/PNEC\ GW*}$**
	negligible	1.72E-02	negligible	3.74E-02

Summary table on calculated ΣPEC/PNEC values - SoC				
	ΣPEC/PNEC$_{STP}$	**ΣPEC/PNEC$_{water}$**	**ΣPEC/PNEC$_{soil}$**	**ΣPEC$_{GW}$**
	4.98E-01	1.09	1.30E-01	3.95E-02

Conclusion: Aggregated risks for chlorate are acceptable for all compartments. Risks are foreseen for SoC. Nevertheless, an aggregated risks considering all the scenarios seems to be too worst case.

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 leading to negligible emissions to the environment, considering a semi-qualitative assessment of chlorate for groundwater and surface water intended for the abstraction of drinking water, for the following uses:

- PT 2/4: Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket.
- PT 2/4: Disinfection of surfaces by spraying : hard surface (ustensils, equipment, furniture)

Risks are acceptable for all the environmental compartments considering a quantitative assessment of the substance of concern: Dodecanenitrile (CAS n° 2437-25-4) only in meta-SPC 8, for the following uses:

- PT 2: Disinfection of surfaces (floors, utensils, equipment, furniture) by wiping with mop/cloth and bucket.
- PT 2: Disinfection of surfaces by spraying : hard surface (ustensils, equipment, furniture)

In PT04, unacceptable risks in surface water and STP are foreseen for disinfection of hard surfaces in contact with food in the scenario 1 (professional applications on large scale catering kitchen and canteens, slaughterhouse). Risks are acceptable for the disinfection in private areas.

This restriction will be indicated in the SPC for the PT04 uses of META-SPC 8 (for which the SoC is relevant): **'The disinfection of hard surfaces in contact with food is restricted to domestic areas'.**

- **NA-MIC minor change application (2022)**

The minor change regarding the extension of the self-life for Meta SPCs 1, 3 and 8 induces an increase of the chlorate concentrations. However, according to the WG-I-2020, it has

been decided that chlorate can be assessed qualitatively for all the environmental compartments. Therefore this minor change has no impact on the environmental risk assessment. Moreover, the highest in-use concentration of chlorate used in the risk assessment remains unchanged as it comes from meta SPC 2. Concerning the other minor changes (modification of the soiling conditions during use for all Meta SPCs; addition of trade names; addition of manufacturing sites of the active substance), they have no impact on classification of the biocidal product, nor on the analysis of the substance of concern nor on the environmental risk assessment as they do not changes the intended dose rates.

2.2.9 Measures to protect man, animals and the environment

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Active chlorine released from sodium hypochlorite is not candidate for substitution in accordance with Article 10 of BPR.

3 ANNEXES[13]

3.1 List of studies for the biocidal product family

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	[redacted]	Evaluation de l'activité bactéricide en solution selon la norme EN 1276:2019-08, BioPreserv, Report No 19BP280 - EN 1276, revision on 30/04/2020	Yes	Notilia
[redacted]	[redacted]	Evaluation de l'activité fongicide en solution selon la norme EN 1650 -2019, BioPreserv, Report No 19BP280 - EN 1650, revision on 30/04/2020	Yes	Notilia
[redacted]	[redacted]	Evaluation de l'activité bactéricide et fongicide de surface non-poreuse selon la norme EN 13697+A1:2019-07, BioPreserv, Report No 19BP280 - EN 13697, revision on 04/05/2020	Yes	Notilia
[redacted]	[redacted]	EN 13697, Bactericidal and fungicidal activity - Actalia (2020) Report No SMI.2020.338.2	Yes	Notilia
[redacted]	[redacted]	NF EN 13697 + A1 : 2019 ACTIVITE BACTERICIDE PRODUIT TESTE : SOLUTION HYPOCHLORITE SODIUM 1,3% Laboratoire Mediterranéen de Microbiologie Report No LMM 2021001L	Yes	Notilia
[redacted]	[redacted]	NF EN 13697 + A1 : 2019 ACTIVITE FONGICIDE PRODUIT TESTE : SOLUTION HYPOCHLORITE SODIUM 1,3% Laboratoire Mediterranéen de Microbiologie Report No LMM 2021002L	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 2.6% (Meta SPC1) Part 1: Physical-chemical properties upon receipt and after cold storage PHYTOSAFE s.a.r.l. 20-30-009-ES Part 1	Yes	Notilia

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

		GLP; Unpublished		
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 2.6% (Meta SPC1) Part 2: Shelf-life determination PHYTOSAFE s.a.r.l. 20-30-009-ES Interim GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 9.6% (Meta SPC2 and Meta SPC7) Part 1: Physical-chemical properties upon receipt and after cold storage PHYTOSAFE s.a.r.l. 20-30-016-ES Part 1 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 9.6% (Meta SPC2 and Meta SPC7) Part 2: Shelf-life determination PHYTOSAFE s.a.r.l. 20-30-016-ES Part 2 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 12.5% Part 1: Physical-chemical properties upon receipt PHYTOSAFE s.a.r.l. 20-30-047-ES Part 1 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 12.5% Part 2: Shelf-life determination PHYTOSAFE s.a.r.l. 20-30-047-ES Interim GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 13-16% Part 1: Physical-chemical properties upon receipt PHYTOSAFE s.a.r.l. 20-30-042-ES Part 1 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 13-16% Part 2: Shelf life determination PHYTOSAFE s.a.r.l. 20-30-042-ES Interim GLP; Unpublished	Yes	Notilia

[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 1.5% (Meta SPC3) Part 1: Physical-chemical properties upon receipt and after cold storage PHYTOSAFE s.a.r.l. 20-30-017-ES Part 1 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 1.5% (Meta SPC3) Part 2: Shelf-life determination PHYTOSAFE s.a.r.l. 20-30-017-ES Interim GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Spray droplet size distribution by laser diffraction before and after a storage procedure for 24 months at 20 °C ± 2 °C on SPRAY JAVEL 1.5% Results at T=0 DEFITRACES Intermediary report 20-914015-001 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 4.9% + 5% neutral detergent (Meta SPC5) Part 1: Physical-chemical properties upon receipt and after cold storage PHYTOSAFE s.a.r.l. 20-30-019-ES Part 1 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 4.9% + 5% neutral detergent (Meta SPC5) PHYTOSAFE s.a.r.l. Amendment to the final report 20-30-019-ES Part 1 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 4.9% + 5% neutral detergent (Meta SPC5) Part 2: Shelf-life determination PHYTOSAFE s.a.r.l. 20-30-019-ES Part 2 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 2.6% + 5% perfumed detergent (Meta SPC8) Part 1: Physical-chemical properties upon receipt and after cold storage PHYTOSAFE s.a.r.l. 20-30-021-ES Part 1	Yes	Notilia

		GLP; Unpublished		
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 2.6% + 5% perfumed detergent (Meta SPC8) Part 2: Shelf-life determination PHYTOSAFE s.a.r.l. 20-30-021-ES Interim GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Test methods for corrosion to metals on SPRAY JAVEL 1.5% DEFITRACES 20-914015-002 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Flash point and Auto-ignition temperature of liquids tests on JAVEL 4.9% + DÉTERGENT EUCALYPTUS DEFITRACES 20-914015-003 GLP; Unpublished	Yes	Notilia

- **NA-MIC minor change application (2022)**

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 2.6% (Meta SPC1) Part 2: Shelf-life determination Phytosafe s.a.r.l. Report No. 20-30-009-ES-FR2 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 1.5% (Meta SPC3) Part 2: Shelf-life determination Phytosafe s.a.r.l. Report No. 20-30-017-ES-FR2 GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	Physical-chemical properties, stability and shelf-life of Sodium hypochlorite 2.6% + 5% perfumed detergent (Meta SPC8) Part 2: Shelf-life determination Phytosafe s.a.r.l. Report No. 20-30-021-ES-FR2 GLP; Unpublished	Yes	Notilia

[redacted]	[redacted]	NF EN 1276 : 2019 - ACTIVITE BACTERICIDE PRODUIT TESTE : Solution hypochlorite de sodium 1,3% Laboratoire Mediterranéen de Microbiologie Report No LMM 2022004L Non-GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	NF EN 1650 : 2019 - ACTIVITE BACTERICIDE PRODUIT TESTE : Solution hypochlorite de sodium à 1,3% Laboratoire Mediterranéen de Microbiologie Report No LMM 2022005L Non-GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	NF EN 1276 : 2019 - ACTIVITE BACTERICIDE PRODUIT TESTE : Solution hypochlorite de sodium 2,6% Laboratoire Mediterranéen de Microbiologie Report No LMM 2023007L Non-GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	NF EN 1276 : 2019 - ACTIVITE BACTERICIDE PRODUIT TESTE : Solution hypochlorite de sodium 2,6% + détergent neutre Laboratoire Mediterranéen de Microbiologie Report No LMM 2023029L Non-GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	NF EN 1650 : 2019 - ACTIVITE BACTERICIDE PRODUIT TESTE : Solution hypochlorite de sodium à 2,6% Laboratoire Mediterranéen de Microbiologie Report No LMM 2023031L Non-GLP; Unpublished	Yes	Notilia
[redacted]	[redacted]	NF EN 1650 : 2019 - ACTIVITE BACTERICIDE PRODUIT TESTE : Solution hypochlorite de sodium à 2,6% + détergent neutre Laboratoire Mediterranéen de Microbiologie Report No LMM 2023032L Non-GLP; Unpublished	Yes	Notilia

3.2 Output tables from exposure assessment tools

Notilia_expo_mopping_wiping_pro.xlsx

Notilia_expo_spray_pro.xlsx

Notilia_Expo_non_pro_avCl.xlsx

- **NA-MIC minor change application (2022)**

The minor changes have no impact on the human health risk assessment.

3.3 New information on the active substance

3.4 Residue behaviour

Please note that the applicant has developed an approach to estimate the risk for consumer via drinking water consumption. This approach have been considered as not relevant by eCA. This assessment is presented in Annex Residue §3.4 as informative data.

Maximum residue limits or equivalent

Residue definitions

'Residue' means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products;

In this case, chlorates are a residue of sodium hypochlorite solutions.

Substance	Exposure route	Reference value
Chlorate	**Oral**	**ARfD = 36 µg chlorate/kg bw**
	Oral	**ADI = 3 µg chlorate/kg bw**

Risk for consumers via residues in food

Currently, no agreed and published guidance is available for the estimation of dietary risk from transfer of biocidal active substances into food in professional settings. Thus, no dietary risk assessment can be provided at this stage for the professional uses of PT4.

Reference values to be used in Risk Characterisation

Exposure route	Reference value
Oral	$NOAEC_{oral}$ = 0.1% available chlorine
Dermal	$NOAEC_{dermal}$ = 1% available chlorine
Inhalation	AEC_{inhal} = 0.5 mg/m^3 available chlorine

Maximum residue limits or equivalent

Residue definitions

'Residue' means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from

the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products;

In this case, chlorates are a residue of sodium hypochlorite solutions.

Substance	Exposure route	Reference value
Chlorate	**Oral**	**ARfD = 36 µg chlorate/kg bw**
	Oral	**ADI = 3 µg chlorate/kg bw**

Risk for consumers via residues in food

Scenarios

As a reminder, chlorates can be found during:

- Disinfection of surfaces (other than floors) by wiping with mop/cloth and bucket whom food and feed areas – Professional
- Disinfection of surfaces (other than floors) by spraying whom food and feed areas – Professional
- Disinfection of surfaces (other than floors) by wiping with mop/cloth and bucket whom food and feed areas – Non-professional
- Disinfection of surfaces (other than floors) by spraying whom food and feed areas – Non-professional

For secondary exposure from professional settings, reference to the EFSA Scientific Opinion of the EFSA CONTAM Panel on "Risks for public health related to the presence of chlorate in food" (EFSA Journal 2015; 13:4135) is preferred over modelling, which includes a comprehensive dietary exposure and risk assessment for chlorate residues in food and drinking water based on occurrence data.

In brief, the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) evaluated the exposure and risk arising from chlorate residues found in food and drinking water. Occurrence data from European national food authorities and similar bodies was collected and approximately 8000 samples were analysed for chlorate contents (e.g. grains and grain-based products, vegetables and vegetable products, legumes, fruit and fruit products, herbs and spices, milk and dairy products, (non-)alcoholic beverages, composition food, and drinking water). Chlorate content in all food commodities assessed ranged from 3 µg/kg (alcoholic beverages) to 417 µg/kg (herbs and spices) (mean upper bound values). The mean chlorate value for drinking water was 39 µg/L (mean upper bound).

An acute and chronic exposure assessment was performed for different population groups, using consumption data from the EFSA Comprehensive Database and the measured chlorate

levels. According to the Scientific Opinion, "mean and 95th percentile acute exposures were below the ARfD [36 µg chlorate/kg bw] for all age groups indicating no concern". Moreover it is stated that, "chronic exposure of adolescent and adult age classes did not exceed the TDI [3 µg chlorate/kg bw]. However, at the 95th percentile, the TDI was exceeded in all surveys for 'Infants' and 'Toddlers', and in some surveys in 'Other children'", indicating that "chronic exposures are of concern in particular in younger age groups with mild or moderate iodine deficiency."

Chlorate is no longer used as pesticide (according to Commission Decision No 2008/865/EC). Thus, chlorate contamination in food is likely to be mainly derived from biocidal uses of chlorine and hypochlorite. Both substances are widely used for disinfection of surfaces and equipment in food and feed processing areas as well as for disinfection of drinking water (i.e. as biocidal products in PTs 4 and 5), and thus, chlorate residues can be carried-over into food and feed during cleaning, washing and processing steps. Accordingly, "CONTAM Panel assumes that chlorate residues in food result mainly from the use of chlorinated water for food processing (e.g. washing) and from the disinfection of surfaces and food processing equipment coming into contact with food."

Potential chlorate residues from the application of chlorine and hypochlorite in PTs 4 are considered to be included in the measured chlorate residue values, and the conclusions drawn by the EFSA CONTAM Panel on chlorate residues cover thus also the dietary risk arising from PT4 uses of chlorine and hypochlorite. Since the EFSA Scientific Opinion on chlorate residues provides actual measured data for chlorate residues in food and an exhaustive exposure and risk assessment based on consumption data, the conclusions drawn in the EFSA Scientific Opinion are superior to any dietary risk assessment based on exposure models.

Therefore it could be assumed that the dietary intake of chlorate resulting from professional uses of NaOCl does not trigger toxicological concern.

<u>For non-professional uses :</u>

Dietary risk assessment for chlorate for intended uses in PT4 has been performed according to the Guidance.

Chlorates exposure was calculated using the "BfR Calculator for Estimating transfer of biocide residues into foods (non-professional uses)".

The risk assessment has been performed according to the EMA "Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides" (2015).

No measured data on chlorate residues after application of the products are available. It is noticed that chlorate residue formation may depend on the formulation of the products as well as on the storage conditions of the product. In the absence of measured residue data, the chlorate content according to sodium hypochlorite specification was used for estimation of chlorate contents in the application solution. According to EN 900:2014, chlorate may be present as a by-product of the production process.

Available active chlorine content in a product is at most 16%. Whereas, the maximum level of Na chlorate (impurity) is specified at 5% w/w (absolute).

The maximum level of Na chlorate (5% w/w) was converted into "% of available chlorine" (ie %avCl) by the following calculation :

$$pourcentage\ of\ available\ chlorine = \frac{5}{16} * 100 = 31.25$$

With an in-use concentration of 49 000 mg/L of sodium hypochlorite (4.9% in-use dilution)[14], the concentration of sodium chlorate ($NaOCl_3$) is 15 312.5 mg/L (1.5%) and the concentration of chlorate is 12 005 mg/L (1.2%), considering:

$$MW(NaClO_3) = 106.44$$
$$MW(ClO_3) = 83.45$$
$$percentage\ of\ chlorate\ into\ sodium\ chlorate = \frac{MW(ClO_3)}{MW(NaClO_3)} * 100 = 78.4\%$$

The product is then rinsed at 10%, the concentration of chlorate falls at 1 200 mg/L.

The relevant reference value for chlorate as agreed during BPC WGIII-2016 is the ADI of 0.003 mg/kg bw and the ARfD of 0.036 mg/kg bw (according to EFSA CONTAM Panel, 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015; 13:4135).

2	**Scenario: Disinfectants in dishwashing detergents (Non-professional use)**		
	Biocidal product		product specific information
	Active substance	Chlorates	product specific information
	concentration of active substance in dishwashing detergent: $c_{as\ in\ bp}$ (mg/kg)	1200	product specific information
	maximal application rate of detergent (= concentration of detergent in dish wash solution): $R_{appl\ detergent}$ (g detergent./L)	1,4	default 1,400 g/L or product specific value

[14] Worst case : 9.6% avCl product (use 2 – non professional use)

maximal application rate of active substance (= concentration of active substance in dish wash solution): $R_{appl\ as}$ (mg as/L)	1,68	calculated as $R_{appl\ as}$ = ($c_{as\ in\ bp}$ ÷ 1000) x $R_{appl\ detergent}$
ADI (mg/kg bw/d)	0,00	<source (year)>
ARfD (mg/kg bw/d) (if applicable)	0,04	<source (year)>
amount of water left on dishes: T_a (L/cm²)	5,50E-07	default value
area of dishes in daily contact with food: S_a (cm²)	5400	default value
mass transfer efficiency: TF	1	default 100% or product specific value
optional: RF (additional refinement factor)	1	<specify refinement, e.g. rinsing factor, if applicable >

Calculation of consumer exposure*	**adult (60 kg bw)**	**toddler (10 kg bw)**	**child (23,9 kg bw)**	**infant (8 kg bw)**
Estimation of daily consumer exposure via food (mg/kg bw/d)	8,32E-05	4,99E-04	2,09E-04	6,24E-04
Estimation of chronic consumer exposure via food (% ADI)	2,7720	16,6320	6,9590	20,7900

Estimation of acute consumer exposure via food (% ARfD)	0,2310	1,3860	0,5799	1,7325

*calculated as Exp_{cons} = ($R_{appl\ as}$ x T_a x S_a x TF x RF) ÷ bw

Conclusion

The estimate intake of chlorates is less than 30% of the ADI (based on appropriately conservative assumptions and margins to cover uncertainties) at all timepoints after application of the product (see the scenarios above), then it could be concluded that an MRL assessment is not necessary for the protection of human health and there would be no need for an evaluation of the substance by the CVMP (EMA, 2015).

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[15]

3.6 Confidential annex

See the confidential PAR

3.7 Other

15 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.