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 type(s) 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

Evaluating Competent Authority: France

Date: [March 2022]

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**Explanatory note for the use of this template:**

The PAR (i.e. “DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS (submitted by the applicant)”) together with the IUCLID file and the SPC replaces the formerly valid formats of Document I, II and III which were in use under Directive 98/8/EC according the former Guidance document “TNsG on Preparation of Dossiers and Study Evaluation”.

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The PAR template is suitable for both a single biocidal product and a biocidal product family. The content of the template can be adapted accordingly.

Table of Contents

[Table of Contents 3](#_Toc73002607)

[*1* CONCLUSION 7](#_Toc73002608)

[*2* ASSESSMENT REPORT 16](#_Toc73002609)

[2.1 Summary of the product assessment 16](#_Toc73002610)

[2.1.1 Administrative information 16](#_Toc73002611)

[**2.1.1.1** Identifier of the product family 16](#_Toc73002612)

[**2.1.1.2** Authorisation holder 16](#_Toc73002613)

[**2.1.1.3** Manufacturer(s) of the products of the family 16](#_Toc73002614)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 16](#_Toc73002615)

[2.1.2 Product family composition and formulation 17](#_Toc73002616)

[**2.1.2.1** Identity of the active substance 17](#_Toc73002617)

[**2.1.2.2** Candidate(s) for substitution 17](#_Toc73002618)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product family2 17](#_Toc73002619)

[**2.1.2.4** Information on technical equivalence 18](#_Toc73002620)

[**2.1.2.5** Information on the substance(s) of concern 18](#_Toc73002621)

[**2.1.2.6** Assessment of endocrine disruption (ED) properties of the biocidal product family 18](#_Toc73002622)

[**2.1.2.7** Type of formulation 18](#_Toc73002623)

[2.1.3 Meta SPC 1 administrative information 19](#_Toc73002624)

[**2.1.3.1** Meta SPC identifier 19](#_Toc73002625)

[**2.1.3.2** Suffix to the authorisation number 19](#_Toc73002626)

[**2.1.3.3** Product type(s) 19](#_Toc73002627)

[2.1.4 Meta SPC 1 composition 19](#_Toc73002628)

[**2.1.4.1** Qualitative and quantitative information on the composition of the meta SPC 1 19](#_Toc73002629)

[**2.1.4.2** Type(s) of formulation of the meta SPC 1 19](#_Toc73002630)

[2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1 19](#_Toc73002631)

[2.1.6 Authorised use(s) of the META SPC 1 20](#_Toc73002632)

[**2.1.6.1** Use description 20](#_Toc73002633)

[**2.1.6.2** Use description 21](#_Toc73002634)

[2.1.7 General directions for use of the meta SPC 1 23](#_Toc73002635)

[**2.1.7.1** Instructions for use 23](#_Toc73002636)

[**2.1.7.2** Risk mitigation measures 23](#_Toc73002637)

[**2.1.7.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 23](#_Toc73002638)

[**2.1.7.4** Instructions for safe disposal of the product and its packaging 23](#_Toc73002639)

[**2.1.7.5** Conditions of storage and shelf-life of the product under normal conditions of storage 23](#_Toc73002640)

[2.1.8 Other information 23](#_Toc73002641)

[2.1.9 Trade name(s), authorisation number and specific composition of each individual product 24](#_Toc73002642)

[2.1.10 Meta SPC 2 administrative information 25](#_Toc73002643)

[**2.1.10.1** Meta SPC identifier 25](#_Toc73002644)

[**2.1.10.2** Suffix to the authorisation number 25](#_Toc73002645)

[**2.1.10.3** Product type(s) 25](#_Toc73002646)

[2.1.11 Meta SPC 2 composition 25](#_Toc73002647)

[**2.1.11.1** Qualitative and quantitative information on the composition of the meta SPC 2 25](#_Toc73002648)

[**2.1.11.2** Type(s) of formulation of the meta SPC 2 25](#_Toc73002649)

[2.1.12 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2 25](#_Toc73002650)

[2.1.13 Authorised use(s) of the META SPC 2 26](#_Toc73002651)

[**2.1.13.1** Use description 26](#_Toc73002652)

[**2.1.13.2** Use description 27](#_Toc73002653)

[2.1.14 General directions for use of the meta SPC 2 29](#_Toc73002654)

[**2.1.14.1** Instructions for use 29](#_Toc73002655)

[**2.1.14.2** Risk mitigation measures 29](#_Toc73002656)

[**2.1.14.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 29](#_Toc73002657)

[**2.1.14.4** Instructions for safe disposal of the product and its packaging 29](#_Toc73002658)

[**2.1.14.5** Conditions of storage and shelf-life of the product under normal conditions of storage 29](#_Toc73002659)

[2.1.15 Other information 30](#_Toc73002660)

[2.1.16 Trade name(s), authorisation number and specific composition of each individual product 30](#_Toc73002661)

[2.1.17 Meta SPC 3 administrative information 31](#_Toc73002662)

[**2.1.17.1** Meta SPC identifier 31](#_Toc73002663)

[**2.1.17.2** Suffix to the authorisation number 31](#_Toc73002664)

[**2.1.17.3** Product type(s) 31](#_Toc73002665)

[2.1.18 Meta SPC 3 composition 31](#_Toc73002666)

[**2.1.18.1** Qualitative and quantitative information on the composition of the meta SPC 3 31](#_Toc73002667)

[**2.1.18.2** Type(s) of formulation of the meta SPC 3 31](#_Toc73002668)

[2.1.19 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3 31](#_Toc73002669)

[2.1.20 Authorised use(s) of the META SPC 3 32](#_Toc73002670)

[**2.1.20.1** Use description 32](#_Toc73002671)

[2.1.21 General directions for use of the meta SPC 3 34](#_Toc73002672)

[**2.1.21.1** Instructions for use 34](#_Toc73002673)

[**2.1.21.2** Risk mitigation measures 34](#_Toc73002674)

[**2.1.21.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 34](#_Toc73002675)

[**2.1.21.4** Instructions for safe disposal of the product and its packaging 34](#_Toc73002676)

[**2.1.21.5** Conditions of storage and shelf-life of the product under normal conditions of storage 34](#_Toc73002677)

[2.1.22 Other information 34](#_Toc73002678)

[2.1.23 Trade name(s), authorisation number and specific composition of each individual product 35](#_Toc73002679)

[2.1.24 Meta SPC 5 administrative information 35](#_Toc73002698)

[**2.1.24.1** Meta SPC identifier 35](#_Toc73002699)

[**2.1.24.2** Suffix to the authorisation number 35](#_Toc73002700)

[**2.1.24.3** Product type(s) 36](#_Toc73002701)

[2.1.25 Meta SPC 5 composition 36](#_Toc73002702)

[**2.1.25.1** Qualitative and quantitative information on the composition of the meta SPC 5 36](#_Toc73002703)

[**2.1.25.2** Type(s) of formulation of the meta SPC 5 36](#_Toc73002704)

[2.1.26 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5 36](#_Toc73002705)

[2.1.27 Authorised use(s) of the META SPC 5 37](#_Toc73002706)

[**2.1.27.1** Use description 37](#_Toc73002707)

[**2.1.27.2** Use description 38](#_Toc73002708)

[2.1.28 General directions for use of the meta SPC 5 40](#_Toc73002709)

[**2.1.28.1** Instructions for use 40](#_Toc73002710)

[**2.1.28.2** Risk mitigation measures 40](#_Toc73002711)

[**2.1.28.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 40](#_Toc73002712)

[**2.1.28.4** Instructions for safe disposal of the product and its packaging 40](#_Toc73002713)

[**2.1.28.5** Conditions of storage and shelf-life of the product under normal conditions of storage 40](#_Toc73002714)

[2.1.29 Other information 41](#_Toc73002715)

[2.1.30 Trade name(s), authorisation number and specific composition of each individual product 41](#_Toc73002716)

[2.1.31 Meta SPC 8 administrative information 41](#_Toc73002753)

[**2.1.31.1** Meta SPC identifier 41](#_Toc73002754)

[**2.1.31.2** Suffix to the authorisation number 42](#_Toc73002755)

[**2.1.31.3** Product type(s) 42](#_Toc73002756)

[2.1.32 Meta SPC 8 composition 42](#_Toc73002757)

[**2.1.32.1** Qualitative and quantitative information on the composition of the meta SPC 8 42](#_Toc73002758)

[**2.1.32.2** Type(s) of formulation of the meta SPC 8 42](#_Toc73002759)

[2.1.33 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 8 42](#_Toc73002760)

[2.1.34 Authorised use(s) of the META SPC 8 43](#_Toc73002761)

[**2.1.34.1** Use description 43](#_Toc73002762)

[**2.1.34.2** Use description 44](#_Toc73002763)

[2.1.35 General directions for use of the meta SPC 8 46](#_Toc73002764)

[**2.1.35.1** Instructions for use 46](#_Toc73002765)

[**2.1.35.2** Risk mitigation measures 46](#_Toc73002766)

[**2.1.35.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 46](#_Toc73002767)

[**2.1.35.4** Instructions for safe disposal of the product and its packaging 46](#_Toc73002768)

[**2.1.35.5** Conditions of storage and shelf-life of the product under normal conditions of storage 46](#_Toc73002769)

[2.1.36 Other information 47](#_Toc73002770)

[2.1.37 Trade name(s), authorisation number and specific composition of each individual product 47](#_Toc73002771)

[2.1.38 Packaging of the biocidal product 48](#_Toc73002772)

[2.1.39 Documentation 49](#_Toc73002773)

[**2.1.39.1** Data submitted in relation to product application 49](#_Toc73002774)

[**2.1.39.2** Access to documentation 49](#_Toc73002775)

[2.2 Assessment of the biocidal product family 50](#_Toc73002776)

[2.2.1 Intended use(s) as applied for by the applicant 50](#_Toc73002777)

[2.2.2 Physical, chemical and technical properties 51](#_Toc73002778)

[2.2.3 Physical hazards and respective characteristics 80](#_Toc73002779)

[2.2.4 Methods for detection and identification 87](#_Toc73002780)

[2.2.5 Efficacy against target organisms 101](#_Toc73002781)

[**2.2.5.1** Function and field of use 101](#_Toc73002782)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 101](#_Toc73002783)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 101](#_Toc73002784)

[**2.2.5.4** Mode of action, including time delay 101](#_Toc73002785)

[**2.2.5.5** Efficacy data 102](#_Toc73002786)

[**2.2.5.6** Occurrence of resistance and resistance management 113](#_Toc73002787)

[**2.2.5.7** Known limitations 113](#_Toc73002788)

[**2.2.5.8** Evaluation of the label claims 113](#_Toc73002789)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 115](#_Toc73002790)

[2.2.6 Risk assessment for human health 116](#_Toc73002791)

[**2.2.6.1** Assessment of effects on Human Health 116](#_Toc73002792)

[**2.2.6.2** Exposure assessment and risk characterisation 125](#_Toc73002793)

[2.2.7 Risk assessment for animal health 180](#_Toc73002794)

[2.2.8 Risk assessment for the environment 180](#_Toc73002795)

[**2.2.8.1** Effects assessment on the environment 182](#_Toc73002796)

[**2.2.8.2** Exposure assessment 185](#_Toc73002797)

[- PT2 - Scenario 1: Disinfection of institutional areas (Meta-SPC 1, 2, 3, 5, 8) 189](#_Toc73002798)

[- PT2 - Scenario 2: Disinfection of industrial premises (Meta-SPC 1, 2, 3, 5, 8) 190](#_Toc73002799)

[- PT4 - Scenario 1: Disinfection in large scale catering kitchens, canteens, slaughterhouses and butcheries (Meta-SPC 1, 2, 3, 5, 8) 192](#_Toc73002800)

[- PT4 - Scenario 2: Assessment of private use of disinfectants used in food and feed areas (Meta-SPC 1, 2, 3, 5, 8) 194](#_Toc73002801)

[**2.2.8.3** Risk characterisation 200](#_Toc73002802)

[2.2.9 Measures to protect man, animals and the environment 205](#_Toc73002803)

[2.2.10 Assessment of a combination of biocidal products 205](#_Toc73002804)

[2.2.11 Comparative assessment 205](#_Toc73002805)

[**2.2.11.1** Screening phase 205](#_Toc73002806)

[**2.2.11.2** Tier IA 205](#_Toc73002807)

[**2.2.11.3** Tier IB 205](#_Toc73002808)

[**2.2.11.4** Tier II 205](#_Toc73002809)

[**2.2.11.5** Overall conclusion 206](#_Toc73002810)

[*3* Annexes 207](#_Toc73002811)

[3.1 List of studies for the biocidal product family 207](#_Toc73002812)

[3.2 Output tables from exposure assessment tools 207](#_Toc73002813)

[3.3 New information on the active substance 208](#_Toc73002814)

[3.4 Residue behaviour 208](#_Toc73002815)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 213](#_Toc73002816)

[3.6 Confidential annex 213](#_Toc73002817)

[3.7 Other 213](#_Toc73002818)

# 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**

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]](#footnote-2), 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)

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 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. |
| Disinfection of hard non porous surfaces by wipping with and without previous cleaning.  Professionals & non-professionals  Contact time: 5 min. |
| **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** |

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[2]](#footnote-3)** | **Country (if relevant)** |
| --- | --- |
| BIOCIDAL PRODUCT FAMILY BASED ON SODIUM HYPOCHLORITE |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Notilia |
| **Address** | ZI de Grezan  30000 Nîmes  France |
| **Authorisation number** | FR-2022-0017 | |
| **Date of the authorisation** | 10/03/2022 | |
| **Expiry date of the authorisation** | Please refer to the decision | |

#### 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 |

#### 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 |

### 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

#### 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- |

#### Candidate(s) for substitution

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

#### Qualitative and quantitative information on the composition of the biocidal product family2

| **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 |

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.

#### 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.

#### 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.

#### 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.

#### 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**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | Meta SPC 1 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |
|  | 4 |

### Meta SPC 1 composition

#### 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)* |
|  |  |  |  |  |  |  |

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

|  |
| --- |
| SL – Soluble concentrate |

### 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 |
| 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. |

### Authorised use(s) of the META SPC 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 |

##### Use-specific instructions for use

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| --- |
|  |

##### Use-specific risk mitigation measures

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| --- |
|  |

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

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| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use of the meta SPC 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. |

#### 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 |

#### 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. |

#### 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. |

#### 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: 9 months |

### Other information

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| --- |
| * 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**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **1 - Eau de javel 2.6% 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)* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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**

### Meta SPC 2 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 2 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |
|  | 4 |

### Meta SPC 2 composition

#### 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)* |

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

|  |
| --- |
| SL – Soluble concentrate |

### 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 |

### Authorised use(s) of the META SPC 2

#### 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use of the meta SPC 2

#### 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. |

#### 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 |

#### 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. |

#### 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. |

#### 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 |

### 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**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **6 - Concentré de javel 9.6%** | | | | |
| **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%** | | | | |
| **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%** | | | | |
| **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**

### Meta SPC 3 administrative information

#### Meta SPC identifier

| **Identification** | Meta SPC 3 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |
|  | 4 |

### Meta SPC 3 composition

#### 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)* |

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

|  |
| --- |
| AL - Any other liquid |

### 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. |
| 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. |

### Authorised use(s) of the META SPC 3

#### 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) |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use of the meta SPC 3

#### 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. |

#### 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 |

#### 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. |

#### 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. |

#### 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: 9 months |

### 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**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **8 - Spray javel 1.5%** | | | | |
| **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** | | | | |
| **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**

### Meta SPC 5 administrative information

#### Meta SPC identifier

| **Identification** | Meta SPC 5 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |
|  | 4 |

### Meta SPC 5 composition

#### 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  *(Active chlorine released from sodium hypochlorite)* | Sodium hypochlorite | Active substance | 7681-52-9 | 231-668-3 | 5.145 *(4.9)* | 5.145 *(4.9)* |

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

|  |
| --- |
| SL – Soluble concentrate |

### 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. |
| 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 |

### Authorised use(s) of the META SPC 5

#### 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### 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 bottle, can |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### 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. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use of the meta SPC 5

#### 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 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. |

#### 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 |

#### 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. |

#### 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. |

#### 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 |

### 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**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **19 - Al’k Chlore Essentiel** | | | | |
| **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** | | | | |
| **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**

### Meta SPC 8 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 8 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |
|  | 4 |

### Meta SPC 8 composition

#### 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 |

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

|  |
| --- |
| SL – Soluble concentrate |

### 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 |
| 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). |

### Authorised use(s) of the META SPC 8

#### 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### 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. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 10. Use # 1 – 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### 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 |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

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| --- |
| * 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. |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use of the meta SPC 8

#### Instructions for use

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| --- |
| * 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. |

#### 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 |

#### 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. |

#### Instructions for safe disposal of the product and its packaging

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| --- |
| * 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. |

#### 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: 9 months |

### Other information

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| --- |
| * 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**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **12 - Eau de javel 2.6% détergente citron** | | | | |
| **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** | | | | |
| **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** | | | | |
| **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** | | | | |
| **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** | | | | |
| **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)* |

### 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 |

### Documentation

#### 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

#### 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.

## Assessment of the biocidal product family

### 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. |

### 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 20-30-047-ES Part 1 | Acceptable |
| 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  Alkalinity: CIPAC MT 191 | 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 |
| 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  Alkalinity: CIPAC MT 191 | 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 |
| Relative density / bulk density | OECD 109 | Meta SPC 1 (2.73% sodium hypochlorite) | D204=1.052 (20°C) | E. Servajean, 2020, report 20-30-009-ES Part 1 | Acceptable |
| OECD 109 | Meta SPC 2 (10.08% sodium hypochlorite) | D204=1.18 (20°C) | E. Servajean, 2020, report 20-30-016-ES Part 1 | Acceptable |
| OECD 109 | Meta SPC 2 (13.125% sodium hypochlorite) | D204=1.218 (20°C) | E. Servajean, 2021, report 20-30-047-ES Part 1 | Acceptable |
| OECD 109 | Meta SPC 2 (15.225% sodium hypochlorite) | D204=1.242 (20°C) | E. Servajean, 2021, report 20-30-042-ES Part 1 | Acceptable |
| OECD 109 | Meta SPC 3 (1.575% sodium hypochlorite) | D204=1.028 (20°C) | E. Servajean, 2020, report 20-30-017-ES Part 1 | Acceptable |
| OECD 109 | Meta SPC 5 (5.145% sodium hypochlorite) | D204=1.091 (20°C) | E. Servajean, 2020, report 20-30-019-ES Part 1 | Acceptable |
| OECD 109 | Meta SPC 8 (2.73% sodium hypochlorite) | D204=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: ANA\_MON\_102  Sodium chlorate method: ANA\_MON\_103 | 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.  \* LOQ : Limit of quantification i.e. 0.0003%.   |  |  |  | | --- | --- | --- | | **Parameter** | **Initial** | **14 days at 54°C** | | Appearance | Colourless liquid with a typical odour of bleach | | | Weight change | - | No variation | | Active chlorine (%w/w) | 0.98 | < LOQ\*  (100.0 % of decrease) | | Sodium chlorate content (%w/w) | 0.03 | 0.13 | | Sodium chlorate/available chlorine (%) | 3 | - | | pH | 10 | 7.8 | | alkalinity (%w/w as NaOH) | 0.4 | 0.0 | | Dilution stability (at 5% dilution and after 18h) | No separated  material. | No separated  material. | | Persistent foaming (mL) (at 100%) | After 10s: 133  After 1min: 124  After 3min: 123  After 12 min: 122 | No persistent foam | | Study report RRCo-000375\_01 | Not acceptable  The degradation of the active content is > 10%.  The biocidal product is not stable after accelerated storage.  The product should not be stored above 30°C. |
| Storage stability test – **accelerated storage** | CIPAC method MT46.3 | 12.78% active chlorine  Product Javel 13-16% - Meta SPC 2 | The test item was stored in glass flasks of 100mL during 14 days at 54°C.   |  |  |  | | --- | --- | --- | | **Parameter** | **Initial** | **14 days at 54°C** | | Appearance | Yellow liquid with a typical odour of bleach | Colourless liquid with a typical odour of bleach | | Weight change | - | No variation | | Active chlorine (%w/w) | 12.78 | 2.01 (84.2% of decrease) | | Sodium chlorate content (%w/w) | 2.57 | 7.43 | | Sodium chlorate/available chlorine (%) | 20% | 369% | | pH | 11.2 | 11.2 | | alkalinity (%w/w as NaOH) | 4.9 | 1.4 | | Dilution stability (at 5% dilution and after 18h) | Presence of particles  in the bottom of the  flask and  supernatant  particles | Presence of white  cloud in the bottom  of the flask and  supernatant  particles. | | Persistent foaming (mL) (at 100%) | No persistent foam | No persistent foam | | Study report RRCo-000377\_01 | Not acceptable  The degradation of the active content is > 10%.  The biocidal product is not stable after accelerated storage.  The product should not be stored above 30°C.  It should also be noted that the chlorate content is higher than the maximum content set in the regulation (sodium chlorate: ≤5.4% of available chlorine) before and after storage. Please refer to human health section regarding conclusion on chlorate content. |
| Storage stability test – **long term storage at ambient temperature** | 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 | Meta SPC 1 (2.73% sodium hypochlorite) | 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.   |  |  |  |  | | --- | --- | --- | --- | | Results | Upon receipt | After 6 months | After 9 months | | Active chlorine | 26.7 g/kg | 22.3 g/kg  (83.5% of initial) | 23.2 g/kg  (86.9% of initial) | | Chlorate | 0.86 g/kg | 1.35 g/kg  (156.6% of initial) | 1.39 g/kg  (161.4% of initial) | | Sodium Chlorate | 1.1 g/kg | 1.7 g/kg | 1.8 g/kg | | Sodium chlorate/available chlorine (%) | 4.1 | 7.7 | 7.6 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | No deformation or alteration | | Weight loss | N/A | 0.05% | 0.12% | | pH on neat item | 12.2 | N/A | 12.3 | | Free alkalinity | 0.12% NaOH w/w | N/A | 0.13% NaOH w/w | | Dilution stability in water at 1.0% v/v and after 24h | No separated material | N/A | No separated material | | Dilution stability in water at 30% v/v and after 24h | No separated material | N/A | No separated material |   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 6 and 9 months of storage. | E. Servajean, 2021, report 20-30-009-ES Interim | The degradation of the active content is >10% after 6 and 9 months of storage.  However, at the November 2019 WG APCP, it was agreed that the shelf life of the products (Tf: final time corresponding to the shelf life of the product) should be set for a maximum of 50% degradation of active chlorine.  Therefore, 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. |
| 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  Persistent foaming: CIPAC MT 47.3 | Meta SPC 2 (10.08% sodium hypochlorite) | The test item was stored in HDPE 1L bottles at ambient temperature for 5.5 months and protected from light.   |  |  |  |  | | --- | --- | --- | --- | | Results | Upon receipt | After 3 months | After 5.5 months | | Active chlorine | 98.7 g/kg | 70.1 g/kg  (71.1% of initial) | 33.9 g/kg  (34.4% of initial) | | Chlorate | 7.05 g/kg | 13.1 g/kg  (185.6% of initial) | 20.4 g/kg  (288.9% of initial) | | Sodium chlorate | 9 g/kg | 16.7 g/kg | 26 g/kg | | Sodium chlorate/available chlorine (%) | 9.1 | 23.8 | 76.7 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | No deformation or alteration | | Weight loss | N/A | 0.03% | 0.06% | | pH on neat item | 12.8 | N/A | 12.8 | | Free alkalinity | 0.38% NaOH w/w | N/A | 0.38% NaOH w/w | | Dilution stability in water at 25% v/v and after 24h | No separated material | N/A | Sparse flocculated material at the bottom (< 2mL) | | Dilution stability in water at 50% v/v and after 24h | No separated material | N/A | Sparse flocculated material at the bottom (<2mL) | | Persistent foaming at 25% v/v | No foam after 1 min | N/A | No foam after 1 min | | Persistent foaming at 50% v/v | No foam after 1 min | N/A | 2mL of foam after 1 min |   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). | E. Servajean, 2021, report 20-30-016-ES Part 2 | The degradation of the active content is >10%.  However, at the November 2019 WG APCP, it was agreed that the shelf life of the products (Tf: final time corresponding to the shelf life of the product) should be set for a maximum of 50% degradation of active chlorine.  Therefore, 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. |
| 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  Persistent foaming: CIPAC MT 47.3 | 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.   |  |  |  | | --- | --- | --- | | Results | Upon receipt | After 3 months | | Active chlorine | 123.5 g/kg | 104.9 g/kg  (85.0% of initial) | | Chlorate | 2.02 g/kg | 16.1 g/kg  (797.0% of initial) | | Sodium chlorate | 2.6 g/kg | 20.5 g/kg | | Sodium chlorate/available chlorine (%) | 2 | 19.6 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | | Weight loss | N/A | 0.09% | | pH on neat item | 12.9 | 12.8 | | Free alkalinity | 0.38% NaOH w/w | 0.38% NaOH w/w | | Dilution stability in water at 1.67% v/v in water and after 24h | 2 mL flocculated material at the bottom | 2 mL flocculated material at the bottom | | Persistent foaming at 0.2% v/v in water | No foam after 1 min | No foam after 1 min | | Persistent foaming at 2% v/v in water | No foam after 1 min | No foam after 1 min |   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). | E. Servajean, 2021, report 20-30-047-ES Interim | The degradation of the active content is >10%.  However, at the November 2019 WG APCP, it was agreed that the shelf life of the products (Tf: final time corresponding to the shelf life of the product) should be set for a maximum of 50% degradation of active chlorine.  Therefore, 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 health section regarding conclusion on chlorate content. |
| 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  Persistent foaming: CIPAC MT 47.3 | Meta SPC 2 (15.225% 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.   |  |  |  | | --- | --- | --- | | Results | Upon receipt | After 3 months | | Active chlorine | 147.1 g/kg | 115.9 g/kg  (78.8% of initial) | | Chlorate | 2.43 g/kg | 22.2 g/kg  (913.4% of initial) | | Sodium chlorate | 3.1 g/kg | 28.3 g/kg | | Sodium chlorate/available chlorine (%) | 2.1 | 24.4 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | | Weight loss | N/A | 0.13% | | pH on neat item | 13.0 | 12.9 | | Free alkalinity | 0.42% NaOH w/w | 0.42% NaOH w/w | | Dilution stability in water at 1.67% v/v in water and after 24h | 2 mL flocculated material at the bottom | 2 mL flocculated material at the bottom | | Persistent foaming at 0.167% v/v in water | No foam after 1 min | No foam after 1 min | | Persistent foaming at 1.67% v/v in water | No foam after 1 min | No foam after 1 min |   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). | E. Servajean, 2021, report 20-30-042-ES Interim | The degradation of the active content is >10%.  However, at the November 2019 WG APCP, it was agreed that the shelf life of the products (Tf: final time corresponding to the shelf life of the product) should be set for a maximum of 50% degradation of active chlorine.  Therefore, 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 health section regarding conclusion on chlorate content. |
| 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  Priming and discharge rate: FEA 643  Spray pattern: FEA 644 | Meta SPC 3 (1.575% sodium hypochlorite) | 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.   |  |  |  |  | | --- | --- | --- | --- | | Results | Upon receipt | After 6 months | After 9 months | | Active chlorine | 15.5 g/kg | 9.1 g/kg  (59.0% of initial) | 13.1 g/kg  (84.6% of initial) | | Chlorate | 0.48 g/kg | 0.62 g/kg  (129.2% of initial) | 0.62 g/kg  (130.1% of initial) | | Sodium chlorate | 0 .6 g/kg | 0.8 g/kg | 0.8 g/kg | | Sodium chlorate/available chlorine (%) | 3.9 | 8.7 | 6 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | No deformation or alteration | | Weight loss | N/A | 0.04% | 0.07% | | pH on neat item | 12.0 | N/A | 12.1 | | Free alkalinity | 0.07% NaOH w/w | N/A | 0.08% NaOH w/w | | Spraying performances - Priming and discharge rate | Primed on the 6th stroke  Discharge rate  1.30 g (Unit 1)  1.34 g (Unit 2)  No clogging | N/A | Primed on the 6th stroke  Discharge rate  1.30 g (Unit 1)  1.31 g (Unit 2)  No clogging | | Spraying performances - Spray pattern | Round shape 20-23 cm diameter | N/A | Round shape 15-19 cm diameter |   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 spray particles size distribution has not been performed after 6 and 9 months, as it is planned to be measured only after 24 months. | E. Servajean, 2021, report 20-30-17-ES Interim | The degradation of the active content is >10%.  However, at the November 2019 WG APCP, it was agreed that the shelf life of the products (Tf: final time corresponding to the shelf life of the product) should be set for a maximum of 50% degradation of active chlorine.  Therefore, 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 conclusion on chlorate content.  Moeover, it should be noted that the spray particles size distribution after storage is missing. |
| GIFAP monograph no.17  CIPAC MT 187 | Meta SPC 3 (1.575% sodium hypochlorite) | Assessment of the spray particles size distribution after storage is ongoing (24-months storage at ambient temperature). | P. Padilla, study 20-914015-001 | The particles size distribution after storage should be provided in post-authorisation. |
| 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  Persistent foaming: CIPAC MT 47.3 | Meta SPC 5 (5.145% sodium hypochlorite) | Storage at ambient temperature for 8 months.  The test item was stored in HDPE 5L cans at 18-22°C protected from light.   |  |  |  |  | | --- | --- | --- | --- | | Results | Upon receipt | After 3 months | After 5.5 months | | Active chlorine | 48.2 g/kg | 34.2 g/kg  (70.8% of initial) | 32.0 g/kg  (66.4% of initial) | | Chlorate | 2.48 g/kg | 3.71 g/kg | 4.93 g/kg | | Sodium chlorate | 3.2 g/kg | 4.7 g/kg | 6.3 g/kg | | Sodium chlorate/available chlorine (%) | 6.5 | 13.8 | 19.6 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | No deformation or alteration | | Weight loss | N/A | % | % | | pH on neat item | 12.4 | N/A | N/A | | Free alkalinity | 0.20% NaOH w/w | N/A | N/A | | Persistent foaming at 1.0% v/v in water | 60 mL of foam after 1 min (30%) | N/A | N/A | | Persistent foaming at 4.0% v/v in water | 82 mL of foam after 1 min (41%) | N/A | N/A | | Dilution stability in water at 4.0% v/v | No separated material | N/A | N/A |  |  |  |  |  | | --- | --- | --- | --- | | Results | Upon receipt | After 7 months | After 8 months | | Active chlorine | 48.2 g/kg | 32.0 g/kg  (66.3% of initial) | 34.5 g/kg  (71.6% of initial) | | Chlorate | 2.48 g/kg | 4.56 g/kg | 3.84 g/kg | | Sodium chlorate | 3.2 g/kg | 5.8 g/kg | 4.9 g/kg | | Sodium chlorate/available chlorine (%) | 6.5 | 18.1 | 14.2 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | No deformation or alteration | | Weight loss | N/A | 0.04% | 0.03% | | pH on neat item | 12.4 | N/A | 11.8 | | Free alkalinity | 0.20% NaOH w/w | N/A | 0.12% NaOH w/w | | Persistent foaming at 1.0% v/v in water | 60 mL of foam after 1 min (30%) | N/A | 54 mL of foam after 1 min (27%) | | Persistent foaming at 4.0% v/v in water | 82 mL of foam after 1 min (41%) | N/A | 84 mL of foam after 1 min (42%) | | Dilution stability in water at 4.0% v/v | No separated material | N/A | No separated material |   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.  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. | E. Servajean, 2021, report 20-30-019-ES Part 2 | The degradation of the active content is >10%.  However, at the November 2019 WG APCP, it was agreed that the shelf life of the products (Tf: final time corresponding to the shelf life of the product) should be set for a maximum of 50% degradation of active chlorine.  Therefore, 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 storage. Please refer to human health section regarding conclusion on chlorate content. |
| 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  Persistent foaming: CIPAC MT 47.3 | Meta SPC 8 (2.73% sodium hypochlorite) | 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.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Results | Upon receipt | After 3 months | After 6 months | After 9 months | | Active chlorine | 27.0 g/kg | 23.5 g/kg  (87.1% of initial) | 20.2 g/kg  (74.9% of initial) | 24.0 g/kg  (88.7% of initial) | | Chlorate | 0.82 g/kg | 1.27 g/kg | 1.36 g/kg | 1.34 g/kg | | Sodium chlorate | 1 g/kg | 1.6 g/kg | 1.7 g/kg | 1.7 g/kg | | Sodium chlorate/available chlorine (%) | 3.9 | 6.9 | 8.6 | 7.1 | | Appearance | Light yellow translucent liquid | Light yellow translucent liquid | Light yellow translucent liquid | Light yellow translucent liquid | | Packaging | N/A | No deformation or alteration | No deformation or alteration | No deformation or alteration | | Weight loss | N/A | 0.02% | 0.03% | 0.09% | | pH on neat item | 12.2 | N/A | N/A | 12.0 | | Free alkalinity | 0.11% NaOH w/w | N/A | N/A | 0.09% NaOH w/w | | Dilution stability in water at 1.0% v/v | No separated material | N/A | N/A | No separated material | | Dilution stability in water at 30% v/v | No separated material | N/A | N/A | No separated material | | Persistent foaming at 1.0% v/v | 32 mL of foam after 1 min (16%) | N/A | N/A | 30 mL of foam after 1 min (15%) | | Persistent foaming at 30% v/v | 100 mL of foam after 1 min (50%) | N/A | N/A | 88 mL of foam after 1 min (44%) |   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. | E. Servajean, 2021, report 20-30-021-ES Interim | The degradation of the active content is >10%.  However, at the November 2019 WG APCP, it was agreed that the shelf life of the products (Tf: final time corresponding to the shelf life of the product) should be set for a maximum of 50% degradation of active chlorine.  Therefore, 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 conclusion on chlorate content. |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | Meta SPC 1 (2.73% sodium hypochlorite) | Storage procedure at 0°C for 7 days.   |  |  |  | | --- | --- | --- | |  | Initial | 7 day at 0°C | | Appearance | Light yellow translucent liquid | | | Available chlorine (g/kg) | 26.7 g/kg | 27.2 g/kg (101.9% of initial) | | pH on neat item | 12.2 | 12.3 | | pH of a 1% w/v dilution | 10.3 | 10.4 | | alkalinity (%w/w as NaOH) | 0.12% NaOH w/w | 0.12% NaOH w/w |   No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures. | E. Servajean, 2020, report 20-30-009-ES Part 1 | The product is stable after a storage of 7 days at 0°C. |
| CIPAC MT 39.3 | Meta SPC 2 (10.08% sodium hypochlorite) | Storage procedure at 0°C for 7 days.   |  |  |  | | --- | --- | --- | |  | Initial | 7 day at 0°C | | Appearance | Light yellow translucent liquid | | | Available chlorine (g/kg) | 98.7 g/kg | 87.2 g/kg (88.3% of initial) | | pH on neat item | 12.8 | 12.8 | | pH of a 1% w/v dilution | 10.9 | 11 | | alkalinity (%w/w as NaOH) | 0.38% NaOH w/w | 0.37% NaOH w/w |   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. | E. Servajean, 2020, report 20-30-016-ES Part 1 | The product is stable after a storage of 7 days at 0°C. |
| CIPAC MT 39.3 | Meta SPC 3 (1.575% sodium hypochlorite) | Storage procedure at 0°C for 7 days.   |  |  |  | | --- | --- | --- | |  | Initial | 7 day at 0°C | | Appearance | Light yellow translucent liquid | | | Available chlorine (g/kg) | 15.5 g/kg | 15.2 g/kg (98.2% of initial) | | pH on neat item | 12.0 | 12.1 | | pH of a 1% w/v dilution | 10.1 | 10.2 | | alkalinity (%w/w as NaOH) | 0.07% NaOH w/w | 0.06% NaOH w/w |   No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures. | E. Servajean, 2020, report 20-30-017-ES Part 1 | The product is stable after a storage of 7 days at 0°C. |
| CIPAC MT 39.3 | Meta SPC 5 (5.145% sodium hypochlorite) | Storage procedure at 0°C for 7 days.   |  |  |  | | --- | --- | --- | |  | Initial | 7 day at 0°C | | Appearance | Light yellow translucent liquid | | | Available chlorine (g/kg) | 48.2 g/kg | 46.2 g/kg (95.9% of initial) | | pH on neat item | 12.4 | 12.5 | | pH of a 1% w/v dilution | 11.6 | 10.7 | | alkalinity (%w/w as NaOH) | 0.20% NaOH w/w | 0.19% NaOH w/w |   No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures. | E. Servajean, 2020, report 20-30-019-ES Part 1 | The product is stable after a storage of 7 days at 0°C. |
| CIPAC MT 39.3 | Meta SPC 8 (2.73% sodium hypochlorite) | Storage procedure at 0°C for 7 days.   |  |  |  | | --- | --- | --- | |  | Initial | 7 day at 0°C | | Appearance | Colourless translucent liquid | | | Available chlorine (g/kg) | 27.0 g/kg | 26.4 g/kg (97.5% of initial) | | pH on neat item | 12.2 | 12.2 | | pH of a 1% w/v dilution | 11.4 | 10.4 | | alkalinity (%w/w as NaOH) | 0.11% NaOH w/w | 0.09% NaOH w/w |   No separated solid or oily matter observed at the end of the storage procedure. The product is therefore stable at low temperatures. | E. Servajean, 2020, report 20-30-021-ES Part 1 | The product is stable after a storage of 7 days at 0°C. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Waived |  | Not relevant (The opaque nature of the containers is sufficient to protect the products from the light). |  | According to the CAR of the active substance, sodium hypochlorite is very sensitive to photolysis in water. An adequate mitigation measure “protect from direct sunlight” should be added on the label 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 |
| 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 |
| 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  Dv(0.9) = 540.5 μm | P. Padilla, 2021, Intermediary report 20-914015-001 | Acceptable |
| 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.  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 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 |
| 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 20-30-017-ES Part 1 | Acceptable |
| 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 |

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| **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. |

### 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. |  |
| 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 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. | 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) |
| 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 family do not possess oxidizing properties. | C&L inventory (harmonised classificaion) |
| Oxidising solids | waived |  |  | Not relevant as products are liquids |  |
| Organic peroxides | waived |  | Not relevant, no organic peroxides present in the products of the BPF. | Not relevant |  |
| Corrosive to metals | UN test C.1 | Meta SPC 3 (1.5% sodium hypochlorite) | 2 mm thickness aluminium and steel plates were exposed to the test item i for 7 days at 55 °C ± 1 °C.   |  |  | | --- | --- | | **Specimen** | **Loss of mass (%)** | | Immersed steel plate | 15.02 | | Half way immersed steel plate | 9.51 | | Non immersed steel plate | 0.67 | | Immersed aluminium plate | 5.60 | | Half way immersed aluminium plate | 3.06 | | Non immersed aluminium plate | 0.05 |   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).  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. | Acceptable  All products of the family are classified as H290. | P. Padilla, 2021, report 20-914015-002 |
| 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 |  |

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| **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 |

### 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 H3O+ --> I2 + Cl- + 3 H2O

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

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| --- | --- |
| 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.

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| --- | --- |
| 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**

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| **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  r²=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. Servajean, 2020, report 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 (0.045 mg chlorate/L)  Level 3: 500 mg of test item/L (0.45 mg chlorate/L)  6 working solutions prepared | 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  r² = 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  0.85-0.88 g/kg | 96.1  97.5  0.85 g/kg  0.87 g/kg  0.86 g/kg | 1.25  0.073  2.55  2.09  1.29 | LOQ = 0.003 mg chlorate/L  (n=5) | E. Servajean, 2020, report 20-30-009-ES Part 1 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 2 (10.08% 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: 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  r²=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. Servajean, 2020, report 20-30-016-ES Part 1 |
| *Chlorate (impurity)* | LC-MS (see above) | Recovery:  Level 1: 0.34 g/kg (n=2)  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 | 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  r² = 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. | 97.7-98.7  96.7-98.1  6.77-7.10 g/kg  7.04-7.42 g/kg  6.84-7.13 g/kg | 98.2  97.4  6.94 g/kg  7.25 g/kg  6.94 g/kg | 0.72  1.02  1.76  1.94  1.50 | LOQ = 0.003 mg chlorate/L (n=5) | E. Servajean, 2020, report 20-30-016-ES Part 1 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 2 (13.125% 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: 2.02% w/w (n=2)  Level 2: 2.84% 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  r²=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. | 100.0-101.0  99.1-101.3  122.04-125.03 g/kg | 100.5  100.2  123.5 g/kg | 0.70  1.56  0.86 |  | E. Servajean, 2021, report 20-30-047-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 (0.005 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  r² = 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. Servajean, 2021, report 20-30-047-ES Part 1 |

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 2 (15.225% 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: 1.91% 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  r²=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. Servajean, 2021, report 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)  Level 3: 60 mg of test item/L (0.144 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) = 1.056\*log(Area) – 5.869  r² = 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  2.39-2.54 g/kg | 99.9  100.2  2.43 g/kg  2.41 g/kg  2.45 g/kg | 0.92  0.42  1.45  2.95  2.16 | LOQ = 0.007 mg chlorate/L (n=5) | E. Servajean, 2021, report 20-30-042-ES Part 1 |

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 3 (1.575% 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: 1.08% w/w (n=2)  Level 2: 1.86% 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  r²=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. Servajean, 2020, report 20-30-017-ES Part 1 |
| *Chlorate (impurity)* | LC-MS (see above) | Recovery:  Level 1: 0.24 g/kg (n=2)  Level 2: 0.38 g/kg (n=2)  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 | 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  r² = 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. | 95.2-96.1  102-103.1  0.46-0.5 g/kg  0.47-0.51 g/kg  0.47-0.51 g/kg | 95.7  102.6  0.48 g/kg  0.48 g/kg  0.48 g/kg | 0.67  0.76  3.44  2.98  3.37 | LOQ = 0.003 mg chlorate/L (n=5) | E. Servajean, 2020, report 20-30-017-ES Part 1 |

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues – Meta SPC 5 (5.145% 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: 4.04% w/w (n=2)  Level 2: 5.86% 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  r²=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. | 99-100.3  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. Servajean, 2020, report 20-30-019-ES Part 1 |
| *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  r² = 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. Servajean, 2020, report 20-30-019-ES Part 1 |

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| **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  r²=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. Servajean, 2020, report 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)  Level 3: 500 mg of test item/L (0.44 mg chlorate/L)  6 working solutions prepared for eache 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  r² = 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  0.82-0.85 g/kg | 105.3  105.4  0.78 g/kg  0.84 g/kg  0.84 g/kg | 0.27  0.13  2.68  2.59  1.46 | LOQ = 0.003 mg chlorate/L (n=5) | E. Servajean, 2020, report 20-30-021-ES Part 1 |

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| **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. |

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| **Analytical methods for air** |
| Residue definition: Cl2/HClO/ClO─  Hypochlorite is a non-volatile species. Hypochlorous acid is volatile, but according to literature data, the Henry’s Law constant is ≈ 0.1 Pa m³ mol-1, i.e. volatilization from the aqueous phase is expected to be slow. Furthermore, there are indications that the half-life is only a few hours, i.e. much shorter than the value derived by Atkinson calculation. So occurrence in air is not probable for this species, either.  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]](#footnote-4), [[4]](#footnote-5)) 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 Cl2/m3. 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). |

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| **Analytical methods for drinking water** |
| Residue definition: HClO/ClO─ and relevant metabolite chlorate ClO3─  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 (ClO3─). |
| **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 (DT50surface water = 56 min at environmental temperature). |

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| **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. |

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |
| Residue definition: HClO/ClO─ and relevant metabolite chlorate ClO3─  Under PT4, fully-validated analytical methods for residues of both active chlorine (HClO/ClO─) and the relevant metabolite chlorate (ClO3─) 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. |

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| **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. |

### Efficacy against target organisms

#### 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

#### 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.

#### 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.

#### 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.

#### Efficacy data

* **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% v/v available chlorine (no perfume and no detergent) from Meta-SPC1
* Product with 2.6% v/v available chlorine (with detergent, no perfume) from Meta-SPC8
* Product with 2.6% v/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:**

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| **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 detergent and perfume) – Meta SPC 8 | **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  Contact time: 15 min  3 replicats/product/test organism  Criteria: at least a 4 log reduction | 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 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 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.*  **Fungi:**  *A. brasiliensis*  **Yeasts:**  *C. albicans* | EN 13697 | Phase 2 step 2 test (surface test)  Dilution: 0.001% and 1%  Temperature: 20°C  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 | Bactericidal and yeasticidal activity demonstrated at 1 % v/v  3 log reduction is not achieved for *A. brasiliensis.*  Therefore, fungicidal activity has not been demonstrated. | BioPreserv (2020). 19BP280 - EN 13697.  Revision on 30/04/2020  (to correct some 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  Available chlorine: 1.3% v/v  Batch: 58-20-001F | **Bacteria:**  *E. coli,*  *E. hirae* | 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 4 log reduction | Activity against *E. coli* and *E. hirae* demonstrated at 30 % v/v. | Au C., 2020  No LMM 2021001L  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% v/v  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 % v/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 % v/v.

META-SPC 3 consists of ready-to-use products containing available chlorine at 1.5 % v/v.

The product tested (2.6% w/w 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 % v/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% v/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% v/v 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% v/v 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% 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 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 % v/v, with a detergent.

The representative product tested with 2.6% v/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% v/v 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% v/v 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% 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 % v/v.

Considering the composition of META-SP8, eCA agreed that the products with 2.6% v/v available chlorine (perfume and detergent) and with 2.6% v/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% v/v 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% v/v 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% 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 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.

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| **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. |

#### 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.

#### Known limitations

None.

#### Evaluation of the label claims

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.

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

### 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 (Cl2). 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.

#### 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,  OECD Guideline 435 (July 2015),  GLP compliance,  Reliability : 1 | Test item name : “AFISE JAVEL 2.6” (Batch LAB2014-14)  4 replicates – 500µl of test item  Negative control: Citric acid 10%  Positive control: sodium hydroxide 50% and sulfuric acid 10% | Performed according to the Corrositex® Method | The test was performed following 3 steps.  Step 1 – Compatibility test: confirmed by a color change (from yellow to purple)  Step 2 – Timescale Category test:  First trial: not conclusive  Confirmation test: liquid turned into a slight grey coloration 🡪 assignment to Category 2  Step 3 – Measurement of membrane barrier penetration:  **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  Conclusion:  According to the OECD 435 guideline and GHS criteria, the test item is **not corrosive** to skin. | A deviation (Dev 120/14) has been recorded in order to define 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 | Faccioli F. (2014)  Final report : S-2014-01731 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***

#### 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 (Cl2)

HClO + H3O+ + Cl─ ↔ Cl2 + 2H2O

The ratio of Cl2/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 | NOAECoral = 0.1 % avCl |
| Dermal | NOAECdermal = 1.0 % avCl |
| Inhalation | AECinhal = 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)   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 | 9.03x10-2 | 0.86 |
| Meta-SPC 3 | | |
| 1 / No PPE | 1.58x10-1 | 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.  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** | **Parameters1** | **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/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**

* + 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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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.  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** | **Parameters1** | **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** | **Parameters1** | **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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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 | Labelling:   * Labelling according to CLP   Trained personnel:   * 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.

***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.  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 | 9.03x10-2 | 0.86 |
| Meta-SPC 3 | | |
| 1 / No PPE | 1.58x10-1 | 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.  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/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**

**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) | No PPE  Labelling:   * Labelling according to CLP * Instructions for use and storage * “Washing on hands after use”   Packaging:   * 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) | No PPE  Labelling:   * Labelling according to CLP * Instructions for use and storage * “Washing on hands after use” * “The product has to be sprayed downward”   Packaging:   * 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 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 |
| HIGH | Eye Dam. Cat 1 (H318) | Eyes | Eye exposure through potential splashed or hand-to-eye transfer  (2.6 to 14.5% avCl) |

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) | None | **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) |

**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/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**

**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) | No PPE  Labelling:   * Labelling according to CLP * Instructions for use and storage * “Washing on hands after use”   Packaging:   * 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) |

**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 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 |
| HIGH | Eye Dam. Cat 1 (H318) | Eyes | Eye exposure through potential splashed or hand-to-eye transfer  (2.6 to 14.5% avCl) |

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)  (**↑**) 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 |
| HIGH | Eye Dam. Cat 1 (H318) | Eyes | Eye exposure through potential splashed or hand-to-eye transfer  (0.8 and 0.82% avCl) |

**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.

***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** (ClO3-) 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.  Not approved as a PPP active substance. | ADI: 0.15 mg/kg bw/d  ARfD: not applicable  Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005. |

*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]](#footnote-6). 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.

Dietary exposure assessment has been performed according to ECHA guidance document[[6]](#footnote-7) for adults only. Indeed, as detailed in ECHA guidance document[[7]](#footnote-8), default value of 0.2 m2 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 Cl2 (%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 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Non professional - Disinfection of surfaces in contact with food by wipping/mopping** | | | | | |
|  | **Meta SPC** | | | | | |
|  | **1** | **2** | **2** | **2** | **5** | **8** |
| Available chlorine eq Cl2 (%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 m2 | 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:

Expcons = Rsurface x Afood contact x TF x D x RF ÷ 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]](#footnote-9) 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/05.08/86[[9]](#footnote-10)  Water Directive  Proposed limit (EC 2020[[10]](#footnote-11)) | Drinking water  Drinking water with disinfection method | 0.7 mg/L |
| Drinking water limit – chlorate | Water Directive  Proposed limit (EC 2020[[11]](#footnote-12)) | 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]](#footnote-13) for adults only and results are detailed below:

**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]*

### Risk assessment for animal health

The risk for animal health is covered by the risk for the general public and therefore is considered acceptable.

### 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 Cl2 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 Cl2 (AR, 2017). The active chlorine equivalent content is:

* 1 g of sodium hypochlorite is equivalent to 0.953 g active chlorine (MWCl2 / MWNaClO = 71/74.5)
* or 1 g active chlorine equivalent to 1.05 g sodium hypochlorite (MWNaClO / MWCl2 = 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 (EC50 = 10 mg/L) is less toxic than the active substance (EC50 = 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.

#### 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, LC50) 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 Koc of 13.22 L/kg. Calculated according to the Guidance part B, vol. IV. |
| soil | - | - | 0.015 μg FAC/kg wwt |
| groundwater | Reference value for groundwater = 0.1 μg/L | | | |
| atmosphere | At environmental pH (6.5-8.5) half of the active chlorine is available as the 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.

#### 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)](https://echa.europa.eu/documents/10162/16908203/pt4_food_disinfectants_en.pdf/e264b048-f2bf-4366-adcc-3b4f5b5d6f9c) |
| 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:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 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 | AREAsurface | 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) | [-] | Fdis | D | 0 |  |
| Fraction released to wastewater | [-] | Fwater | D | 1 |  |

Output:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Vform \* Cform \* AREAsurface \* Nappl \* (1-Fdis) \* Fwater / 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:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 6.85E-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.

**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 m2 (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:

|  |
| --- |
| Elocalwater = Qa.i.appl • AREAsurface • Nappl • (1 - Fdis) • (1 – Felim) • Fwater / 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 | Qa.i.appl | 1.54E+00 | | 1.38E-01 | 1.58E-02 | | g/m2 | See above |
| Surface area to be disinfected for slaughterhouses | AREAsurface | 10 000 | | | | | m2 | Default |
| Surface area to be disinfected for kitchens & canteens | AREAsurface | 2 000 | | | | | m2 | Default |
| Number of applications per day | Nappl | 1 | | | | | d-1 |  |
| Fraction of substance disintegrated during or after application, before release to the sewer system | Fdis | 0 | | | | | - | Default |
| Fraction of the substance eliminated due to on-site pre-treatment of the plant waste water | Felim | 0 | | | | | - | Default |
| Fraction released to wastewater | Fwater | 1 | | | | | - | Default |

Output:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Qa.i.appl\*AREAsurface\*Nappl\*(1-Fdis)\*(1-Felim)\*Fwater/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:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Catering kitchens:  Elocalwater = 1.37E-19 kg av Cl/d  Slaughterhouse:  Elocalwater = 6.86E-19 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.

#### 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 m2 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 | Qa.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 | Fhouse | 0.1 | | | - |  |
| Disinfected surface area of a private kitchen | AREAsurface | 2 | | | m2 | Default |
| Number of applications per day | Nappl | 1 | | | d-1 |  |
| Fraction released to wastewater | Fwater | 1 | | | - | Default |
| Fraction released to air | Fair | 0 | | | - | Default |
| Penetration factor of disinfectant | Fpenetr | 0.5 | | | - | Default |

Output:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Calculations:  Elocalwater = Qa.i.appl\*AREAsurface\*Nappl\*Fpenetr\*Fwater\*Fhouse\*Nhouses/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:  Mt1 = Mt0\* EXP(-k \* t1)  Mt1 = total amount of substance present at time 1 [kg/d]  Mt0 = total amount of substance at time 0 [kg/d]  k = rate constant (k = 44.56 h-1, calculated from the DT50 at 12°C: ln2/DT50)  t 1 = time [h] (= 1 h) | Elocalwater = 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:  Assessment of private use of disinfectants used in food and feed areas | ++ | + | n.r. | + | n.r. |

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 oC) | 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** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| **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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – Chlorate** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| **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** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsoil\*** | **PECGW\*\*** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| **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.

#### 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/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsoil** | **PEC/LimitGW** | **PECair** |
| **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/PNECSTP** | **PECsurface water intented for the abstraction of drinking water /LimitGW\*** | **PEC/PNECsoil** | **PECGW//LimitGW\*** | **PECair** |
| **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/PNECSTP** | **PEC/PNECwater covering sediment as EPM** | **PEC/PNECsoil twa** | **PECGW**  **[µg/L]** | **PECair** |
| **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 PEC/PNEC values - Chlorates** | | | | |
|  | **PEC/PNECSTP** | **PEC/PNECwater intented for the abstraction of drinking water\*** | **PEC/PNECsoil** | **PECGW/PNEC GW\*** |
|  | negligible | 1.72E-02 | negligible | 3.74E-02 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values - SoC** | | | | |
|  | **PEC/PNECSTP** | **PEC/PNECwater** | **PEC/PNECsoil** | **PECGW** |
|  | 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’.** |

### Measures to protect man, animals and the environment

*[Please refer to summary of the product assessment and to the relevant sections of the assessment report.]*

### Assessment of a combination of biocidal products

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

*[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several products ]*

### Comparative assessment

*[Please, delete if not relevant]*

*[Please include a reference to the comparative assessment report to be forwarded to ECHA and the other MSs, in accordance with Art. 23(2) of the BPR].*

#### Screening phase

- Description of the assessement of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance.

- Consideration on whether the active substance(s) meet(s) at least one of the exclusion criteria listed in Article 5(1) but that benefit from derogation in accordance with Article 5(2) of the BPR.

- Conclusion of the screening phase: Stop comparative assessment / Tier IA / Tier IB / Tier II

#### Tier IA

- Description of biocidal products included in the comparison

- Main outcome of the comparison for:

- risk for human health, animal health and the environment

- significant economic or practical disadvantages

- Conclusion of Tier IA: Tier IB / Tier II

#### Tier IB

- Main outcome of the comparison for:

- risk for human health, animal health and the environment

- significant economic or practical disadvantages

- Conclusion of Tier IB: End of comparative assessment / Tier II

#### Tier II

- Description of non-chemical alternatives included in the comparison

- Main outcome of the comparison for:

- risk for human health, animal health and the environment

- efficacy

- significant economic or practical disadvantages

- Conclusion of Tier II: stop comparative assessment/ End of comparative assessment

#### Overall conclusion

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

*[Please see the latest version of the SPC in the relevant Member State to see all the authorised uses and RMMs authorised for the product].*

# Annexes[[13]](#footnote-14)

## 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)** |
| Thierry Lacour | 2020 | 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 |
| Thierry Lacour | 2020 | 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 |
| Thierry Lacour | 2020 | 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 |
| Aurélie HANIN | 2020 | EN 13697, Bactericidal and fungicidal activity - Actalia (2020)  Report No SMI.2020.338.2 | Yes | Notilia |
| Au Chryslène | 2021 | NF EN 13697 + A1 : 2019 ACTIVITE BACTERICIDE PRODUIT TESTE : SOLUTION HYPOCHLORITE SODIUM 1,3%  Laboratoire Mediterranéen de Microbiologie  Report No LMM 2021001L | Yes | Notilia |
| Au Chryslène | 2021 | NF EN 13697 + A1 : 2019 ACTIVITE FONGICIDE PRODUIT TESTE : SOLUTION HYPOCHLORITE SODIUM 1,3%  Laboratoire Mediterranéen de Microbiologie  Report No LMM 2021002L | Yes | Notilia |
| Dr Elisabeth Servajean | 2020 | 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  GLP; Unpublished | Yes | Notilia |
| Dr Elisabeth Servajean | 2021 | 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 |
| Dr Elisabeth Servajean | 2020 | 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 |
| Dr Elisabeth Servajean | 2021 | 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 |
| Dr Elisabeth Servajean | 2021 | 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 |
| Dr Elisabeth Servajean | 2021 | 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 |
| Dr Elisabeth Servajean | 2021 | 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 |
| Dr Elisabeth Servajean | 2021 | 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 |
| Dr Elisabeth Servajean | 2020 | 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 |
| Dr Elisabeth Servajean | 2021 | 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 |
| Pauline Padilla | 2021 | 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 |
| Dr Elisabeth Servajean | 2020 | 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 |
| Dr Elisabeth Servajean | 2020 | 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 |
| Dr Elisabeth Servajean | 2021 | 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 |
| Dr Elisabeth Servajean | 2020 | 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  GLP; Unpublished | Yes | Notilia |
| Dr Elisabeth Servajean | 2021 | 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 |
| Pauline Padilla | 2021 | Test methods for corrosion to metals on SPRAY JAVEL 1.5%  DEFITRACES  20-914015-002  GLP; Unpublished | Yes | Notilia |
| Pauline Padilla | 2021 | Flash point and Auto-ignition temperature of liquids tests on JAVEL 4.9% + DÉTERGENT EUCALYPTUS  DEFITRACES  20-914015-003  GLP; Unpublished | Yes | Notilia |

## Output tables from exposure assessment tools

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## New information on the active substance

## 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 | NOAECoral = 0.1% available chlorine |
| Dermal | NOAECdermal = 1% available chlorine |
| Inhalation | AECinhal = 0.5 mg/m3 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.

For non-professional uses :

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 :

With an in-use concentration of 49 000 mg/L of sodium hypochlorite (4.9% in-use dilution)[[14]](#footnote-15), the concentration of sodium chlorate (NaOCl3) is 15 312.5 mg/L (1.5%) and the concentration of chlorate is 12 005 mg/L (1.2%), considering:

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: cas in bp (mg/kg) | 1200 | product specific information |  |  |  |  |
|  | maximal application rate of detergent  (= concentration of detergent in dish wash solution): Rappl detergent (g detergent./L) | 1,4 | default 1,400 g/L or product specific value |  |  |  |  |
|  | maximal application rate of active substance  (= concentration of active substance in dish wash solution): Rappl as (mg as/L) | 1,68 | calculated as  Rappl as =  (cas in bp ÷ 1000) x  Rappl 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: Ta (L/cm²) | 5,50E-07 | default value |  |  |  |  |
|  | area of dishes in daily contact with food: Sa (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 Expcons = (Rappl as x Ta x Sa 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).

## Summaries of the efficacy studies (B.5.10.1-xx)[[15]](#footnote-16)

## Confidential annex

See the confidential PAR

## Other

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 [↑](#footnote-ref-2)
2. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-3)
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 [↑](#footnote-ref-4)
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 [↑](#footnote-ref-5)
5. Assessment report, January 2017 – Active chlorine released from sodium hypochlorite. Italy [↑](#footnote-ref-6)
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 [↑](#footnote-ref-7)
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 [↑](#footnote-ref-8)
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 [↑](#footnote-ref-9)
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 [↑](#footnote-ref-10)
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. [↑](#footnote-ref-11)
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. [↑](#footnote-ref-12)
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 [↑](#footnote-ref-13)
13. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-14)
14. Worst case : 9.6% avCl product (use 2 – non professional use) [↑](#footnote-ref-15)
15. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-16)