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

**RISK ASSESSMENT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS**



Nopa Nordic

Product type 2

Active chlorine released from sodium hypochlorite

Case Number in R4BP: [BC-ME047997-24]

Evaluating Competent Authority: Sweden

Date: [15/12/2021]

Table of Contents

[Table of Contents 2](#_Toc89093741)

[1. CONCLUSION 4](#_Toc89093742)

[2 ASSESSMENT REPORT 6](#_Toc89093743)

[2.1 Summary of the product assessment 6](#_Toc89093744)

[2.1.1 Administrative information 6](#_Toc89093745)

[2.1.1.1 Identifier of the product family 6](#_Toc89093746)

[2.1.1.2 Authorisation holder 6](#_Toc89093747)

[2.1.1.3 Manufacturer of the products of the family 6](#_Toc89093748)

[2.1.1.4 Manufacturers of the active substance 6](#_Toc89093749)

[2.1.2 Product (family) composition and formulation 7](#_Toc89093750)

[2.1.2.1 Identity of the active substance 7](#_Toc89093751)

[2.1.2.2 Candidate(s) for substitution 7](#_Toc89093752)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family 7](#_Toc89093753)

[2.1.2.4 Information on technical equivalence 8](#_Toc89093754)

[2.1.2.5 Information on the substance(s) of concern (SoC) 8](#_Toc89093755)

[2.1.2.6 Type of formulation 8](#_Toc89093756)

[2.1.3 Hazard and precautionary statements 8](#_Toc89093757)

[2.1.4 Authorised use(s) 10](#_Toc89093758)

[2.1.4.1 META SPC 1 Use description use 1 10](#_Toc89093759)

[2.1.4.2 META SPC 2 Use description use 1 11](#_Toc89093760)

[2.1.5 General directions for use 12](#_Toc89093761)

[2.1.5.1 Instructions for use 12](#_Toc89093762)

[2.1.5.2 Risk mitigation measures 12](#_Toc89093763)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 12](#_Toc89093764)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 12](#_Toc89093765)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 12](#_Toc89093766)

[2.1.6 Other information 13](#_Toc89093767)

[2.1.7 Packaging of the biocidal product 13](#_Toc89093768)

[2.1.8 Access to documentation 13](#_Toc89093769)

[2.2 Assessment of the biocidal product family 14](#_Toc89093770)

[2.2.1 Intended uses as applied for by the applicant 14](#_Toc89093771)

[2.2.2 Physical, chemical and technical properties 15](#_Toc89093772)

[2.2.3 Physical hazards and respective characteristics 23](#_Toc89093773)

[2.2.4 Methods for detection and identification 27](#_Toc89093774)

[2.2.5 Efficacy against target organisms 32](#_Toc89093775)

[2.2.5.1 Function and field of use 32](#_Toc89093776)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 32](#_Toc89093777)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 32](#_Toc89093778)

[2.2.5.4 Mode of action, including time delay 32](#_Toc89093779)

[2.2.5.5 Efficacy data 32](#_Toc89093780)

[2.2.5.6 Occurrence of resistance and resistance management 35](#_Toc89093781)

[2.2.5.7 Known limitations 35](#_Toc89093782)

[2.2.5.8 Evaluation of the label claims 35](#_Toc89093783)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 35](#_Toc89093784)

[2.2.6 Risk assessment for human health 36](#_Toc89093785)

[2.2.6.1 Assessment of effects on Human Health 36](#_Toc89093786)

[2.2.6.2 Exposure assessment 44](#_Toc89093787)

[2.2.6.3 Risk characterisation for human health 54](#_Toc89093788)

[2.2.7 Risk assessment for animal health 61](#_Toc89093789)

[2.2.8 Risk assessment for the environment 62](#_Toc89093790)

[2.2.8.1 Effects assessment on the environment 63](#_Toc89093791)

[2.2.8.2 Exposure assessment 76](#_Toc89093792)

[2.2.8.3 Risk characterisation 79](#_Toc89093793)

[2.2.9 Measures to protect man, animals and the environment 83](#_Toc89093794)

[2.2.10 Assessment of a combination of biocidal products 83](#_Toc89093795)

[2.2.11 Comparative assessment 83](#_Toc89093796)

[3 Annexes 84](#_Toc89093797)

[3.1 List of studies for the biocidal product (family) 84](#_Toc89093798)

[3.2 Output tables from exposure assessment tools 84](#_Toc89093799)

[3.3 New information on the active substance 87](#_Toc89093800)

[3.4 Residue behaviour 87](#_Toc89093801)

[3.5 Summaries of the efficacy studies 87](#_Toc89093802)

[3.6 Confidential annex 87](#_Toc89093803)

[3.7 Other 87](#_Toc89093804)

# CONCLUSION

Nopa Nordic is a biocidal product family that contains the active substance *active chlorine released from sodium hypochlorite* at 2.4% w/w. The intended use of the products is surface disinfection (PT2) of bathrooms under clean conditions by pouring.

The Nopa Nordic family consists of the formulations HK0014 in metaSPC 1 and HK0016in metaSPC 2. The formulations are divided into two meta SPCs based on the difference in alkalinity. The alkalinity for metaSPC 1 and metaSPC 2 are 1.434 % NaOH and 3.875 % NaOH respectively.

All products in the biocidal family are soluble concentrates (SL formulations). The physical and chemical properties are adequately addressed. Degradation of the active substance was observed but a shelf-life of 18 months in HDPE packaging can be supported based on available efficacy data, however, further efficacy data is required for post authorisation (see section 1.1). Storage conditions should include the following restrictions: “Store at 5-25°C and away from sunlight.” and “Protect from frost.” Nopa Nordic will be classified as Met. Corr. 1 – H290: May be corrosive to metals.

Efficacy tests performed according to the respective EN European standards for efficacy testing, confirm that the minimum concentration of product needed to exhibit sufficient bactericidal, yeasticidal and fungicidal activity for pouring within PT2 for clean conditions is 10% (1 part product + 9 parts water) at minimum 5 minutes of exposure time under clean conditions, which correspond to 0.25% w/w active chlorine

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

The concentration of the relevant impurity chlorate exceeds 5.4% of the active chlorine concentration, which would require a risk assessment. Even though this requirement is met a health risk assessment of the exposure to chlorate has not been made due to lack of guideline and reference values (WGTOX`I 2021).

Based on the fact that the duration of exposure to concentrated product is short, the concentration of the in-use solutions are below relevant AEC for available chlorine and have pH below 11,5 and based on the conclusions from the local risk characterisation; i.e. that relevant risk mitigating measures are in place such as child proof closure (certified), small package size, labelling the products as eye damaging, instructions for use to minimise exposure for reducing risk, the use of the Nopa Nordic products are considered safe.

The environmental risk assessment of the biocidal product family is focused on the active substance, more specifically the hypochlorite ion.

All releases of the active substance to the environment will take place indirectly via sewage treatment plants (STP).

The estimated PEC/PNEC values of the active substance for the described uses of the biocidal product family are below the trigger value of 1. The PEC/MPC value of the co-formulant for the pore water in the upper soil layer – being a conservative estimate for the ground water – exceeds 1 slightly. However, a concentration in the lower soil would be one or more orders of magnitude lower, so the MPC will not be exceeded at a soil depth of 1 m.

Thus, the use of the biocidal product family indicates no unacceptable risk for the environment.

The ingredients in the product family are not suspected of showing synergistic effects.

The aggregated exposure of active hypochlorite was considered as well, and it was found that there are no high concerns for cumulative environmental risks for the hypochlorite ion.

Based on the above it was therefore concluded that the use of Nopa Nordic products for disinfection purposes for private use within PT2 is considered to be efficacious and safe with regards to human and animal health and the environment.

1.1 Requirement for further information

DATA REQUIRMENTS FOR POST AUTHORISATION

In order to confirm that a shelf life of 18 months is supported by efficacy data for metaSPC2, efficacy testing on aged product is required.

The efficacy test data must be submitted no later than 24 months from the date of authorisation to the rapporteur member state.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| Nopa Nordic | Sweden, Denmark, Norway, Finland, Germany |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Nopa Nordic A/S |
| **Address** | Havrevænget 13  9500 Hobro |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | Nopa Nordic A/S |
| **Address of manufacturer** | Havrevænget 13  9500 Hobro  Denmark |
| **Location of manufacturing sites** | Havrevænget 13  9500 Hobro  Denmark |

#### Manufacturers of the active substance

|  |  |
| --- | --- |
| **Active substance** | Active chlorine released from sodium hypochlorite |
| **Name of manufacturer** | Nouryon Industrial Chemicals BV |
| **Address of manufacturer** | Velperweg 76, 6824 BM  Arnhem, The Netherlands |
| **Location of manufacturing sites** | Nouryon Industrial Chemicals BV  Oosterhorn 4, 9936 HD Delfzijl (Farmsum),  The Netherlands |
|  |  |
| **Name of manufacturer** | Borregard AS |
| **Address of manufacturer** | PO Box 162  N-1701 Sarpsborg  Norway |
| **Location of manufacturing sites** | Borregaard AS  20 C-Port  N-1701 Sarpsborg  Norway |

### Product (family) composition and formulation

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** | Active chlorine released from 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** | Aqueous solution with an available active chlorine concentration of ≤180 g/kg, in compliance with the EN 901:2013 |
| **Relevant impurity** | Sodium chlorate: ≤5.4% of the active chlorine content |
| **Structural formula** | Na+ ClO- |
| **Molecular mass** | 74.44 g/mol |

#### Candidate(s) for substitution

The active substance is not a candidate for substitution.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Active chlorine released from sodium hypochlorite  (Sodium hypochlorite)  (Sodium hypochlorite solution, 15% w/w avail. Cl) | Sodium hypochlorite | Active substance | 7681-52-9 | 231-668-3 | 2.40  (2.52)  (16) | 2.40  (2.52)  (16) |

The full composition of the biocidal product family is given in the Confidential Annex.

#### Information on technical equivalence

The Borregard AS source was evaluated during the active substance approval and considered to comply with the reference specification.

The Nouryon Industrial Chemicals B.V. (previously Akzo Nobel Industrial Chemicals B.V.) source was considered technically equivalent to the reference specification. (Case number: BC-NG040944-37)

#### Information on the substance(s) of concern (SoC)

The Nopa Nordic biocidal product family contains no substance of concern.

#### Type of formulation

|  |
| --- |
| Soluble concentrate (SL) |

### Hazard and precautionary statements

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

The classification of the two metaSPCs is identical. The classification is listed below.

| **Classification** | |
| --- | --- |
| Hazard category | Skin Irrit. 2; H315  Eye Dam. 1; H318  Aquatic Chronic 3; H412  Met. Corr. 1; H290 |
| Hazard statement | H315 Causes skin irritation.  H318 Causes serious eye damage.  H412 Harmful to aquatic life with long lasting effects.  H290 May be corrosive to metals. |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H315 Causes skin irritation.  H318 Causes serious eye damage.  H412 Harmful to aquatic life with long lasting effects.  H290 May be corrosive to metals. |
| Precautionary statements | P101 If medical advice is needed, have product container or label at hand.  P102 Keep out of reach of children.  P234 Keep only in original packaging.  P273 Avoid release to the environment.  P264 Wash hands thoroughly after handling.  (P280 Wear protective gloves/eye protection.)  P302+P352 IF ON SKIN: Wash with plenty of water and soap.  P332+ P313 If skin irritation occurs: Get medical advice.  P305+P351+P338+P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor  P501 Dispose of contents/container should be disposed according to local waste regulations.  EUH206 Warning! Do not use together with other products. May release dangerous gases (chlorine).  Absorb spillage to prevent material damage. |
| Pictograms |  |
|  | |
| Note | H318 triggers P280 (Wear eye protection). However, based on the qualitative risk assessment for local effects the additional advice “Avoid contact of the concentrate with eyes” should be added on the label. This advice and P305+P351+P338+P310 (IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTRE/doctor) are considered sufficient to protect non-professionals from the corresponding risk.  H315 triggers P280 (Wear protective gloves) but as the product is for non-professional use only no PPE could be applied. Also note that as shown in the quantitative local risk assessment the in-use concentration is below the dermal AEC.  P103 “Read lable before use” was not added as it is an optional phrase, but “Comply with the instructions for use” was added in section 2.1.5.1 of the PAR and 5.1 in the SPC.  P321 “Specific treatment…” was not addes as there is no specific treatment available.  P362+P364 “Take off contaminated clothing and wash it before reuse.” was not be added as it is optional. |

### Authorised use(s)

#### META SPC 1 Use description use 1

Table 1. Use # 1 – Surface disinfection by pouring

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria (*Development stage: No data*):  Fungi (*Development stage: No data*):  Yeasts (*Development stage: No data*): |
| **Field of use** | Surface disinfection of bathrooms under clean conditions |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | 20 ml product/m2 |
| **Dilution and concentration a.s. in diluted product** | Dilution: 10% (1 part product + 9 parts water, which correspond to 0.24% active chlorine) |
| **Category(ies) of users** | Non-professional user |
| **Pack sizes and packaging material** | 750 ml, 1500 ml  HDPE bottle with PP closure |

**Use-specific instructions for use**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Clean surface before applying the product and allow time to dry. Pour diluted product on surface to be disinfected and leave on for minimum 5 minutes.  Make sure to wet the surface completely.  When mixing the product, pour approximately 100 ml of the product into a bucket and add water to a total volume of 1 litre. One litre is sufficient to treat 5 m2.   |  |  |  | | --- | --- | --- | | m2 surface | ml product | ml water | | 1 | 20 | 180 | | 2 | 40 | 360 | | 5 | 100 | 900 |   Use should be limited to non-porous surfaces. |

#### META SPC 2 Use description use 1

Table 2. Use # 1 – Surface disinfection by pouring

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria (*Development stage: No data*):  Fungi (*Development stage: No data*):  Yeasts (*Development stage: No data*): |
| **Field of use** | Surface disinfection of bathrooms under clean conditions |
| **Application method(s)** | Pouring |
| **Application rate(s) and frequency** | 19 ml product/m2 |
| **Dilution and concentration a.s. in diluted product** | Dilution: 10% (1 part product + 9 parts water, which correspond to 0.24% active chlorine) |
| **Category(ies) of users** | Non-professional user |
| **Pack sizes and packaging material** | 750 ml, 1500ml  HDPE bottle with PP closure |

**Use-specific instructions for use**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Clean surface before applying the product and allow time to dry. Pour diluted product on surface to be disinfected and leave on for minimum 5 minutes.  Make sure to wet the surface completely.   |  |  |  | | --- | --- | --- | | m2 surface | ml product | ml water | | 1 | 19 | 171 | | 2 | 38 | 342 | | 5 | 95 | 855 |   Use should be limited to non-porous surfaces. |

### 

### General directions for use

#### Instructions for use

|  |
| --- |
| Comply with the instructions for use.  See use specific instructions for each use. |

#### Risk mitigation measures

|  |
| --- |
| * Avoid contact of the concentrate with eyes. * Keep out of reach of children * Wash hands after mixing. * Child proof closure (certified) |

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

|  |
| --- |
| If medical advice is needed, have product container or label at hand.  In case of an accident: Contact a POISON CENTRE or a doctor.  IF INHALED: If symptoms occur 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.  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: 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 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. |

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

|  |
| --- |
| Dispose of contents/container should be disposed according to local waste  regulations. Container may not be re-used. |

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

|  |
| --- |
| Store at 5-25˚C and away from sunlight.  Protect from frost.  Shelf-life: 18 months  Keep only in the original container﻿ away from acids. (Reacts with acids and releases (highly) toxic gases/vapours (chlorine).)  Keep out of reach of children and non-target animals/pets. |

### Other information

|  |
| --- |
| H318 triggers P280 (Wear eye protection) and H315 triggers P280 (Wear gloves), but as the product is for non-professional use only no PPE could be applied and therefore P280 is omitted. |

### 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)** |
| Bottle | 750 ml  1500 ml | HDPE | Child proof closure (PP) | non-professional | Yes |

### Access to documentation

The applicant holds a letter of access (LoA) to the complete active substance dossier from Inovyn Trade Services SA which is a member of the consortium (co-ordinated by EuroChlor) that made a joint submission for approval of active chlorine released from sodium hypochlorite.

## Assessment of the biocidal product family

### Intended uses as applied for by the applicant

Table 4. Intended use # 1 – Surface disinfection by pouring

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Surface disinfection of bathrooms |
| Target organism (including development stage) | Bacteria, yeast and fungi |
| Field of use | Private household area |
| Application method(s) | Pouring |
| Application rate(s) and frequency | 20ml/m2 |
| Category of user | Private user |
| Pack sizes and packaging material | 750 ml  1500 ml  PE |

Table 5. Intended use # 2 – Surface disinfection by wiping

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use | Surface disinfection of bathrooms |
| Target organism (including development stage) | Bacteria, yeast and fungi |
| Field of use | Private household area |
| Application method(s) | Wiping |
| Application rate(s) and frequency | 20ml/m2 |
| Category of user | Private user |
| Pack sizes and packaging material | 750 ml  1500 ml  PE |

### Physical, chemical and technical properties

The physical, chemical and technical properties of the biocidal product family, Nopa Nordic, are detailed in the following table.

| **Property** | **Guideline and Method** | **Purity of the test product (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | OPPTS 830-6303 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | Liquid  Liquid | Feierabend (2021), LAUS GmbH, Germany;  Study No.  19061305G001and Study No.: 19061306G001 |
| Colour at 20 °C and 101.3 kPa | OPPTS 830-6302 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | Colourless with minimal yellow tint  Colourless with minimal yellow tint | Feierabend (2021), LAUS GmbH, Germany;  Study No.  19061305G001and Study No.: 19061306G001 |
| Odour at 20 °C and 101.3 kPa |  |  | Not performed as the test item irritates respiratory tracts.  Some people exhibit adverse responses to odors/scents even if the airborne concentration does not meet the defined levels for being hazardous. The smell of bleach can be unpleasant and therefore the applicants waiving argument is acceptable. |  |
| pH | CIPAC MT 75.3 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | pH at 25 °C  HK0014  *1% aq. soln.*  10.71  *Neat*  12.02  HK0016  *1% aq. soln.*  10.99  *Neat*  11.98 | Feierabend (2021), LAUS GmbH, Germany;  Study No.  19061305G001and Study No.: 19061306G001 |
| Acidity / alkalinity | CIPAC MT 191 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | HK0014  T0: 1.434 % m/m as NaOH  T18: 1.148 % m/m as NaOH  HK0016  T0: 3.875 % m/m as NaOH  T18: 3.168 % m/m as NaOH | Feierabend (2021), LAUS GmbH, Germany;  Study No.  19061305G001and Study No.: 19061306G001 |
| Relative density / bulk density | EC A.3  Pycnometer method | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | HK0014: 1.0457 at 20 °C  HK0016: 1.1034 at 20 °C | Muckle (2019), LAUS GmbH, Germany, Study No. 19010401G912  Study No. 19010402G912 |
| Accelerated storage stability test | Test waived – “Store at 5 – 25 °C” will be added to the label as indicated in section 2.1.5.5 in the PAR and section 5.5 in the SPC.  This is acceptable according to the Guidance on the BPR Vol I Parts A+B+C (May 2018). | | | |
| Storage stability test – **long term storage at ambient temperature** | FAO/WHO Manual, CropLife International Technical Monograph No. 17 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2  Validated methods: study no. 19010401G926 and 19010402G926. | | Feierabend (2021), LAUS GmbH, Germany;  Study No.  19061305G001and Study No.: 19061306G001 |
| HK0014  (20 ± 2 °C, HDPE (750 ml))  **Appearance**  T0  Colourless with minimal yellow tint  **Active chlorine** (% w/w):  T0: 2.72%  T6: 2.61%  T12: 2.56%  T18: 2.48% (8.8% degradation) | | T18  No change  **Impurity – ClO3-/NaClO3** (% w/w):  T0: 0.224%/0.287% (10.5% of active Cl)  T6: 0.273%/0.349%  T12: 0.294%/0.376%  T18: 0.327%/0.419% (+46%) | |
| **pH**  *1% aq. soln.*  T0 10.71  T6 10.68  T12 10.75  T18 10.74 | | *Neat*  T0 12.02  T6 12.14  T12 12.16  T18 12.12 | |
| **Alkalinity**  T0: 1.434 % m/m as NaOH  T6: 1.399 % m/m as NaOH  T12: 1.387 % m/m as NaOH  T18: 1.148 % m/m as NaOH | |  | |
| **Dilution stability**  T0: N/A  T15: After 30 min and 24 h, white sediment (flakes) was observed in the clear solution. Wet sieving test adapted from CIPAC MT 185 (b) was performed in order to determine the amount of residue. A quantitative determination of residue was not possible due to a very small amount (<1 mg). Therefore, the determination of active ingredient in the residue was not performed.  T18: Same result as T15. | | | |
| **Stability of packaging**  T0:  Weight: 827.1 g  The packaging was well closed and without any deformation, anomalies or leaks. | | T18:  Weight: 821.0 g (-0.7 %)  No visual change. | |
| HK0016  (20 ± 2 °C, HDPE (750 ml))  **Appearance**  T0  Colourless with minimal yellow tint  **Active chlorine** (% w/w):  T0: 2.83%  T6: 2.62%  T12: 2.52%  T18: 2.38% (15.9% degradation) | | T18  No change  **Impurity – ClO3-/NaClO3** (% w/w):  T0: 0.239%/0.306% (10.8% of active Cl)  T6: 0.303%/0.389%  T12: 0.363%/0.465%  T18: 0.423%/0.541% (+77%) | |
| **pH**  *1% aq. soln.*  T0 10.99  T6 11.02  T12 11.06  T18 10.95 | | *Neat*  T0 11.98  T6 12.09  T12 12.13  T18 12.08 | |
| **Alkalinity**  T0: 3.875 % m/m as NaOH  T6: 3.828 % m/m as NaOH  T12: 3.853 % m/m as NaOH  T18: 3.168 % m/m as NaOH | |  | |
| **Dilution stability**  T0: N/A  T15: After 30 min and 24 h, white sediment (flakes) was observed in the clear solution. Wet sieving test adapted from CIPAC MT 185 (b) was performed in order to determine the amount of residue. A quantitative determination of residue was not possible due to a very small amount (<1 mg). Therefore, the determination of active ingredient in the residue was not performed.  T18: Same result as T15. | | | |
| **Stability of packaging**  Bottle 2:  T0 = 873.4 g, T6 = 873.2 g  Bottle 3:  T0 = 873.2 g, T15 = 872.7 g | | Bottle 4:  T0 = 873.3 g, T15 = 872.6 g  (-0.08%), T18 = 738.4 g  (An error was made when the weight was measured at T18. Based on the weight at T15 and the fact that bottles 2 and 3 showed no signs of leakage, the T18 value will be disregarded.) | |
| The packaging was well closed and without any deformation, anomalies or leaks in all bottles (including bottle 4). | | | |
| Low temperature stability test | Test waived – “Protect from frost” will be added to the label as indicated in section 2.1.5.5 in the PAR and section 5.5 in the SPC. | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - light | Test waived – “Store at 5-25˚C and away from sunlight” will be added to the label. Furthermore, products are packaged in opaque containers. | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity | Temperature: Refer to storage stability testing, in the long term stability study the effect of ambient temperature is assessed. Also “Store at 5-25˚C and away from sunlight” will be added to the label.  Humidity: Not relevant. The products in Nopa Nordic BPF are aqueous formulations. | | | |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | Refer to storage stability testing. Long-term storage stability studies have been performed in HDPE packaging and no changes were observed in the packaging. | | | |
| **Technical characteristics of the biocidal products** | | | | |
| Wettability | The study does not need to be conducted because the products are not solid formulations. | | | |
| Suspensibility | The study does not need to be conducted because the products do not form suspensions. | | | |
| Wet sieve test | The study does not need to be conducted for soluble concentrates. | | | |
| Emulsifiability | The study does not need to be conducted for soluble concentrates. | | | |
| Disintegration time | The study does not need to be conducted for soluble concentrates. | | | |
| Particle size distribution | The study does not need to be conducted for soluble concentrates. | | | |
| Persistent foaming | CIPAC method MT 47.2 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | HK0014  At 10% conc.  0.0 mL (1 min)  At 33.3% conc.  0.0 mL (1 min)  HK0016  At 10% conc.  0.0 mL (1 min)  At 33.3% conc.  0.0 mL (1 min) | Muckle (2019), LAUS GmbH, Germany  Study No.: 19010401G968and Study No.: 19010402G968 |
| Flowability / Pourability / Dustability | The study does not need to be conducted for soluble concentrates. | | | |
| Burning rate – smoke generators | The study does not need to be conducted because the products are not smoke generators. | | | |
| Burning completeness | The study does not need to be conducted because the products are not smoke generators. | | | |
| Composition of smoke | The study does not need to be conducted because the products are not smoke generators. | | | |
| Spraying patterns | The study does not need to be conducted because the products are not aerosols. | | | |
| Dilution stability | CIPAC MT 41.1 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | 5 mL test item was diluted to 100 mL with Standard Water D.  HK0014  After 30 min and 24 hours white precipitation (flakes) was observed in the solution.  Trace amount of residue was obtained after wet sieving of the separated material.    HK0016  After 30 min and 24 hours white precipitation (flakes) was observed in the solution.  Trace amount of residue was obtained after wet sieving of the separated material. | Feierabend (2021), LAUS Feierabend  Study No.: 19061305G001and Study No.: 19061306G001 |
| Physical compatibility | Not relevant. The products in Nopa Nordic BPF are not intended to be used in combination with other products. | | | |
| Chemical compatibility | Not relevant. The products in Nopa Nordic BPF are not intended to be used in combination with other products. | | | |
| Surface tension | EC A.5 and OECD 115 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | Determined at the highest use solution 33.3%.  HK0014:  72.65 ± 0.22 mN/m at 20 °C  HK0016:  71.63 ± 0.12 mN/m at 20 °C  The products of the BPF have a surface tension > 60 mN/m and are not surface active. | Muckle (2019), LAUS GmbH, Germany  Study No.: 19010401G960 and Study No.: 19010402G960 |
| Viscosity | OECD 114 | HK0014 as representative product for metaSPC 1  HK0016 as representative product for metaSPC 2 | HK0014  20 °C: 1.213 ± 0.001 mPa\*s  40 °C: 0.807 ± 0.003 mPa\*s  HK0016  20 °C: 2.022 ± 0.003 mPa\*s  40 °C: 1.103 ± 0.002 mPa\*s | Muckle (2019), LAUS GmbH, Germany  Study No.: 19010401G984 and Study No.: 19010402G984 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| Results are available for the representative products, HK0014 for metaSPC 1 and HK0016 for metaSPC 2, of the biocidal product family.  HK0014  The biocidal product is a clear, slightly yellow tinted liquid with a relative density of 1.0438 g/mL, pH of 10.71 (1% soln.), alkalinity of 1.434 %, surface tension of 72.65 mN/m, and a dynamic viscosity of 1.213 mPa·s. The biocidal product is not surface active. No foam is formed when the product is diluted. In the dilution stability test, trace amount of white flakes were observed after 30 min and 24 h.  HK0016  The biocidal product is a clear, slightly yellow tinted liquid with a relative density of 1.1014 g/mL, pH of 10.99 (1% soln.), alkalinity of 3.875 %, surface tension of 71.63 mN/m, and a dynamic viscosity of 2.022 mPa·s. The biocidal product is not surface active. No foam is formed when the product is diluted. In the dilution stability test, trace amount of white flakes were observed after 30 min and 24 h.  Regarding product stability, neither accelerated storage data nor low temperature data are available. This is acceptable with the addition of the following storage restrictions: “Store at 5-25˚C and away from sunlight” and “Protect from frost”.  Long term storage studies at ambient temperature are available.  However, the chlorate test results for the timepoint T0 are not acceptable. The sodium chlorate content is greater than 5.4% of the active chlorine concentration: 0.287% (10.5% of active Cl for HK0014) and 0.306% (10.8% of active Cl for HK0016). A certificate of analysis from the supplier of the active substance showed that the chlorate content is ≤ 5.4%. The applicant therefore investigated the logistics around the T0 analysis, and it turned out that more than a month had passed from the day the products were produced until the T0 analysis was performed. The elapsed time between production and analysis could explain the high chlorate content at T0.  Furthermore, the active chlorine content for HK0016 at T0 is not within specification. At T0 the active chlorine content is 2.83 % which is 17.9% greater than the declared content of 2.4 % and therefore not within the tolerance limit of ±15%.  The applicant was therefore asked to submit new T0 data. The new data are shown below and they are considered acceptable. (Feierabend (2021), LAUS GmbH, Germany; Study No.: 21031105G001 and Study No.: 21031106G001)   |  |  | | --- | --- | | HK0014  **Active chlorine** (% w/w):  2.618%  **Impurity – NaClO3** (% w/w):  0.082% (3.1% of active Cl)  **pH** (1 % soln.; undiluted):  10.40; 12.12  **Alkalinity** (%):  1.459 | HK0016  **Active chlorine** (% w/w):  2.624%  **Impurity – NaClO3** (% w/w):  0.082% (3.1% of active Cl)  **pH** (1 % soln.; undiluted):  10.93; 12.03  **Alkalinity** (%):  3.291 |   After 18 months the active substance content for HK0014 and HK0016 had decreased with 8.8% and 15.9% respectively. As the degradation of the active substance is > 10% for HK0016, an assessment of the degradation products and their effect on the efficacy should be performed.    The degradation products were identified in the CAR as chlorate and chloride. In the CAR it was concluded that chlorate is a relevant impurity. Sodium chlorate concentrations were therefore monitored and an increase was observed in the storage stability study: HK0014: 0.287% (T0) and 0.419% (T18); HK0016: 0.306% (T0) and 0.541% (T18). The increased level of chlorate is addressed in section 2.2.6.1 of the PAR.  Despite the greater than 10% degration of the active substance, a shelf-life of 18 months is acceptable based on the result from three efficacy tests. The three tests are EN 1276 against bacteria, EN 1650 against yeast and fungi and EN 13697 against bacteria, yeast and fungi. The results from these efficacy tests show that the pass criteria for efficacy is met with samples that contain 0.24% active chlorine (dilution to 10% of product). At the concentration of 0.24% the degradation of 15.9% is accounted for at the recommended dilution of 1:5. (see section 2.2.5.5 for more details).  The products in Nopa Nordic BPF are SL formulations. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable to grant a shelf-life of 18 months.  DATA REQUIRMENTS FOR POST AUTHORISATION  In order to confirm that a shelf life of 18 months is supported by efficacy data for metaSPC2, efficacy testing on aged product is required.  The efficacy test data must be submitted no later than 24 months from the date of authorisation to the rapporteur member state. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | In the CAR is was concluded that a solution of sodium hypochlorite (15.9% avail. Cl) does not have explosive properties. Chlorate is a chemical group that can have explosive properties. However, according to the harmonised classification of sodium chlorate, it is not classified as explosive. And according to the SDS for all co-formulants, none are classified as explosive.  Based on the information in the CAR and that the co-formulants are not classified as explosive, the biocidal product family is not considered to have explosive properties. | | | |
| Flammable gases | The study does not need to be conducted because the products in the biocidal product family are liquids. | | | |
| Flammable aerosols | The study does not need to be conducted because the products in the biocidal product family do not meet the definition of aerosols. | | | |
| Oxidising gases | The study does not need to be conducted because the products in the biocidal product family are liquids. | | | |
| Gases under pressure | The study does not need to be conducted because the products in the biocidal product family are liquids and not under pressure. | | | |
| Flammable liquids | EC A.9  Pensky-Martens | HK0016 | No flash point was observed up to the boiling temperature (101.5 °C) of the product.  The only difference in the composition between both metaSPCs is the presence of an additional stabilizer in metaSPC 2. Therefore, the test result that “*no flash point is observed up to the boiling point”* is expected to apply for metaSPC 1 as well.  The products in the Nopa Nordic BPF should not be classified as flammable liquids. | Muckle (2019) CRO, LAUS GmbH, Germany  Study No.: 19010402G964 |
| Flammable solids | The study does not need to be conducted because the products in the biocidal product family are liquids. | | | |
| Self-reactive substances and mixtures | The products in Nopa Nordic contain the chemical group chlorate that is associated with self-reactive properties. However, sodium chlorate is not classified as self-reactive according to Regulation (EC) No 1272/2008.  According to the SDS for the remaining co-formulants, none are classified as being self-reactive.  The products in the Nopa Nordic BPF should not be classified as self-reactive mixtures. | | | |
| Pyrophoric liquids | The study does not need to be conducted because the products in the BPF do not contain any substances that ignite spontaneously in contact with air at normal temperature. The products in the BPF are known to be stable at room temperature for prolonged periods of time. (Reference: Feierabend (2021), LAUS Feierabend (2021), GmbH, Germany; study no.: 19061305G001 and study no.: 19061306G001) | | | |
| Pyrophoric solids | The study does not need to be conducted because the products are liquids. | | | |
| Self-heating substances and mixtures | The study does not need to be conducted because the phenomenon of self-heating applies only to solids or to liquids that are adsorbed on a large surface (e.g. on powder particles). | | | |
| Substances and mixtures which in contact with water emit flammable gases | The study does not need to be conducted because the products in the BPF do not contain any substances that emit flammable gases in contact with water. The products in the BPF are manufactured with water and known to be stable at room temperature (Reference: Feierabend (2021), LAUS Feierabend (2021), GmbH, Germany; study no.: 19061305G001 and study no.: 19061306G001). | | | |
| Oxidising liquids | EC A.21 | HK0016 | Mean pressure rise time  HK0016  30.682 ± 5.336 s  Reference:  nitric acid (65% w/w)  2.436 ± 0.450 s  The test item will not classified as an oxidising liquid since a 1:1 mixture, by mass, of HK0016 and cellulose exhibits a mean pressure rise time greater than the mean pressure rise time of a 1:1 mixture of 65 % (w/w) aqueous nitric acid and cellulose. | Krebs (2019) CRO, LAUS GmbH, Germany  Study No.: 19010402G939 |
| Oxidising solids | The study does not need to be conducted because the products in the biocidal product family are liquids. | | | |
| Organic peroxides | The study does not need to be conducted because there are no organic peroxides present in the biocidal product family. | | | |
| Corrosive to metals | UN Test C.1 | HK0016 | The corrosion tests were performed at 55°C for 20 days.  Uniform corrosion  (Half-dipped)  Mass loss:  Steel 9%, 5%, 19%  Aluminium 1%, 5%, 2%  (Fully immersed)  Mass loss:  Steel 16%, 4%, 22%  Aluminium 0.5%, 2%, 3%  The mass loss for both metals were below the classification criteria.  Localised corrosion  Steel  Pitting was observed on some specimens. The max intrusion depth was determined to 692 μm.  Aluminium  Shallow pitting was observed on some of the specimens that were half-dipped and fully immersed.    The product HK0016 was found to be non-corrosive to aluminium for both uniform and localised corrosion. The product HK0016 was found to be corrosive to steel for localised corrosion. The maximum intrusion depth for steel is 692 μm which corresponds to a localised corrosion that exceeds 6.25 mm/year.  The Nopa Nordic BPF will be classified as Met. Corr. 1 – H290: May be corrosive to metals. | Berchter, 2019  Report no.  19-07913 |
| Auto-ignition temperatures of products (liquids and gases) | Test waived based on the flash point result.  The auto-ignition temperature is defined as the lowest temperature at which a gas or vapor of a liquid will spontaneously ignite without an ignition source.  Since the flash point could not be determined up to the boiling point of HK0016, the Nopa Nordic BPF is not considered to have flammability property at ambient temperature. | | | |
| Relative self-ignition temperature for solids | The study does not need to be conducted because the products in the biocidal product family are liquids. | | | |
| Dust explosion hazard | The study does not need to be conducted because the products in the biocidal product family are liquids. | | | |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| HK0016 is considered to be representative for the whole family when testing for individual endpoints concerning physical hazards. The difference in the composition between the two metaSPCs is that metaSPC 2 contains an additional stabilizer. Due to the presence of the stabilizer and its influence on alkalinity/pH, metaSPC 2 is considered worst case.  HK0016 is found to be corrosive to steel for localised corrosion. The maximum intrusion depth for steel is 692 μm which corresponds to a localised corrosion that exceeds  6.25 mm/year.  The Nopa Nordic biocidal product family will be classified as Met. Corr. 1 – H290: May be corrosive to metals.  The biocidal product family is not classified for other physical hazards. |

### Methods for detection and identification

The validated analytical methods for the determination of the active substance and chlorate content, are given below. The methods were validated for both metaSPCs.

The content of active substance expressed as available chlorine is determined by iodometric titration. The principle of iodometric titration involves formation of triiodide in the reaction between sodium hypochlorite and potassium iodide under acidic conditions, followed by titration of the liberated triiodide with sodium thiosulfate and using starch as an indicator. The content of chlorate is determined by ion chromatography.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte** | **Analytical method** | **Fortification range / Number of measure-ments** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Precision** | **Limit of quantifica-tion (LOQ)** | **Reference** |
| **Range** | **Mean** | **RSD** |
| *MetaSPC 1* | | | | | | | | | | |
| Active chlorine released from sodium hypochlorite(expressed as available chlorine) | Iodometric titration | Calibration range (7 conc, duplicate determination)  0.96 – 3.0 g/L | Slope 1.80355  Intercept-0.04951  R2 = 0.9999 | Interferences < 3 %  No formation of triiodide detected in the formulation blank or standard solution of chlorate. | Recovery was not determined due to lack of reliable reference material. | | | n = 5  Sample concentration 100 g product/L (approx. 2.4 g active Cl/L)  Mean active substance expressed as available chlorine: 2.661% (w/w)  RSD = 0.24%  Horwitz RSDr 2.31% | 0.96 g/L  (the lowest validated fortification level) | Heib (2019a), LAUS GmbH,  Study no.: 19010401G926 |
| Chlorate (relevant impurity) | Ion chromato-graphy (IC) | Calibration range (7 conc, duplicate determination)  2 - 30 mg/L | Slope 0.15012  Intercept -0.11771  R2 = 0.9991 | Interferences < 3 %  No signal at the retention time of chlorate was detected in the formulation  blank. | 95.7 – 117.9 | 106.1 | 10.1 | n = 5 (duplicate determination)  Sample conc. 10 g product/L  Mean content: 0.0715% (7.2 mg/L)  RSD = 2.60 %  Horwitz RSDr 3.99% | 2 mg/L  (the lowest validated fortification level) | Heib (2019a), LAUS GmbH,  Study no.: 19010401G926 |
| Fortification levels of formulation blank (n = 2, duplicate determination):  2 mg/L and 20 mg/L | | |
| *MetaSPC 2* | | | | | | | | | | |
| Active chlorine released from sodium hypochlorite(expressed as available chlorine) | Iodometric titration | Calibration range (7 conc, duplicate determination)  0.96 – 3.0 g/L | Slope 1.77274  Intercept 0.19921  R2 = 0.9960 | Interferences < 3 %  No formation of triiodide detected in the formulation blank or standard solution of chlorate. | Recovery was not determined due to lack of reliable reference material. | | | n = 5  Sample conc. 100 g product/L (approx. 2.4 g active Cl/L)Mean active substance expressed as available chlorine: 2.695% (w/w)  RSD = 0.12%  Horwitz RSDr 2.31% | 0.40 g/L  (the lowest validated fortification level) | Heib (2019b)  Study no.: 19010402G926 |
| Chlorate (relevant impurity) | Ion chromate-graphy (IC) | Calibration range (5 conc, duplicate determination)  1 - 20 mg/L | Slope 0.13332  Intercept -0.01663  R2 = 0.9998 | Interferences < 3 %  No signal at the retention time of chlorate was detected in the formulation  blank. | 97.9 – 115.6 | 102.4 | 6.23 | n = 5 (duplicate determination)  Sample conc. 10 g product/L  Mean content: 0.0722% (7.2 mg/L)  RSD = 3.34 %  Horwitz RSDr 3.98% | 1 mg/L  (the lowest validated fortification level) | Heib (2019b)  Study no.: 19010402G926 |
| Fortification levels of formulation blank (n = 2, duplicate determination):  2 mg/L and 20 mg/L | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for soil** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Residue definition: HClO/ClO-  Not required. For the intended use, soil is not the first receiving compartment. Active chlorine (HClO/ClO-) can reach the soil compartment only indirectly, via sewage sludge where rapid degradation with organic matter therein is expected.  (Reference: CAR Active chlorine released from sodium hypochlorite; January 2017) | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for air** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Residue definition: Cl2/HClO/ClO-  Hypochlorite is a non-volatile species. Hypochlorous acid is volatile, but since Henry’s Law constant is low (0.1 Pa m3 mol-1) volatilization from the aqueous phase is expected to be slow. Furthermore, there are indications that the half-life in air is only a few hours, therefore, occurrence in air is not probable. Exposure to gaseous chlorine is not expected and can only happen through accidental events (chlorine can be formed and released when the active chlorine equilibrium is shifted to low pH 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 for the monitoring of chlorine in workplace air are available in the CAR.  (Reference: CAR Active chlorine released from sodium hypochlorite; January 2017) | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for water** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Analytical method for residues in drinking water  Residue definition: HClO/ClO- and relevant metabolite chlorate ClO3-  An analytical method according to EN ISO 7393-2:2000 was evalutated in the CAR and considered acceptable for the determination of active chlorine in water down to 30 µg/L.  Analytical method for residues in surface water  Residue definition: HClO/ClO-  Not required due to rapid degradation with organic matter in the STP and in surface water.  (Reference: CAR Active chlorine released from sodium hypochlorite; January 2017 (updated November 2018)) | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for animal and human body fluids and tisues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Residue definition: HClO/ClO-  Not required. Hypochlorous acid/ hypochlorite anion are oxidizing agents and degrade rapidly with organic matter.  (Reference: CAR Active chlorine released from sodium hypochlorite; January 2017) | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Residue definition: HClO/ClO-  Not required for PT2.  (Reference: CAR Active chlorine released from sodium hypochlorite; January 2017) | | | | | | | | | |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The content of the active substance in the product was determined by iodometric titration. For both metaSPCs, the titration method was validated for the parameters specificity, linearity and precision. Accuracy and recovery were not determined. Because of the instability of the active substance, there is no reliable reference material with an exact analyte content available for accuracy and recovery determinations. This is considered acceptable since the analytical method is based on a stoichiometric reaction. The method can be considered suitable and applicable for the determination of the active substance in Nopa Nordic BPF.  The relevant impurity chlorate was analysed by ion chromatography (IC). The method was validated for the parameters specificity, linearity, accuracy and precision. The method can be considered suitable and applicable for the determination of chlorate in Nopa Nordic BPF.  Analytical methods for the detection of the active substance and its residues were referred to the ones that are available in the active substance dossier (January 2017). |

### Efficacy against target organisms

#### Function and field of use

The products within the biocidal product family are intended to be used for disinfection of non-porous surfaces in bathrooms. The product are intended for private use only. The products exhibit bactericidal, yeasticidal and fungicidal properties within product-type 2.

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

The primary object to protect is bathroom surfaces from bacteria, fungi and yeast. Secondary humans are protected from bacteria, fungi and yeast due to the use of the product.

#### Effects on target organisms, including unacceptable suffering

Inhibition of enzyme activity essential for growth of the cell. Damage to the membrane of the cell.

#### Mode of action, including time delay

Exerting oxidizing action on the outside of the cell mebrane.

#### Efficacy data

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects\*** | **Reference** |
| Basic requirement for label claim of bactericidal effect of pouring (PT2) | PT02 | HK0016 | *Staphylococcus aureus,*  *Enterococcus hirae,*  *Pseudomonas aeruginosa,*  *Escherichia coli* | Quantitative suspension test.  Bactericidal activity (phase 2, step 1), Study according to EN 1276  *Dirty* conditions | EN 1276/  5%, 10% and 16,7% product / **5min** | Log reduction>5 at ≥10% (v/v) dilution | Brill, Test report no L18/0578.1 |
| Basic requirement for label claim of bactericidal effect of pouring (PT2) | PT02 | HK0016 | *Staphylococcus aureus,*  *Enterococcus hirae,*  *Pseudomonas aeruginosa,*  *Escherichia coli* | Quantitative non-porous surface test.  Bactericidal activity (phase 2, step 2), Study according to  EN 13697  *Dirty* conditions | EN 13697/  5%, 10%, 16,7%, 20%, 25%, 33,33% and 40% product/  **5-15 min** | Log reduction>4 at > 16,7% (v/v)  Dilution at min. 15 min. | Brill, Test report no L18/0578.2  Brill, Test report no L18/0578.3 |
| Basic requirement for label claim of yeasticidal and fungicidal effect of pouring (PT2) | PT02 | HK0016 | *Candida albicans*  *Aspergillus brasiliensis* | Quantitative Suspension test Yeasticidal and fungicidal activity  (phase 2 step 1), Study according to  EN 1650  *Dirty* conditions | EN 1650/  5%, 10%, and 16,7% product/  **15 min** | Yeast:  Log reduction>4 at > 5% (v/v)  Dilution at min. 15 min.  Fungi:  Log reduction>3 at > 5% (v/v)  Dilution at min. 15 min. | Brill, Test report no L18/0578.2 |
| Basic requirement for label claim of yeasticidal and fungicidal effect of pouring (PT2) | PT02 | HK0016 | *Candida albicans*  *Aspergillus brasiliensis* | Quantitative non-porous surface test.  Yeasticidal and fungicidal l activity (phase 2, step 2), Study according to  EN 13697  *Dirty* conditions | EN 13697/  5%, 10%, 16,7%, product/  **15 min** | Log reduction>3 at > 5% (v/v)  Dilution at min. 15 min. | Brill, Test report no L18/0578.3 |
| Basic requirement for label claim of bactericidal effect of pouring (PT2) | PT02 | HK0016 | *Staphylococcus aureus,*  *Enterococcus hirae,*  *Pseudomonas aeruginosa,*  *Escherichia coli* | Quantitative suspension test.  Bactericidal activity (phase 2, step 1), Study according to EN 1276  *Clean* conditions | EN 1276/  10%, 16,7% and 20% product / **5min** | Log reduction>5 at ≥10% (v/v) dilution | Brill, Test report no L18/0578.5 |
| Basic requirement for label claim of yeasticidal and fungicidal effect of pouring (PT2) | PT02 | HK0016 | *Candida albicans*  *Aspergillus brasiliensis* | Quantitative Suspension test Yeasticidal and fungicidal activity  (phase 2 step 1), Study according to  EN 1650  *Clean* conditions | EN 1650/  10%, 16,7%, 20% product/  **5 min** | Log reduction>4 at ≥10% (v/v) dilution | Brill, Test report no L18/0578.6 |
| Basic requirement for label claim of bactericidal, yeasticidal and fungicidal effect of pouring (PT2) | PT02 | HK0016 | *Staphylococcus aureus,*  *Enterococcus hirae,*  *Pseudomonas aeruginosa,*  *Escherichia coli Candida albicans*  *Aspergillus brasiliensis* | Quantitative non-porous surface test.  Yeasticidal and fungicidal l activity (phase 2, step 2), Study according to  EN 13697  *Clean* conditions | EN 13697/  10%, 16,7%, 20% product/  **5 min** | Log reduction >4 for bacteria and >3 fungi at ≥10% (v/v) dilution | Brill, Test report no L18/0578.4 |

*\*The concentration of a.s. (active chlorine) in the tested undiluted biocidal product HK 0016 is 2.4% w/w. The 10% v/v and the 16.7% v/v dilutions that resulted in desired effects in the studies contain a.s. concentration of respectively 0.24% w/w and 0.41% w/w.*

In summary, the efficacy studies presented have been performed with HK0016. The composition between the two meta SPCs differs, i.e. HK0016 (metaSPC2) contains 5.5% of the stabiliser sodium carbonate while HK0014 and HK0017 (metaSPC1) do not. The presence of sodium carbonate in the formulation of HK0016 increase the buffer capacity of the product keeping the pH more stable and in the higher end pH-range. However, active chlorine products are known to be less effective in the higher pH-range. Therefore, the efficacy of products that contain a alkaline buffer are likely to be less effective than products that do not contain a buffer. Therefore, the efficacy tests performed on HK0016 represent a worst case and since HK0016 passed the efficacy test criteria the results can be bridged to HK0014 and HK0017 as the active chlorine content is the same for all the meta SPCs.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| According to the respective EN European standards for efficacy testing, the above tests confirm that the minimum concentration of product needed to exhibit sufficient bactericidal, yeasticidal and fungicidal activity for pouring within PT2 is 10% (1 part product + 9 parts water) at minimum 5 minutes of exposure time under clean conditions, which correspond to 0.24% active chlorine. |

#### Occurrence of resistance and resistance management

Although different species vary in their sensitivity to active chlorine, development of acquired resistance is not expected since its multiple molecular sites of attack on the surface and withinthe 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.

#### Known limitations

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. The product is not to be used with other products due to the risk of development of toxic gases.

#### Evaluation of the label claims

According to the respective EN European standards for efficacy testing, the tests confirm that the minimum concentration of product needed to exhibit sufficient bactericidal, yeasticidal and fungicidal activity for pouring within PT2 is 10% (1 part product + 9 parts water) at minimum 5 minutes of exposure time under clean conditions, which correspond to 0.24% active chlorine.

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

Not relevant

### Risk assessment for human health

The products within the biocidal product family (Nopa Nordic) containing 2.4% active chlorine released from sodium hypochlorite are intended to be used for disinfection of non-porous surfaces in the bathroom (PT 2). The products are intended to be used by non-professionals.

The human health risk assessment was conducted for the active substance active chlorine released from sodium hypochlorite listed in the Union list of approved active substances under Regulation No. 528/2012. The primary mode of action of sodium hypochlorite and thereby active chlorine is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity. The active substance does not become systemically available upon dermal contact, ingestion or inhalation. Any systemic effects seen in animal studies (at high doses) are considered to be secondary to local effects. Consequently, only a local exposure and risk assessment was performed for all relevant routes of exposure (i.e. dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

#### Assessment of effects on Human Health

A local risk assessment was performed according to Guidance on BPR: Vol III, Part B, version 2.1 2017, section 4.3. Overall testing of the product family for eye irritation, skin sensitization, respiratory sensitization and acute toxicity was not conducted as there are valid data available for all components in the mixture for classification assessments according to Regulation (EC) No 1272/2008 (CLP). Test data from a skin irritation study is however available. The conclusions of the individual effects of human health are listed in the tables below.

No synergistic effects between any of the components are expected.

***Skin corrosion and irritation***

Due to the high pH of the products indicating risk for corrosivity, an *in vitro* test for skin corrosion was performed according to OECD TG 431. The test was performed on the formulation LHK0JOKJHS002ILJ which is similar to HK0016, except that it has a very low (well below 1 %) concentration of an anti-foaming agent that HK0016 does not have. This anti-foaming agent is notified as skin irrit 2, but as it is present in a concentration well below 1 % it does not trigger classification as Skin. irrit 2. Even though it does not trigger the classification the test formulation in the study can be considered more skin irritating than HK0016.

Compared to HK0014 the formulation in the skin corrosion study contains an anti-foaming agent that is notified as skin. irrit 2 in a concentration well below 1 % and a stabiliser that has no classification for skin corrosion/irritation. For all other components HK0014 and the tested formulation have the same concentrations. We consider that the test formulation would be worst case, i.e. more skin irritating than HK0014.

LHK0JOKJHS002ILJis therefore considered to be representative for the whole family regarding skin irritating potential. See confidential annex section 3.6.2.1 for details.

| **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 Epiderm skin corrosion test (EPI–200-SCT)  OECD 431 | 2.4% Sodium hypochlorite  LHK0JOKJHS002ILJ | 2 tissues per test material and neg/pos control.  Contact time, 3 and 60 minutes | Non corrosive to skin | Justification for using NaOH instead of KOH as positive control in the *study*:  NaOH and KOH are both alkali metal hydroxides of similar action with KOH being the somewhat stronger base due to its slightly easier ionization in water. However, in corrosive action on reconstructed human skin in this model they perform equally well at the same concentration (8N), and it is therefore scientifically justified to use either of the chemicals as positive control in this test. | Eurofins 2013 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The biocidal product family is classified as skin irritating. The products are not corrosive to the skin. No further tests are needed. |
| Justification for the value/conclusion | The products are classified as skin irritating 2, H315 (causes skin irritation). This is due to that the active substance is classified as skin corrosive 1B and present in the products in a concentration of 2,4 %. |
| Classification of the biocidal product family according to CLP | The products are classified as skin irritating 2, H315 |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | The biocidal product family is eye damaging. No further tests are needed. |
| Justification for the value/conclusion | The conclusion is based on the high pH (pH 12 in the concentrate) of the biocidal products. Classification has been assessed according to the rules laid down in the Regulation (EC) 1272/2008 (CLP). |
| Classification of the biocidal product family according to CLP | The products are classified as eye damaging 1, H318. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Point 8.2 of Annex III to the BPR states that the assessment of this endpoint shall be carried out according to the sequential testing strategy for eye irritation and corrosion as set down in the Appendix to Test Guideline B.5. Acute Toxicity: Eye Irritation/Corrosion (Annex B.5. to Regulation (EC) No 440/2008). |
| Justification | The study does not need to be conducted as the biocidal product family is classified as eye damaging based on the high pH (> 11.5) of the products. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Value/conclusion | The biocidal product family is not classified for respiratory tract irritation. |
| Justification for the conclusion | The conclusion is based on the fact that there is sufficient knowledge of the different components in the products to assess the respiratory effects of the products. |
| Classification of the biocidal product family according to CLP | The BPF is not classified for respiratory tract irritation. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | There are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. |
| Justification | For the products in the BPF, the conclusion is based on the information on the active substance “active chlorine released from sodium hypochlorite” and co-formulants. For the active substance, the intrinsic properties have been described in the CAR; for the co-formulants harmonised classifications have been searched for. Consequently, classification of mixtures can be made accordingly to the rules laid down in the Regulation (EC) 1272/2008 (CLP) and testing of the biocidal products are not required. |

***Skin sensitisation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | The biocidal product family is not skin sensitising. No further test is needed. |
| Justification for the value/conclusion | The conclusion is based on the fact that there is sufficient knowledge of the different components in the products in relation to skin sensitising effects and therefore no tests of the product is needed. |
| Classification of the biocidal product family according to CLP | The products are not classified for skin sensitisation. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Point 8.3 of Annex III to the BPR states that the assessment of this endpoint shall comprise the following consecutive steps:  1. an assessment of the available human, animal and alternative data  2. in vivo testing.  In addition, *in vivo testing does not need to be conducted if:*   * *the available information indicates that the substance should be classified for skin sensitisation or corrosivity, or* * *the substance is a strong acid (pH < 2,0) or base (pH > 11,5).* |
| Justification | A study does not need to be conducted as the products in the biocidal product family have a high pH (> 11.5). |

***Respiratory sensitisation (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | The biocidal product family is not respiratory sensitising. |
| Justification for the value/conclusion | The conclusion is based on sufficient knowledge of the different components in the products regarding toxicity. Currently no testing methods or test guidelines are available. |
| Classification of the biocidal product family according to CLP | The product is not classified for respiratory sensitisation. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Point 8.4 of Annex III to the BPR states the information requirements. |
| Justification | Studies on potential respiratory sensitisation properties of the biocidal product family are not required.  According to Annex III , Title 1 of the Biocidal Product Regulation (BPR) (EU) 528/2012 and chapter III, section 8.4 “ Respiratory sensitisation” of the Guidance on the Biocidal Product Regulation, Part A, Volume III, Human Health (version 1.2 May 2018), “*Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected”*.  For the biocidal product family, the composition is based on active substance “active chlorine released from sodium hypochlorite” and co-formulants. For the active substance, the intrinsic properties have been described in the CAR; for the co-formulants harmonised classifications have been searched for. Consequently, classification of mixtures can be made accordingly to the rules laid down in the Regulation (EC) 1272/2008 (CLP) and testing of the biocidal products are not required. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | The biocidal product family is not classified with acute oral toxicity. No further tests are needed. |
| Justification for the selected value | The conclusion is based on sufficient knowledge of the different components in the products regarding oral toxicity and therefore no tests are needed. |
| Classification of the biocidal product family according to CLP | The product is not classified with acute oral toxicity. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Point 8.5 of Annex III to the BPR states that:  • Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach  Testing on the product/mixture does not need to be conducted if:  • there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |
| Justification | For the products in the BPF, the conclusion is based on information on the active substance “active chlorine released from sodium hypochlorite” and co-formulants. For the active substance, the intrinsic properties have been described in the CAR; for the co-formulants harmonised classifications have been searched for. Consequently, classification of mixtures can be made accordingly to the rules laid down in the Regulation (EC) 1272/2008 (CLP) and testing of the biocidal products are not required. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | The biocidal product family is not classified with acute inhalation toxicity. No further tests are needed |
| Justification for the selected value | The conclusion is based on the fact that there is sufficient knowledge of the different components in the product and therefore no studies are needed. |
| Classification of the biocidal product family according to CLP | Not classified. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Point 8.5 of Annex III to the BPR states that:  • Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach  Testing on the product/mixture does not need to be conducted if:  • there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |
| Justification | For the products in the BPF, the conclusion is based on information on the active substance “active chlorine released from sodium hypochlorite” and co-formulants. For the active substance, the intrinsic properties have been described in the CAR; for the co-formulants harmonised classifications have been searched for. Consequently, classification of mixtures can be made accordingly to the rules laid down in the Regulation (EC) 1272/2008 (CLP) and testing of the biocidal products are not required. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | The biocidal product family is not classified with acute dermal toxicity. No further tests are needed |
| Justification for the selected value | The conclusion is based on the fact that there is sufficient knowledge of the different components in the product and therefore no studies are needed. |
| Classification of the biocidal product family according to CLP | The BPF is not classified with acute dermal toxicity. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Point 8.5 of Annex III to the BPR states that:  • Classification using the tiered approach to classification of mixtures for acute toxicity in Regulation (EC) No 1272/2008 is the default approach  Testing on the product/mixture does not need to be conducted if:  • there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |
| Justification | For the products in the BPF, the conclusion is based on information on the active substance “active chlorine released from sodium hypochlorite” and co-formulants. For the active substance, the intrinsic properties have been described in the CAR; for the co-formulants harmonised classifications have been searched for. Consequently, classification of mixtures can be made accordingly to the rules laid down in the Regulation (EC) 1272/2008 (CLP) and testing of the biocidal products are not required. |

***Information on dermal absorption***

The primary mode of action of active chlorine released from sodium hypochlorite in aqueous solutions is characterised by local irritation/corrosion and oxidation at the site of first contact triggered by direct chemical reactivity. Any systemic effects seen in animal studies are considered to be secondary to local irritation/corrosion. In the absence of clear systemic effects, it has been concluded that dermal absorption values are not deemed necessary[[2]](#footnote-3). Consequently, only a local risk assessment was performed and no values for dermal absorption are given.

***Information on endocrine disrupting properties***

Regarding the ED properties of the active substance in the products there are several relevant studies listed in the CAR for ‘active chlorine released from sodium hypochlorite’ (2017).

Based on the available experimental results, there is no indication that active chlorine released from sodium hypochlorite affects the endocrine system. Structural characteristics and SAR do not hint to possible effects of active chlorine released from sodium hypochlorite as endocrine disruptor.

*Co-formulants*

A step-wise evaluation has been made to screen the co-formulants for endocrine disruptive properties.

As there are no indications of EATS mediated adversity or other endocrine disrupting effects on fertility or development, the criteria for identification as an endocrine disruptor were not met for any of the co-formulants, for more information see conf. annex.. In conclusion, neither the active substance, nor the co-formulants are therefore regarded as endocrine disruptors.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Endocrine disruption** | |
| Value | The products in the biocidal product family are not endocrine disrupting, as no endocrine disrupting substances have been identified. |
| Justification for the selected value | The conclusion is based on current knowledge of the endocrine disruptive properties of the active substance and co-formulants. |
| Classification of the biocidal product family according to CLP | The products are not containing endocrine disruptors. |

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

Nopa Nordic BPF contains no substance of concern (SoC) for human health. See *Confidential Annex* for discussion of SoCs.

***Available toxicological data relating to a mixture***

Chlorate is a relevant impurity for active chlorine released from hypochlorite. It has been proven that chlorate is formed during degradation of chlorine species. Chlorate is identified in the Nopa Nordic products in a concentration of maximum 0.363% after 12 month and maximum 0.423% after 18 month of storage. As the concentration of chlorate compared to the amount of active chlorine in the products are above 5.4% after 12 month of storage a risk assessment of the impurity is required according to the decisions made during the active substance approval.

However, no guideline is available on how to perform a risk assessment for chlorate formed during degradation of chlorine species. During 2021 WGI-TOX risk assessment for chlorate was discussed and the conclusion was that it was not considered possible to perform the risk assessment of chlorate formation during storage at this stage due to the lack of reference values and other parameters. Due to this and the lack of guidance no risk assessment has been done for the formed chlorate.

***Other***

No other information

#### Exposure assessment

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

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

Secondary exposure of non-professional bystanders/non-users upon dermal contact with treated surfaces is considered to be non-relevant. Due to the high reactivity of chlorine species such as NaOCl, residues on surfaces degrade very rapidly. Decomposition to physiological sodium and chloride ions takes place which are not expected to arise any health risk. Furthermore, the applied in-use solutions are of a low concentration and/or are further diluted during the water-rinse procedure which normally takes place. Therefore, only inhalation exposure after application of diluted NaOCl solutions is considered to be relevant for the assessment of secondary exposure.

| **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 | No | No | Yes | No | No | Yes | No |
| Dermal | No | No | Yes | No | No | No | No |
| Oral | No | No | No | No | No | No | No |

As the AEC value used in the risk assessment is based on available chlorine (avCl), the concentration of sodium hypochlorite is converted into avCl by the following conversion factor:

MWCl2 / MWNaOCl =70.91/74.44 = 0.95[[3]](#footnote-4)

The amount of avCl present in the products are therefore calculated to be 2.28% (2.4\*0.95). The Nopa Nordic formulations must be diluted in 1+9 (10%) before use.

ConsExpo web[[4]](#footnote-5) developed by RIVM, National Institute for Public Health and the Environment was used, with values derived from the Disinfectant Products Factsheet[[5]](#footnote-6).

Since in aqueous solutions, sodium hypochlorite (NaOCl) and chlorine share the same anion (ClO─) and, thus, release the very same active substance (i.e. active chlorine, thought to consist of hypochlorite, hypochlorous acid and chlorine in equilibrium), read-across is possible for all the toxicological end-points.

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 minute fraction of volatile hypochlorous acid (HClO) is considered negligible (CAR 20174).

The concentrated products of the family have pH 12 and the 1 % solutions pH 11. The in-use dilution of HK0014 (10% solution) has pH 10,96 and HK0016 (10% solution) has pH 11,40.



***List of scenarios***

The Nopa Nordic formulations are products intended to be used for disinfection of surfaces in bathrooms. The list of scenarios for the use of Nopa Nordic products can be seen below.

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Mixing/loading | Non-professional user – Primary exposure; diluting the concentrate with water in 1+9 (10%) relation. The dilution will take place in a bucket. | Non-professionals |
|  |  |  |  |
| 2. | Application | Non-professional user – Primary exposure; application by pouring the 1+9 diluted product on surface to be disinfected | Non-professionals |
| 3. | Post-application | Non-professional user – Primary exposure; The treatment solution is poured into the drain. Empty containers are handled, stored and finally disposed of. | Non-professionals |
| 4. | Post-application | By-standers - Secondary exposure - adult/child in the same room and thereby exposed via inhalation | General public /By-standers |

***Industrial/p******rofessional exposure***

The products from the product family are to be used by the non-professional users only. Thus, an exposure assessment for industrial/professionals is not relevant.

***Non-professional exposure***

*Scenario 1 – mixing and loading*

The Nopa Nordic formulations must be diluted before use. The concentrate is diluted 1+9 to 10 % dilution.

| **Description of Scenario 1 – mixing and loading – active chlorine** | | |
| --- | --- | --- |
| The non-professional user is diluting the product before use. According to the ‘Disinfectant Product Fact Sheet’[[6]](#footnote-7) for mixing and loading the *Exposure to Vapour:* Evaporationmodel should be used for inhalation and “Direct contact - instant application” for dermal exposure.  In the scenario a non-professional user mixes and loads liquid into a bucket filled with water to produce 5 litres of a ready-for-use product. The active substance evaporates from a one-litre bottle with a not-too small circular opening with a 5-cm diameter, resulting in a surface area of 20 cm2. During mixing and loading the user stays in the vicinity of the evaporating compound and it is therefore assumed that the user is present in a ‘personal volume’ instead of a room volume.  Dermal exposure during mixing and loading of biocides for indoor use will almost always be restricted to the hands. As no systemic toxicity should be considered for active chlorine after dermal exposure a local risk assessment is performed. | | |
|  | **Parameters** | **Value** |
| **Tier 1** | Adult | 60 kg |
| Exposure duration1 | 1.33 minutes |
| Inhalation rate (default light exercise) | 22.9 l/min |
| Room volume (personal area)2 | 1 m3 |
| Ventilation rate[[7]](#footnote-8) | 0.6/hr |
| Release area3 | 20 cm2 |
| Weight fraction compound:  avCl | 2.28% |
| Molecular weight matrix4 | 76.2 g/mol |
| Product amount5 | 500 g |
| Vapour pressure sodium hypochlorite6 | 10-5 Pa |
| Mass transfer rate (Langmuir’s method) | 22.6\*105 m/hr |

1After mixing and loading the user closes the bottle; consequently, the exposure duration equals the application duration. ‘Pest Control Products Fact Sheet’ gives a default value of 1.33 minutes for both application duration and exposure duration when mixing and loading liquid in a plant sprayer. Data for mixing and loading a liquid in a bucket filled with water is not available; therefore, the above-mentioned duration of 1.33 minutes is set as default value for both exposure duration and application duration (‘Disinfectant Products Fact Sheet’).

2‘Room volume’ is interpreted here as ‘personal volume’: a small area of 1 m3 around the user. A small area around the user is relevant for the inhalation exposure of the user, for the short use duration in which the treatment takes place, as it enables the evaporation of the active substance from the concentrate to be described. Since no data

with regard to the personal volume were found, a quality factor Q = 1 is assigned (‘Disinfectant Products Fact Sheet’).

3Release area. It is assumed that evaporation takes place from a bottle with a not-too-small circular opening with a 5-cm. diameter which gives a release area of 20 cm2 (‘Disinfectant Products Fact Sheet’).

4 Molecular weight matrix. Calculated based on Mw / fraction solvents (74.4 g/mol : 0.977 = 76.2)

5This parameter is for limiting the evaporated amount of active substance from the product. It is not the used product amount but half of the bottle content. For a one-litre bottle the averaged amount liquid in the bottle is estimated at 500 g (density 1 g/cm3), which is set as default value (‘Disinfectant Products Fact Sheet’).

6At pH >11 the hypochlorite anion is the predominant species. As an ionic species, the hypochlorite anion has high water solubility and is unlikely to evaporate from the aqueous solution. Thus, it can be assumed that the hypochlorite anion has a vapour pressure significantly less than 10-5 Pa (CAR 2017)

**Calculations for Scenario 1 – mixing and loading**

For ConsExpo output files, see annex 3.2.

| **Summary table: Inhalation exposure from non-professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated air concentration**  **mg/m3 (peak conc)** | |
| Scenario 1 Mixing and loading | 1/No PPE | 3.1 × 10⁻4 | |

**Further information and considerations on scenario 1 – mixing and loading**

See Local Risk characterisation 2.2.6.3

*Scenario 2 – Application- by pouring diluted product on the surface to be disinfected*

The product is applied by pouring.The diluted solution is contained in a bucket. The products are intended for use on hard surfaces in bathrooms. It is estimated that the worst case scenario is disinfection of surfaces in a small bathroom with the in-use dilution of 1 part concentrate and 9 parts water (10%).

| **Description of Scenario 2 – application** | | |
| --- | --- | --- |
| A non-professional user is treating surfaces in a bathroom with the diluted product (1+9). According to the ‘Disinfectant Products Fact Sheet’[[8]](#footnote-9) the *Exposure to Vapour: Evaporation model* should be used for the exposure to the active substance. Dermal exposure is not relevant for the active substance.  As a worst case it is estimated that the application occurs in a small bathroom (10 m3). According to the applicant’s estimation, a surface area of 5 m2 is disinfected. | | |
|  | Parameters1 | Value |
| Tier 1 | Adult | 60 kg |
| Exposure duration1 | 60 minutes |
| Inhalation rate (default light exercise) | 22.9 l/min |
|  | Room volume (bathroom)2 | 10 m3 |
| Ventilation rate[[9]](#footnote-10) | 0.6/hr |
| Surface area3 | 5 m2 |
| Weight fraction compound:  avCl (diluted 1+9) | 0.228% |
| Molecular weight matrix4 | 76.2 g/mol |
| Product amount5 | 104.823 g |
| Vapour pressure sodium hypochlorite6 | 10-5 Pa |
| Mass transfer rate (Langmuir’s method) | 22.6\*105 m/hr |
| Application time7 | 5.3 min |

IAs a worst-case it is assumed that the private user stays in the room for other tasks for 60 min after application.

2Room volume is set to a small bathroom as worst case (10 m3) according to RIVM ‘general factsheet’.

3Surface area of a bathroom is not given in the General factsheet from RIVM (RIVM report 0900013003). 5 m2 (surface area estimated by applicant) is used as a worst case estimation, which is considered to be conservative.

4 Molecular weight matrix. Calculated based on Mw / fraction solvents (74.4 g/mol : 0.977 = 76.2)

5 Calculated from the application rate x surface area, 19 ml/m2 x density of 1.1034 g/cm3 x 5 m2. Due to the higher density a smaller volume of META 2 has been used. The concentration of avCL is the same in the application solutions in both META.

6At pH >11 the hypochlorite anion is the predominant species. As an ionic species, the hypochlorite anion has high water solubility and is unlikely to evaporate from the aqueous solution. Thus, it can be assumed that the hypochlorite anion has a vapour pressure significantly less than 10-5 Pa (CAR 2017)

7 According to Weerdesteijn et al.[[10]](#footnote-11), the averaged cleaning duration for an area of 60 x 60 cm is 22.3 sec. (SD 25.9; N=10) with a 75th percentile of 16.5 sec. The averaged cleaning duration is extrapolated for the surface area of 5 m2 i.e. 5.3 min

**Calculations for Scenario 2 - application**

For ConsExpo output files, see annex 3.2.

| **Summary table: Inhalation exposure from non-professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated air concentration**  **mg/m3 (peak conc.)** |
| Scenario 2 Application | 1/No PPE | 6.7 × 10⁻7 |

**Further information and considerations on scenario 2 – application**

See Local Risk characterisation 2.2.6.3.

*Scenario 34 - Post-application- cloths are rinsed and the treatment solution is poured into the drain. Empty containers are handled, stored and finally disposed of.*

| **Description of Scenario 3** |
| --- |
| The post-application phase comprises of different tasks.  Following application the treatment solution is poured into the drain. Although the in-use concentrations are low and the product is further diluted with water, dermal and inhalation exposure can occur. However, it is estimated that the exposure will not exceed the exposure arising from the application scenarios, which is estimated to represent worst-case. Therefore, the post-application process is indirectly covered by the existing worst-case use scenarios 1 and 2.  After application of the disinfectant, the empty containers are handled, stored and finally disposed of. As only minor amounts remain in the containers, exposure to sodium hypochlorite from empty containers is negligible and thus considered not relevant. |

***Exposure to the general public***

*Scenario 4 Secondary exposure – adult/child in the same room and thereby exposed via inhalation*

| **Description of Scenario 4** |
| --- |
| Secondary exposure of bystanders/non-users upon dermal contact with treated surfaces is considered to be non-relevant. Due to the high reactivity of chlorine species such as NaOCl, residues on surfaces degrade very rapidly. Decomposition to physiological sodium and chloride ions takes place which are not expected to arise any health risk. Hence, residue formation and chronic secondary exposure is assumed to be negligible for aqueous solutions of NaOCl.  Therefore, only inhalation exposure after application of NaOCl solutions is considered to be relevant for the assessment of secondary exposure. As the primary user is present in the room during and after application, the risk of the secondary exposure is considered to be covered by the risk assessment for inhalational exposure performed for the primary user in scenario 1 and 2. And will cover for exposure of both children and adults. |

***Monitoring data***

No monitoring data available

***Dietary exposure***

By definition PT2 biocidal products are for application on surfaces that are not used for direct contact with food or feeding stuffs. Thus no dietary exposure is foreseen.

*Information of non-biocidal use of the active substance*

The biocidal products are also used in other household areas. See table below.

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s)** |
| 1. | Household products | Cleaning of surfaces | None identified |
| 2. | Household products | Bleaching of fabrics | None identified |

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

There will be no livestock exposure for PT2 products.

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

Not relevant

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

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

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

No data

***Aggregated exposure***

Not applicable

***Combined scenarios***

Not applicable as systemic uptake is not relevant for active chlorine.

***Summary of exposure assessment***

Not applicable as systemic uptake is not relevant for active chlorine.

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

As NaOCl does not become systemically available upon dermal contact, ingestion or inhalation, only the risk of local effects were evaluated. AEC for local effects is listed in the table below. The values are expressed for avCl and are derived from the CAR for ‘active chlorine released from sodium hypochlorite’ (CAR 2017).

**Reference values to be used in the Risk Characterisation for local effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEC** | **AF** | **Correction for oral absorption** | **Value** |
| AEC dermal | Data on human skin | 1% | - | - | 1% avCl |
| AEC inhalation | Data on humans and rhesus monkeys | 1.5 mg/m3 | 3.21 | - | 0.5 mg/m3 |
| NOAEC oral | Data on rats and mice | 0.1 % avCL | - | - | 0.1 % avCl |

1 Inter-species AF: 1, intra-species toxicodynamics AF: 3.2, AF for duration: 1, AF for other uncertainties: 1.

**Maximum residue limits or equivalent**

Not applicable

**Specific reference value for groundwater**

According to the CAR for ‘active chlorine released from sodium hypoochlorite’ (CAR 2017) the reference value for groundwater is 0.1 μg/L.

***Risk for industrial/professional users***

The biocidal product is foreseen to be used by private users only. Thus, a risk characterization for industrial/professional users is not relevant.

***Risk for non-professional users***

**Systemic effects**

As active chlorine released from sodium hypochlorite does not become systemically available upon dermal contact, ingestion or inhalation, no risk assessment for systemic effects were performed for the active substance.

**Local effects**

According to the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017 section 4.3.2 a risk characterisation for local effects is triggered, when the product is classified for local effects.

The products in the Nopa Nordic family are classified as eye damaging, H318 (causes serious eye damage) due to the high pH of the products. The products are skin irritating, H315 (causes skin irritation) as they contain 2,4 % of the active substance which is classified skin corr. 1B, but with non-corrosive effects in a skin corrosion test.

As the products/formulations are classified for local effects according to the CLP regulation, a local risk assessment must be performed. The products are not classified for respiratory tract irritation, however due to the corrosive/irritant properties of sodium hypochlorite, a local risk assessment was performed using an AEC of 0.5 mg available Cl/m3 (NOAEC of 1.5 mg/m3 divided by safety factor of 3.2 for intra species variations) derived from the CAR[[11]](#footnote-12). AECs for exposure to avCl exists and these are used in the present assessment of local risks.

The local risks of dermal, eye and inhalational exposure are considered in the present assessment. Oral exposure is not included as it is not considered relevant or likely in the present uses. A quantitative risk assessment is performed, and if needed a qualitative risk assessment according to Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017 section 4.3.2.5 is performed.

The following scenarios are considered as worst case scenarios:

1. Mixing and loading (concentrate)
2. Application by pouring (diluted product)

***Local quantitative risk characterisation***

**Inhalation of avCL**

At the pH >10 the hypochlorite anion is expected to be the dominant species in the solution. As an ionic species, the hypochlorite anion has high water solubility and is unlikely to evaporate from the aqueous solution. Exposure to aerosols is not expected due to the use (i.e. pouring, and not spraying).

For the evaluation of the risk of local effects of inhalation of avCl, an AEC of 0.5 mg/m3 exists. This is compared to the level of avCl which as a worst case can be expected to be available in the air during the use of the products. The expected worst case air concentrations of avCl were calculated for application of the product during mixing and loading (scenario 1) and during pouring (scenario 2). For scenario 1, the peak air concentration of avCl was calculated to be 3.1 × 10-4 mg/m3. For scenario 2 (pouring), the peak air concentration of avCl was calculated to be 6.7 × 10⁻7 mg/m3. As these concentrations are far below the AEC of avCl of 0.5 mg/m3, the inhalational exposure to avCl is considered to be negligeable and the use is considered acceptable with regards to local effects from inhalation.

A qualitative risk assessment of the local effects by inhalation was not performed.

**Dermal exposure to avCL**

The AEC of avCl for dermal exposure is 1%. The concentration of avCl in the concentrated products are calculated to be 2.28%. As the private user may be exposed to the concentrate during mixing and loading, this concentration must be considered in the risk assessment. A concentration of 2.28% avCL constitute 228% of the AEC of 1%. A qualitative risk charaterisation must therefore be performed.

In the in-use solutions of the products dilution of 1+9 (10% solution) was considered. In this solution, the concentration of sodium hypochlorite (as avCl) is 0.23%, which is below the classification limit of local effects according to the CLP regulation[[12]](#footnote-13).

However, as an AEC exits, the in use solutions should also be compared to this. Compared to the AEC of 1% described for dermal effects of exposure to NaCIO as avCl, the avCL

concentration of 0.23% constitute 23% of the AEC. The concentration of the active substance in the diluted products is below the AEC set for dermal effects. Therefore, the risk of handling the diluted products is considered acceptable for dermal effects during application of the products.

***Local qualitative risk characterisation***

**Dermal exposure to avCl**

In the quantitative risk characterisation of dermal exposure to the concentrated product an non acceptable risk was identified. A qualitative risk assessment was therefore performed. The concentrated product was placed in hazard category *low* as it is classified skin irritating, H315 (causes skin irritation). The exposure to the concentrated product will only take place during mixing and loading as the product is to be used diluted. Dermal exposure during mixing and loading of biocides for indoor use will almost always be restricted to the hands[[13]](#footnote-14) considering this, the short duration of exposure and including the following instruction “Wash hands after mixing” the risk of dermal exposure to concentrated product is considered acceptable. The summary can be seen in the table below.

**Eye exposure to avCl**

For eye irritating effects a qualitative risk assessment was performed.

The concentrated products were placed in the hazard category *high* based on the classification as eye damaging H318 (causes serious eye damage). The products are contained in a bottle with a child proof closure (certified) and are only available in small package size (max 1.5 L). The products are labelled as eye damaging and with thourogh instructions for use minimising exposure and reducing risk. The risk of eye exposure to the concentrated Nopa Nordic formulations is considered acceptable. The summary can be seen in the table below.

The in-use dilution of HK0014 (10% solution) has pH 10,96 and HK0016 (10% solution) has pH 11,40. As the pH of the dilutions are less than 11,5 and the concentration of the active substance and co-formulants are less than 1 % the dilutions will not be classified as eye irritant. Therefore performance of a qualitative risk assessment is not relevant for the in-use solutions.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** | |
|  | | |  | | | | | | |  | |
| **Hazard cate-gory** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed** | **Tasks, uses, processes** | **Potential exposures route** | **Frequency and duration of potential exposure** | **Potential degree of exposure** | **Relevant RMM & PPE** | **Conclusion on risk** | **Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)** |
| **Concentrated product (avCL 2.28%)** | | | | | | | | | | | |
| High | Eye damage |  | 2 | Non-professionals | Mixing and loading | Hand to eye transfer  (Splashes in eyes) | Few minutes per day or less | Practically no exposure, due to short duration of the mixing step, pouring of a small volume and pouring downwards  Practically no exposure, due to relevant RMMs and instructions on label | Packaging:  Child proof closure (certified)  Small package size  Labelling:  Labelling as eye damaging  P-sentences on the label  Instructions for use:  Instructionsminimising exposure and reducing risk  "Avoid contact of the concentrate with eyes”  “Washing hands after mixing” | Acceptable | The risk is acceptable with the relevant RMM and use pattern.  (↓) Child proof closure  (↓) Small package size makes it easier handling the product without causing splashes  (↓) Labelling and RMMs to avoid contact of the product with eyes  (↓) Short duration of the mixing step, pouring downwards during mixing reduces the risk of splashes to eyes  Adherence to instructions for use may vary (↑) |
| Low | Skin irritating | A skin corrosion test was performed with non-corrosive results | 2 | Non-professionals | Mixing and loading | Skin splashes | Few minutes per day or less | Medium due to risk of skin splashes | Packaging:  Small package size  Labelling:  Labelling as skin irritating,  P-sentences on the label  Instructions for use:  instructions minimizing exposure and reducing risk  “Wash hands after mixing” | Acceptable | The risk is acceptable with the relevant RMM and use pattern.  (↓) Small package size makes it easier handling the product without causing splashes  (↓) Labelling and RMMs to avoid contact of the product with skin  (↓) Short duration of the mixing step, pouring downwards during mixing reduces the risk of splashes to skin  Adherence to instructions for use may vary (↑) |
|  | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |

**Conclusion**

It can be concluded that exposure via inhalation to the concentrated product is acceptable as the exposure is below the AEC for the avCl.

Based on the local qualitative risk characterisation it can also be concluded that although the concentrated product is classified as eye damaging and skin irritating, and a risk was identified in the dermal local quantitative risk assessment, the risk is considered acceptable as the product should be supplied in a small package with certified child proof closure and labelled according to CLP, the exposure duration is short and provided that the following risk mitigation measures are adhered to:

* Avoid contact of the concentrate with eyes
* Wash hands after mixing

Furthermore, it can be concluded that exposure via skin and inhalation to the diluted product is considered acceptable as the local quantitative risk characterisation shows that the exposures are below the relevant AECs for avCl. In addition eye exposure to diluted solution is acceptable as the in-use dilutions will not be classified for eye irritation due to pH below 11,5 and concentrations of the active substance and co-formulants below 1 %.

***Risk for the general public***

The risk of the general public is considered to be fully covered by the risk assessment performed for the non-professional user for sodium hypochlorite.

***Risk for consumers via residues in food***

Not relevant for PT2 products.

### Risk assessment for animal health

No risk to animal health is expected, due to the use of the products (disinfection of hard surfaces by pouring (PT2).

### Risk assessment for the environment

The assessment should be performed on the active chlorine released from sodium hypochlorite. Further the assessment has been based on data on intrinsic ecotoxicological properties and environmental fate available in the literature and public databases.

Sodium carbonate rapidly dissolves in water and dissociates into sodium and carbonate. Sodium and carbonate are not considered in the risk assessment because of their ubiquitous nature.

Sodium Metasilicate is the chemical substance with formula Na2SiO3, which is the main component of commercial sodium silicate solutions. It is an ionic compound consisting of sodium cations (Na+) and the polymeric metasilicate anions [–SiO2−3–]n. Sodium and metasilicate anions are not considered in the risk assessment because of their ubiquitous nature.

At the product pH of 12.6, the main constituent will be the hypochlorite anion (ClO-) and thus the evaluation of the product will only be based on this ion. The product will be diluted before disinfection to 10% (1 part product + 9 parts water, which correspond to an active chlorine concentration of 0.24% w/w). The dilution will lower the pH slightly, but the main constituent will still be the hypochlorite ion.

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

On the assessment of the active substance:

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

The use of the product Nopa Nordic BPF, when used as described in the authorised use section of this product assessment report, won’t lead to a direct release to the surface water compartment (See “Fate and distribution in exposed environmental compartments” below). Therefore, a qualitative assessment for the active substance has been performed. See section 2.2.8.3 for further details.

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

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

See section 2.2.8.3 for further details.

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

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

See section 2.2.8.3 for further details.

#### Effects assessment on the environment

**Environmental fate**

The intended use of the Nopa Nordic product family is all indoor and thus the only route for the product to reach the environment is basically via sewage treatment plants.

Data on physico-chemical properties and environmental fate of the evaluated single components of the biocidal product are summarised in the table below.

**Degradation**

**Active chlorine released from sodium hypochlorite**: Chlorine is inorganic and will not biodegrade. Hydrolysis: Hypochlorous acid (HClO) dissociates readily into hypochlorite ion (ClO-). The ratio between the two species is determined by the pH and can be calculated from the pKa (7.54) of hypochlorous acid. There are three species of chlorine in equilibrium in aqueous solution: gaseous chlorine, HOCl (also a gas at room temperature and pressure), and ClO-. Chlorine is only present at pH below 5, which is not the case here. At pH of 10.7 (the expected lowest pH), more than 99.9% of hypochlorous acid is dissociated forming the hypochlorite ion, which is readily transformed to the chloride ion.

Active chlorine is highly reactive in contact with organic material and the substance therefore has a short half-life(DT50) in the environment.

**Bioaccumulation**

No scientific studies of the bioaccumulation potential of the single components were found in the literature. Therefore the assessment of the potential for bioaccumulation and biomagnification was based on information on biodegradation and physico-chemical properties. A substance is considered to have a bioaccumulation potential if not readily biodegradable, highly lipophilic (Log Kow > 4.5) and poorly water soluble (≤ 1 mg/L) (ECHA, 2007).

In conclusion: The considered substances are neither B nor vB substances.

**Volatility/Long range transport**

The Henry´s law constant expresses the distribution of a substance between air and water phase at equilibrium. Substances that are considered to be volatile and subject to long range transport are substances with a Henry's law constant, H> 10-3 atm × m3/mole (101 Pa⋅m3/mole). If not measured, the Henry´s law constant can be estimated based on the water solubility (Sw), the vapour pressure (Psat) and the molecular weight (Mw) of the single substance applying the equation:

In conclusion: Based on the calculated Henry’s law constants, H, none of the assessed single compounds have a H > 101 Pa⋅m3/mole and are therefore not subject to long range transport.

***Data on physico-chemical and environmental fate of single components in the product.***

|  |  |
| --- | --- |
| Substance | Sodium hypochlorite (NaClO) |
| CAS | 7681-52-9 |
| Conc. (wt%) | 2.4 |
| Mw (g/mole) | 74.44 |
| Melting point (oC) | - |
| Psat (Pa) | Involatile – it is ionic |
| Sw (mg/L) | Sodium hypochlorite is completely miscible in water. |
| Log Kow | -3.42 (-0.87 hypochlorous acid)# |
| Koc (L/kg) | 13.22 |
| Ready biodegradability | Inorganic. The substance is a strong oxidizing agent and will be readily degraded in the environment by reduction- It forms chloride ions by this reaction. |
| DT50 (STP) | The substance has a low half-life in the compartments, as it will interact with other substances / components and be degraded to chloride (Cl-).  DT50 in the sewer and soil is determined to 20 s (PAR, PT2)  DT50 in the sediment is determined to 20 min (PAR, PT2) |
| DT50 (surface water) |
| DT50 (soil) |
| H (Pa∙m3/mole) | Not relevant as it is ionic - << 10-5. |
| Reference |  |

Mw: Molar mass

Sw: water solubility

Log Kow: logarithm to the octanol-water partition coefficient

Psat: vapor pressure

H: Henry’s law constant

According to the ESD on the general exposure pathways for PT2 the relevant receiving compartments are the sewer and the STP. In accordance with the conclusion of the ENV WG-I-2020 regarding the harmonisation of the assessment of the products containing chlorine based active substances, for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively.

**Environmental effects**

**Sodium Hypochlorite**

A Risk Assessment Report is available for hypochlorite (RAR, 2007). Only the data reported as valid and considered for the risk assessment is included in the table below. For supportive data please refer to the RAR (2007)[[14]](#footnote-15).

Valid short term toxicitydata are available for invertebrates with a 24h LC50 of 5 µg FAC/L (Free Available Chlorine/L). For fish, studies performed under intermittent exposure were reported. No valid NOEC values from standard long term tests with freshwater organism are reported. However, microcosm studies provided a 7d NOEC for algae of 3 µg TRC/L (Total Residue Chlorine) corresponding to 2.1 µg FAC /l.

Data for marine water organism are available formolluscs and fish showing a similar sensitivity with EC50 (48h) = 26 µg TRC/L and LC50 (96h) = 32 µg TRO/L, respectively. For long term toxicity, a 15d NOEC of 7 and a 28 d NOEC of 40 were reported for mulluscs and fish, respectively. The 21-day EC50 of 1-10 µg TRC/l reported after intermitten exposure to periphyton suggests that a chronic NOEC (derived after continuous exposure) for algae is probably lower than the reported value. For further details on the available data please refer to the RAR.

In the RAR (2007), data derived during for studies with freshwater and saltwater organisms have been pooled and three NOEC values are therefore available (fish, molluscs and algae). Applying an AF of 50 to the lowest NOEC of 3 µg TRC/l (corresponding to 2.1 µg FAC /l) a **PNECaquatic = 0.06 µg TRC/l corresponding to 0.042 µg FAC/l** is derived covering both fresh water and marine water**.**

In the assessment report on active chlorine released from sodium hypochlorite (PT2), the **PNECfresh water sediment** was calculated to be **0.045 µg FAC/kg ww (corresponding to 2.1∙10-4 mg FAC/kg dw)** on the basis of the **PNECfresh water** and a Koc of 13.22 using the equilibrium partitioning method (CAR, PT2, 2017)[[15]](#footnote-16).

The **PNECSTP** is calculated applying an AF of 10 to a NOEC of 41.1 mg available chlorine/l resulting in a **PNECSTP = 4.11 mg available chlorine/l** (PT2, 2017).

**PNECsoil** was calculated to be **0.015 µg FAC/kg ww** **(corresponding to 1.7∙10-5 mg FAC/kg dw**) on the basis of PNECaquatic and a Koc of 13.22 using the equlibrium pratitioning method (PT2, 2017).

available for algae, daphnids and fish. Algae is the most sensitive species with an EC10(*Selenastrum,* 72hr*)* of 0.11 mg/L.

As three chronic NOEC values are available, the assessment factors of 10 and 100 is considered applicable in line with the recommendations given in the ECHA Guidance document R10 (ECHA, 2008) for deriving the PNEC[[16]](#footnote-17) for fresh water and marine water. Based on the long term EC10 of 110 µg/L derived for algae, a **PNECfresh water of 0.011 mg/L** and a **PNECmarine water of 0.0011 mg/L** is thus applied in the risk assessment.

The **PNEC for sewage treatment plant micro-organisms (PNECSTP)** is **24 mg/L** applying an assessment factor of 1.

Applying the equilibrium partitioning method, the PNEC values for sediment are derived: The resulting **PNECfresh water sediment** equals to **0.083 mg/kg dw** and resulting **PNEC marine water sediment,** equals to **0.008 mg/kg dw**. The same method has been applied for deriving the PNEC for soil. The resulting **PNECsoil** equals to **0.010 mg/kg soil dw.**

***Data on ecotoxic effects applied in the Risk Assessment (NOEC: No Observed Effect Concentration; E(L)C50: Effect(Lethal) Concentration 50%). TRC: Total Residue Chlorine; TRO: Total Residue Oxidant; FAC: Free Available Chlorine; CPO: Chlorine-Produced Oxidants).***

|  | **Scientific name** | **Effect** | **Duration** | **Endpoint** | **Concentration (mg/L)** | **Reference** |
| --- | --- | --- | --- | --- | --- | --- |
| Sodium hypochlorite (NaClO) (CAS 7681-52-9) | | | | | | |
| Algae | Periphyton  Microcosm study (lab.) | Biomass | 7d | NOEC | 3 μg  TRC/l  **(2.1 μg FAC/l)** | RAR, Sodium hypochlorite, 2007 |
| Crustacean (freshwater) | *Ceriodaphnia* | Mortality | 24h | LC50 | 5  μg FAC/l | RAR, Sodium hypochlorite, 2007 |
| Fish (marine/brakish) |  | Mortality | 96h | LC50 | 32 μg TRO/l | RAR, Sodium hypochlorite, 2007 |
|  |  | Mortality | 96h | LC50 | 90 μg TRC/l | RAR, Sodium hypochlorite, 2007 |
|  |  | Fry survival | 28d | NOEC | 40 μg CPO/l | RAR, Sodium hypochlorite, 2007 |
| Molluscs (marine/brakish) | *Crassostrea virginica* | - | 48h | EC50 | 26 μg TRC/l | RAR, Sodium hypochlorite, 2007 |
|  |  | Shell deposit | 15d | NOEC (LOEC/2) | 7 μg TRO/l | RAR, Sodium hypochlorite, 2007 |
| Microorganism | *Activated sludge* | Microbial inhibition | Continuous exposure | EC50 | 3000 μg/l | RAR, Sodium hypochlorite, 2007 |

\*no information on sludge concentration and pH

In summary the following PNECs have been considered relevant for the assessment.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Summary table on calculated PNEC values (Concentrations of sodium hypochlorite are reported as mg Free Available Chlorine (FAC))*** | | | | | | |
|  | **PNECSTP** | **PNECfresh water** | **PNECmarine water** | **PNECfresh water sediment** | **PNECsoil** | **MPCGW (MPC: Maximum Permissible Concentration for ground water)** | |
| [mg /L] | [mg /L] | [mg /L] | [mg /kgdw] | [mg /kgdw] | [μg/L] | |
| Sodium hypochlorite (NaClO) | 4.11 mg available chlorine/L | 0.042\*10-3 | 0.042\*10-3 | 21\*10-3 | 1.7\*10-5 | 0.1 | |

***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***

No data were provided for the representative co-formulants.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Further ecotoxicological studies** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 9.2 “Further Ecotoxicological studies” |
| Justification | Further ecotoxicological studies of the components and/or of the biocidal product are not required.  According to Annex III, of the BPR (Regulation (EU) 528/2012) and chapter III, section 9.2 “Further Ecotoxicological studies” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), “*testing on the product/mixture or the components of the biocidal product does not need to be conducted if the data on the active substance give sufficient information and if there are not any indications of risk due to specific properties of the biocidal product.”*  The exact composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through material safety data sheets and other information for each of the individual components in the product. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal product itself is not required. |

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Effects on specific, non-target organisms** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 9.3 “Effects on any other specific, non-target organisms” |
| Justification | Studies on non-target organisms of the components and/or of the biocidal product are not required.  According to Annex III, of the BPR (Regulation (EU) 528/2012) and chapter III, section 9.2 “Effects on any other specific, non-target organisms” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), “*testing on the product/mixture or the components of the biocidal product does not need to be conducted if the data on the active substance give sufficient information and if there are not any indications of risk due to specific properties of the biocidal product.”*  The exact composition of the biocidal product is known. Sufficient data on the intrinsic properties are available through material safety data sheets and other information for each of the individual components in the product. There is no indication of risk caused by synergistic effects between any of the components or due to specific properties of the biocidal product. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal product itself is not required. |

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – supervised trial to non-target organisms in field conditions** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further studies are not required. |
| Justification | Based on intrinsic properties of individual components of the biocidal product. |

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Aceptance by ingestion by non-target organisms** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further studies are not required. |
| Justification | Based on intrinsic properties of individual components of the biocidal product. |

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

Not relevant.

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

The considered substances will enter the environment via waste water discharged off to a sewage treatment plant.

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Data on the intrinsic fate properties are available for each of the individual components in the product. |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 10.2 “Further studies on fate and behaviour in the environment” |
| Justification | Studies on environmental fate and behaviour of the components and/or of the biocidal product are not required.  According to the BPR (Regulation (EU) 528/2012) and chapter III, section 10.2 “Further studies on fate and behaviour in the environment” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), “*in principle, no further distribution and dissipation studies with the product in soil are required and information on distribution and degradation for the active substance, transformation products and substances of concern present in the biocidal product is sufficient.”*  Data on the intrinsic properties are available for each of the individual components in the product. It is not expected that the composition or the application may exert any relevant influence on effects on organisms, degradation, transformation, mobility, or adsorption properties of the active substances in a way that the outcome of the risk characterization is altered. There is no indication of synergistic effects between any of the components. Classification of the mixtures can be made according to the rules of the Regulation (EC) No 1272/2008 (CLP). |

***Leaching behaviour (ADS)***

The active ingredient is not suspected for leaching to ground water.

***Testing for distribution and dissipation in soil (ADS)***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –Distribution and dissipation in soil** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intended use, neither direct nor indirect releases to the soil will take place. Data on the intrinsic properties are available for each of the individual components in the product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 10.4 “Testing for distribution and dissipation” |
| Justification | Studies on environmental fate and behaviour of the components and/or of the biocidal product are not required.  According to the BPR (Regulation (EU) 528/2012) and chapter III, section 10.4 “Testing for distribution and dissipation” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), in principle, no further distribution and dissipation studies in soil with the product are required and information on distribution and degradation for the active substance, transformation products and substances of concern present in the biocidal product is sufficient.  No direct emission to soil will take place by the intended uses of the product, but the soil may be exposed via sludge application on agricultural soil. Data on the intrinsic properties are available for each of the individual components in the product. It is not expected that the composition or the application may exert any relevant influence nor effects on organisms, degradation, transformation, mobility, or adsorption properties of the active substance in a way that alters the outcome of the risk characterization considerably. In addition, there is no indication of synergistic effects between any of the components. |

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –distribution and dissipation in water and sediment** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 10.4 “Testing for distribution and dissipation” |
| Justification | Studies on environmental fate and behaviour of the components and/or of the biocidal product are not required.  According to the BPR (Regulation (EU) 528/2012) and chapter III, section 10.4 “Testing for distribution and dissipation” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), in principle, no further distribution and dissipation studies in air with the product are required and information on distribution and degradation for the active substance, transformation products and substances of concern present in the biocidal product is sufficient. In addition, both the active ingredient and the substance of concern are involatile and do not evaporate from water solution. |

***Testing for distribution and dissipation in air (ADS)***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –distribution and dissipation in air** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 10.4 “Testing for distribution and dissipation” |
| Justification | Studies on environmental fate and behaviour of the components and/or of the biocidal product are not required.  According to the BPR (Regulation (EU) 528/2012) and chapter III, section 10.4 “Testing for distribution and dissipation” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), in principle, no further distribution and dissipation studies in air with the product are required and information on distribution and degradation for the active substance, transformation products and substances of concern present in the biocidal product is sufficient. In addition, both the active ingredient and the substance of concern are involatile and do not evaporate from water solution. |

***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)***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Acute aquatic toxicity** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | The biocidal product will not be sprayed near to surface waters. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 10.5 “Overspray study” and section 10.6 “Data on overspray behaviour” |
| Justification | Studies on environmental fate and behaviour of the components and/or of the biocidal product are not required.  According to the BPR (Regulation (EU) 528/2012) and chapter III, section 10.5 “Overspray study” and section 10.6 “Data on overspray behaviour” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), a study may be required to assess risks to aquatic organisms or plants under field conditions if the biocidal product is to be sprayed near to surface waters.  The biocidal product will not be sprayed near to surface waters and data on overspray behaviour is not required as there is no potential for large scale formation of dust and aerosols. |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment- Chronic Aquatic toxicity** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on the intended uses and the intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 10.5 “Overspray study” and section 10.6 “Data on overspray behaviour” |
| Justification | Studies on environmental fate and behaviour of the components and/or of the biocidal product are not required.  According to the BPR (Regulation (EU) 528/2012) and chapter III, section 10.5 “Overspray study” and section 10.6 “Data on overspray behaviour” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), a study may be required to assess risks to aquatic organisms or plants under field conditions if the biocidal product is to be sprayed near to surface waters.  The biocidal product will not be sprayed near surface waters and data on overspray behaviour is not required as there is no potential for large scale formation of dust. |

**Measured aquatic bioconcentration**

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment –Aquatic bioconcentration** | |
| Value/conclusion | Further studies are not required. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the biocidal product. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Annex III of BPR, point 10.5 “Overspray study” and section 10.6 “Data on overspray behaviour” |
| Justification | Studies on environmental fate and behaviour of the components and/or of the biocidal product are not required.  According to the BPR (Regulation (EU) 528/2012) and chapter III, section 10.5 “Overspray study” and section 10.6 “Data on overspray behaviour” of the Guidance on the Biocidal Products Regulation, Part A, Volume IV, Environment (version 1.1, Nov. 2014), a study may be required to assess risks to aquatic organisms or plants under field conditions if the biocidal product is to be sprayed near to surface waters.  The biocidal product will not be sprayed near surface waters and data on overspray behaviour is not required as there is no potential for large scale formation of dust. |

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

Not relevant as the biocidal product will not be sprayed outside and as there is no potential for large scale formation of dust during the application of the biocidal product.

#### Exposure assessment

The product family is to be used by the private users only. Thus, exposure assessment for industrial/professionals is not relevant.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | Scenario 1: Surface disinfection of bathrooms (PT2) |
| ESD(s) used | Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector), March 2001[[17]](#footnote-18) |
| Approach | The approach is based on average consumption. |
| Distribution in the environment | Calculated based on TGD 2003 (excel version)  As an add-on, the degradation of the hypochlorite in the sewer system before reaching the STP has been accounted for. A very short retention time of 5 minutes have been applied in the present calculations, which is very conservative as the retention time in the sewer is typically in the range of hours. |
| Groundwater simulation | - |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1:  Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks |  |

***Emission estimation***

**Scenario [1]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario 1: Surface disinfection of bathrooms (PT2) | | | |
| Application rate of biocidal product | - | *l/m²* |  |
| Concentration of active substance in the product | 2.4 | *% (wt)* | Maximum value |
| Amount used per capita | 0.007 | l/capita/day | Default, ESD PT 2, Table 4, general purpose+lavatory |
| Fraction release to waste water | 1 | - | Default, ESD PT 2, Table 4, general purpose+lavatory |
| Penetration factor of disinfectant | 1 | - | Conservative approach, ESD PT 2, suggests 0.5. |
| Number of inhabitants feeding one STP | 10000 | - | ESD PT 2, default |

Calculations for Scenario [1]

|  |  |
| --- | --- |
| **Compartment** | Active chlorine released from sodium hypochlorite |
| Freshwater | 0 |
| Freshwater sediment | 0 |
| Seawater | 0 |
| Seawater sediment | 0 |
| Sewage | 1.68 |
| STP | 5.1E-05[[18]](#footnote-19) |
| Air | 0 |
| Soil | 0 |
| Groundwater | 0 |

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | |
| Scenario 1 | I1 | I1 | I1 | I1 | D | I | I2 | I2 | |

D: direct release to compartment

I1: indirectly receiving through water releases from STP

I2: Indirectly receiving compartment through application of sludge on soil

I3: Indirectly receiving compartment due to releases from STP

|  |  |
| --- | --- |
| Substance | Sodium hypochlorite (NaClO) |
| CAS | 7681-52-9 |
| Conc. (wt%) | 2.4 |
| Mw (g/mole) | 74.44 |
| Melting point (oC) | - |
| Sw (mg/L) | Sodium hypochlorite is completely miscible in water. |
| Log Kow | -3.42 (-0.87 hypochlorous acid) |
| Koc (L/kg) | 13.22 |
| Ready biodegradability | Inorganic. The substance is a strong oxidizing agent and will be readily degraded in the environment by reduction- It forms chloride ions by this reaction. |
| DT50 (STP) | The substance has a low half-life in the compartments, as it will interact with other substances/components and be degraded to chloride.  DT50 is the sewer and soil is measured at 20 s (PAR, PT2)  DT50 is the sediment is measured at 20 min (PAR, PT2) |
| DT50 (surface water) |
| DT50 (soil) |
| Psat (Pa) | Involatile – it is ionic |
| H (Pa∙m3/mole) | Not relevant as it is ionic |
| Reference |  |

|  |  |
| --- | --- |
| Compartment | Sodium hypochlorite (NaClO) |
| Air | <0.01 |
| Water | 0.12 |
| Sludge | <0.01 |
| Degraded in STP | 99.88 |

***Calculated PEC values (Scenario 1)***

Please note that PEC is not shown for the marine and fresh water sediments. This is considered irrelevant for the current risk assessment, as the PEC/PNEC ratio will be the same for both the water compartment and the sediment compartment.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | |
| Substance | **PECSTP** | **PECfresh water** | **PECmarine water** | **PECsoil** | **PECGW1** | **PECair** |
| [mg/l] | [mg/l] | [mg/l] | [mg/kg dw3] | [μg/l] | [mg/m3] |
| Active chlorine released from sodium hypochlorite | 3.0E-08 | 3.0E-09 | 3.0E-10 | 1.4E-11 | 2.9E-13 | 3.0E-08 |

1 No ground water modelling has been carried out.

***Primary and secondary poisoning***

Primary poisoning

Not relevant

Secondary poisoning

Secondary poisoning is not relevant, as the active substance and the other constituents in the product will not bioaccumulate and biomagnify in aquatic or terrestrial environment.

#### Risk characterisation

***Atmosphere***

**Sodium hypochlorite:** No or very limited exposure to the atmosphere will take place.

As mentioned before, air is not considered an environmental compartment of concern.

The CAR indicates that at environmental pH values (6.5-8.5) half of the active chlorine is in the un-dissociated form of hypochlorous acid and half is dissociated to the hypochlorite anion. Only the hypochlorous acid fraction is volatile. The measured Henry’s Law constant for hypochlorous acid of 0.11 Pa m³ mol-1 indicates that concentration in air is very low.

Furthermore, the CAR also indicates that as the concentration of chlorine gas in water is low at environmentally relevant pH, thus the amount of chlorine that could volatilise from water into air compartment is expected to be negligible.

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

|  |
| --- |
| **Conclusion** |
| No unacceptable risk for the atmosphere compartment is expected. |

***Sewage treatment plant (STP)***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
| Component | **PEC/PNECSTP** |
| Active chlorine released from sodium hypochlorite | <0.01 |

**Sodium hypochlorite:** The STP is not considered at risk: each scenario results in RCR(STP) well below 1. In addition, the sum of RCR(STP) for all three scenario is well below 1.

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

|  |
| --- |
| **Conclusion** |
| No unacceptable risk for the aquatic micro-organisms of the STP is expected. |

***Aquatic compartment***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
| Component | **PEC/PNECfresh water** | **PEC/PNECfresh water ediment** | **PEC/PNECmarine water** | **PEC/PNECmarine sediment** |
| Active chlorine released from sodium hypochlorite | <0.01 | Equal to PEC/PNECfresh water | <0.01 | Equal to PEC/PNECmarine water |

**Sodium hypochlorite:** The scenario results in RCRwater (and RCRseawater) well below 1, indicating that the surface water is not at risk.

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

|  |
| --- |
| **Conclusion** |
| No unacceptable risk for the organisms of the aquatic compartment is expected. |

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
| Component | **PEC/PNECsoil** | |
| Active chlorine released from sodium hypochlorite | <0.01 | |

**Sodium hypochlorite:** The scenario results in RCRsoil well below 1, indicating that the soil is not at risk.

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

|  |
| --- |
| **Conclusion** |
| No unacceptable risk for the organisms of the terrestrial compartment is expected. |

***Groundwater***

**Sodium hypochlorite:** The MPC (maximum permissible concentration, laid down by Directive 98/83/EC) is set equal to 0.1 µg/l for all considered substances. The below table shows the calculated ratio between the Predicted Environmental Concentration in ground water (PECGW) derived from the EUSES calculation,

|  |  |
| --- | --- |
| **Calculated RCRGW = PECGW(µg/l)/MPC** | |
| Component | **Scenario 1** |
| Active chlorine released from sodium hypochlorite | <<0.01 |

The RCRGW are well below 1 for the active ingredient. Thus, it is concluded that the active substance will exhibit no risk to ground water.

In addition, there are no direct releases to groundwater, and the distribution to ground water via soil due to the application of sewage sludge to agricultural soil is considered to be negligible. Under real life conditions, it is very unlikely that any hypochlorite will reach the groundwater because hypochlorite rapidly degrades in sewage sludge and soil.

**Chlorate:** Given the high water solubility of sodium chlorate it is expected to mainly distribute to the waterphase and not to sludge in the STP. Therefore, no unacceptable risks are expected for groundwater due to sludge application on soil.

|  |
| --- |
| **Conclusion** |
| No unacceptable risk for the groundwater compartment is expected. |

***Primary and secondary poisoning***

Primary poisoning

**Sodium hypochlorite & Chlorate:** Primary poisoning is not expected to occur during normal use of the product. Primary poisoning is therefore considered to be not relevant.

**Sodium hypochlorite:** The active substance, according to the CAR, reacts rapidly with organic matter in the sewer, STP and soil. For this reason, primary poisoning is not considered relevant.

Secondary poisoning

**Sodium Hypochlorite:** Active chlorine does not bioaccumulate or bioconcentrate due to its high water solubility and high reactivity. Secondary poisoning is not of concern.

**Chlorate:** Sodium chlorate is not expected to bioaccumulate. Secondary poisoning is not of concern.

|  |
| --- |
| **Conclusion** |
| No unacceptable risk of primary or secondary poisoning trough the ingestion of contaminated terrestrial or aquatic animals is expected. |

***Mixture toxicity***

The considered constituents are not expected to have the same mode-of-action and they are not likely to show synergestic effects. Therefore, mixture toxicity does not need to be considered.

***Aggregated exposure (combined for relevant emmission sources)***

There are no high concerns for cumulative environmental risks for the active substance.

Aggregated exposure to the active hypochlorite cannot be excluded, as the active ingredients will be used by industrial and professional users and may also be used in swimming pools.

However, as the hypochlorite is very rapidly degraded in the sewer, only a very minor fraction of the hypochlorite will reach the STP, from which further releases to the environment will take place. The calculated daily consumptions at which the releases to waste water in a local scenario results in an PEC/PNECwater ratio of 1 was found to be >>1000 tons/d, which is highly unlikely to be the case. Therefore, aggregated exposure to the active hypochlorite is of low concern.

|  |
| --- |
| **Conclusion** |
| No unacceptable risks for the environment are expected from the aggregated exposure. |

***Assessment of disinfection-by-products (DBPs)***

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

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The environmental risk assessment of the product family focused on the substances hypochlorite ion  All releases of the active substances to the environment will take place indirectly via a sewage treatment plant (STP).  The estimated PEC/PNEC values for the described uses of the product family of the BPF are below the trigger value of 1. The PEC/MPC value for the pore water in the upper soil layer – being a conservative estimate for the ground water – exceeds 1 slightly; however a concentration in the lower soil would be one or more orders of magnitude lower, so the MPC will not be exceeded in a soil depth of 1 m.  Thus, the use of the product family indicates no unacceptable risk for the environment.  The ingredients in the product family are not suspected of showing synergistic effects.  The aggregated exposure of active hypochlorite was considered as well, and it was found that there are no high concerns for cumulative environmental risks for the hypochlorite ion.  No unacceptable risks for the chlorates formed during storage (relevant impurity) is expected neither for the aquatic compartment, nor for the terrestrial compartment. No unacceptable risk of secondary poisoning trough the aquatic or the terrestrial food chain is to be expected. |

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

The following measures to protect man have been installed:

* The products are contained in a bottle with a child proof closure (certified), and
* The products are only available in small package size (max 1.5 L).
* The products are labelled as eye damaging, and
* Throurogh instructions for use minimizing exposure

### Assessment of a combination of biocidal products

Not applicable.

The biocidal products are not intended to be authorised for use with other biocidal products.

### Comparative assessment

Not applicable

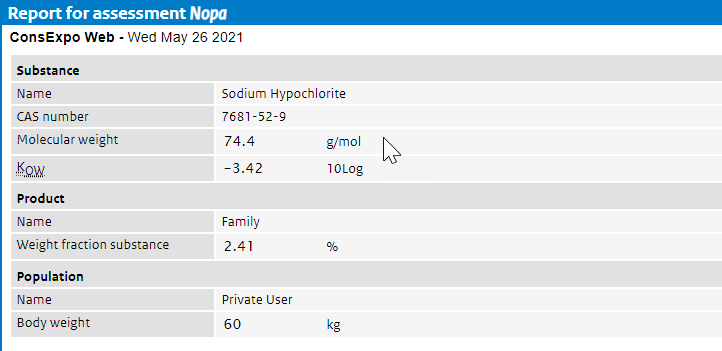
# Annexes

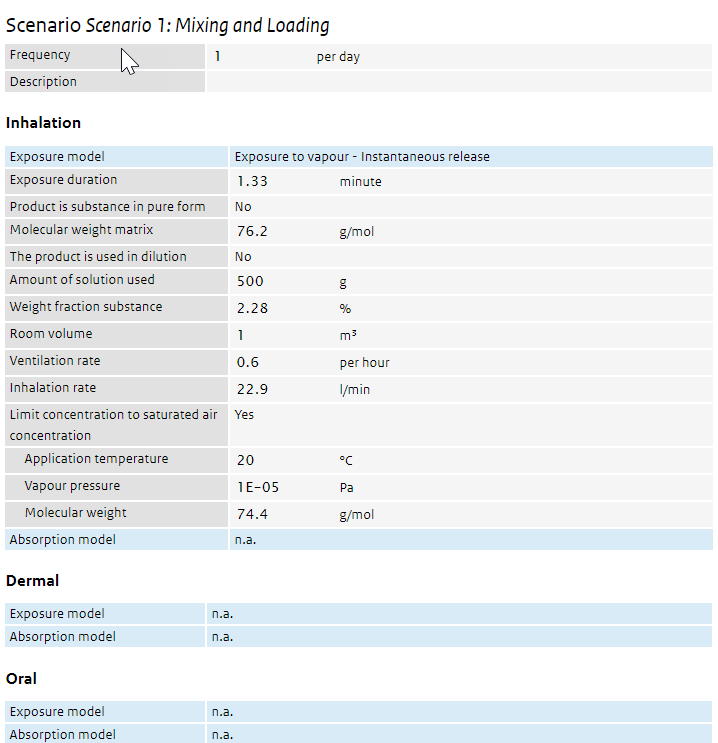
## List of studies for the biocidal product (family)

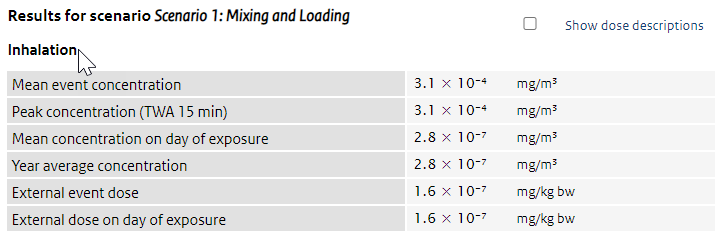
Please refer to separate IUCLID file

## Output tables from exposure assessment tools

Scenario 1 Mixing and loading







Scenario 2: Application

En bild som visar bord

Automatiskt genererad beskrivning

En bild som visar text

Automatiskt genererad beskrivning

EUSES files can be provided by request

## New information on the active substance

No new information available

## Residue behaviour

## Summaries of the efficacy studies

See IUCLUD section 6.7

## Confidential annex

Please see separate document.

## Other

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Assessment Report, Active chlorine released from sodium hypochlorite, Product-type 2

   (Disinfectants and algaecides not intended for direct application to humans or animals)

   January 2017 [↑](#footnote-ref-3)
3. Assessment Report, Active chlorine released from sodium hypochlorite Product-type 2

   (Disinfectants and algaecides not intended for direct application to humans or animals)

   January 2017, IT [↑](#footnote-ref-4)
4. <https://www.rivm.nl/en/consexpo> [↑](#footnote-ref-5)
5. Disinfectant Products Fact Sheet To assess the risks for the consumer, RIVM report 320005003/2006. <https://www.rivm.nl/sites/default/files/2018-11/Disinfectant_Products_Fact_Sheet.pdf> [↑](#footnote-ref-6)
6. Disinfectant Products Fact Sheet To asse ss the risks for the consumer, RIVM report 320005003/2006. <https://www.rivm.nl/sites/default/files/2018-11/Disinfectant_Products_Fact_Sheet.pdf> [↑](#footnote-ref-7)
7. J.D.te Biesebeek et al General fact sheet – general parameters for estimating consumer exposure, RIVM report 090013003/2014 <https://www.rivm.nl/bibliotheek/rapporten/090013003.pdf> [↑](#footnote-ref-8)
8. Prud’homme de Lodder, LCH, Bremme, HJ., et al (2006) Disinfection Products Fact Sheet. RIVM report 320005003/2006 [↑](#footnote-ref-9)
9. J.D.te Biesebeek et al General fact sheet – general parameters for estimating consumer exposure, RIVM report 090013003/2014 <https://www.rivm.nl/bibliotheek/rapporten/090013003.pdf> [↑](#footnote-ref-10)
10. Weerdesteijn, M.C.H., H.J. Bremmer, M.J. Zeilmaker and M.P. van Veen, 1999. Hygienic cleaning products used in the kitchen. Exposure and risks. Bilthoven, the Netherlands: National Institute for Public Health and the Environment (RIVM). Report 612810008 [↑](#footnote-ref-11)
11. Assessment Report, Active chlorine released from sodium hypochlorite, Product-type 2

    (Disinfectants and algaecides not intended for direct application to humans or animals)

    January 2017 [↑](#footnote-ref-12)
12. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [↑](#footnote-ref-13)
13. Disinfectant Products Fact Sheet To assess the risks for the consumer, RIVM report 320005003/2006. <https://www.rivm.nl/sites/default/files/2018-11/Disinfectant_Products_Fact_Sheet.pdf> [↑](#footnote-ref-14)
14. European Union (2007): European Union Risk Assessment Report. SODIUM HYPOCHLORITE. CAS No: 7681-52-9. EINECS No: 231-668-3. [↑](#footnote-ref-15)
15. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. Evaluation of active substances Assessment Report. Active chlorine released from sodium hypochlorite. Product-type 2(Disinfectants and algaecides not intended for direct application to humans or animals) [↑](#footnote-ref-16)
16. ECHA (2008): Guidance on information requirements and chemical safety assessment

    Chapter R.10: Characterisation of dose [concentration]-response for environment [↑](#footnote-ref-17)
17. RIVM (2001): Supplement to the methodology for risk evaluation of biocides. RIVM report 601450008 [↑](#footnote-ref-18)
18. Calculate assuming a DT50 in sewer of 20 seconds and a retention time in the sewer of 5 minutes [↑](#footnote-ref-19)