**Bijlage II**

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

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

(submitted by the eCA)



Product name: Purox® Clean

Product type: 6

Active substance: Sodium benzoate

Case Number in R4BP: xxxxx

Evaluating Competent Authority: NL

Date: 2-8-2019

\*adaptations in yellow (November 2019, in the process of Mutual Recognition in Sequence)

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# CONCLUSION

Kalaguard® SB (tradename of the product Purox Clean) is a white granular and odourless biocidal product containing sodium benzoate as active substance. The product is intended for industrial application, and the intended use of the product is in-can preservation.

The active substance sodium benzoate is included in annex I of Regulation (EU) 528/2012. As handling of the product requires personal protective equipment, the product is deemed not to be eligible for the simplified authorisation procedure of the Regulation. Instead, a national authorisation was applied for in the Netherlands according to chapter VI of the BPR, and mutual recognition in parallel in several member states of the Union.

As sodium benzoate is included in Annex I of the BPR, it is considered approved under the BPR, although no complete active substance dossier and no CAR is available. Where considered relevant, data on the active substance in accordance with the data requirements of Annex II of Regulation (EU) No. 528/2012, were submitted as part of the product application. Products containing this active substance are eligible for authorization in accordance with Art. 19, point (1)(a) of (EU) No. 528/2012, provided other conditions of Art. 19 are met.

The product contains 100 % w/w sodium benzoate (>99.99 %(w/w) pure). The pH value of a 1% solution in water is 7.21. The density of the biocidal product is 1.5 at 20 °C. The size of 98.6 % of the particles was between 0.125-2.36 mm whilst 1.4 % of the particles were smaller than 0.125 mm. It is not classified with regard to physical and chemical hazards.

A shelf life of 2 years in the proposed PE and PP bags is considered provisionally acceptable, based on accelerated study data. A real-time shelf-life study including all necessary variables for SP formulations (active substance content, pH, particle size, and the effects of stacking on the particle size as outlined in the BPR guidance) in the worst-case packaging (PE or PP bags) was not yet provided by the applicant, which results in a post-authorisation condition.

The efficacy of Kalaguard® SB as in-can preservative in detergents was successfully demonstrated against bacteria and yeasts. The substance was shown to be efficacious at concentrations ≥5g sodium benzoate per L matrix and pH ≤ 5.7.

The risk assessment for human health demonstrated no adverse effects for protected industrial users (gloves, eye protection) from exposure to sodium benzoate during automated or manual addition of the product Kalaguard® SB into the treated articles. No adverse effects are expected for the unprotected professional users from exposure to sodium benzoate due to the use of treated articles preserved with the product, during loading of liquid laundry detergents into washing machines, mopping of the surfaces using a mop and a wringer bucket, wiping of the surfaces using a wrung cloth, and cleaning of the surfaces using a hand-held trigger spray or combined exposure. Furthermore, no adverse effects are expected for general public users from exposure to sodium benzoate due to the use of treated articles preserved with the product, during the use of dishwashing liquids, laundry detergents, and cleaners or combined exposure. No adverse effects are expected for general public, including children, from exposure to sodium benzoate residues on laundered clothes and on washed dinnerware or combined exposure.

The risk assessment for the environment demonstrated an acceptable risk for all relevant environmental compartments. The PEC/PNEC values were below the trigger value, based on aggregated exposure of all relevant professional and non-professional emission scenarios for in-can preservation of dishwashing liquids, laundry liquids and cleaners.

The eCA concludes that the biocidal product fulfils the criteria of article 19(1) of Regulation (EU)528/2012 for granting an authorisation. To confirm a 2-years shelf-life of the product, real-time shelf-life data has to be provided by the applicant as soon as possible and no later than six months post-authorisation.

# ASSESSMENT REPORT

## Summary of the product assessment

## Administrative information

### Identifier of the product

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| Product name: Purox® Clean | The Netherlands Trade name: Kalaguard® SB |

### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Emerald Kalama Chemical B.V. |
| **Address** | Montrealweg 15, 3197 KH Rotterdam, The Netherlands |
| **Authorisation number** | NL-0018125-0000 |
| **Date of the authorisation** | 2 August 2019 |
| **Expiry date of the authorisation** | 1 August 2029 |

### Manufacturer of the biocidal product

|  |  |
| --- | --- |
| **Name of manufacturer** | Emerald Kalama Chemical B.V. |
| **Address of manufacturer** | Mijnweg 1, 6167 AC Geleen, The Netherlands |
| **Location of manufacturing sites** | Montrealweg 15, 3197 KH Rotterdam, The Netherlands |

### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Sodium benzoate |
| **Name of manufacturer** | Emerald Kalama Chemical B.V. |
| **Address of manufacturer** | Mijnweg 1, 6167 AC Geleen, The Netherlands |
| **Location of manufacturing sites** | Montrealweg 15, 3197 KH Rotterdam, The Netherlands |

## Product composition and formulation

The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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

Yes [ ]

No [x]

### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | Sodium benzoate |
| **IUPAC or EC name** | Sodium benzoate |
| **EC number** | 208-534-8 |
| **CAS number** | 532-32-1 |
| **Index number in Annex VI of CLP** | Not available |
| **Minimum purity / content** | 99.9% |
| **Structural formula** | sodium benzoate structure |

### Candidate(s) for substitution

Not applicable.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Sodium benzoate | Sodium benzoate | Active substance | 532-32-1 | 208-534-8 | TC100%Pure99.9% |

### Information on technical equivalence

Not applicable. The substance is included in annex I of the BPR and therefore there is no reference source or specification.

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

The product does not contain any substances of concern.

### Type of formulation

|  |
| --- |
| DP (dustable powder) |

**eCA remark**

Considering the product is a powder for direct application, the SP formulation type, originally proposed is not considered appropriate. For dossier requirement purposes, the product is assumed to be a DP (dustable powder).

## Hazard and precautionary statements

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

| **Classification** |
| --- |
| Hazard category | Eye Irrit. 2 |
| Hazard statement | Causes serious eye irritation |
|  |
| **Labelling** |
| Signal words | Warning |
| Hazard statements | H319: Causes serious eye irritation |
| Precautionary statements | P264: Wash hands thoroughly after handlingP280~~g~~: Wear eye protectionP305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsingP337+P313: If eye irritation persists: Get medical advice/attention |
| Note | **-**  |

## Authorised use(s)

### Use description

Table 1. Use # 1 – In-can preservative

|  |  |
| --- | --- |
| **Product Type** | PT 6 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Bacteria, yeasts  |
| **Field of use** | IndoorIn-can preservation of dishwashing liquids, laundry products and cleaning liquids |
| **Application method(s)** | Automated or manual dosing during production |
| **Application rate(s) and frequency** | The product is ready-to-use.*Application rate:* 5-29.5 g sodium benzoate per L matrix (corresponding to 0.42-2.5% benzoic acid). Assure that the final formulation does not exceed pH 6, since the preventive properties of the active substance against growth of microorganisms diminishes at pH above 7.The dose strongly depends on the formulation and intended use of the product to which the preservative is added. Therefore, the user should determine dosage requirements for their specific matrix/system to be preserved. The lowest effective dose should be used.Frequency: The product is added to the articles to be preserved once during their manufacture. Filling of dosage systems used to add the product to the matrix is dependent on production schedule and layout of the factory, but typically in the range of once a week/month to multiple times per day. |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | Bags 25 kg, polyethyleneBags 500 kg, 650 kg, 1000 kg, polypropylene |

### Use-specific instructions for use

|  |
| --- |
| See section 2.1.5 |

### Use-specific risk mitigation measures

|  |
| --- |
| See section 2.1.5 |

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

|  |
| --- |
| See section 2.1.5 |

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

|  |
| --- |
| See section 2.1.5 |

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

|  |
| --- |
| See section 2.1.5 |

## General directions for use

### Instructions for use

|  |
| --- |
| The product Kalaguard® SB is intended to be used as an in-can preservative (PT6) in detergents, including dishwashing liquids, liquid laundry detergent and cleaners. The product is added to the articles needed to be preserved by either automated or manual dosing, to achieve the concentration of 5-29.5 g sodium benzoate per L matrix (corresponding to 0.42-2.5% benzoic acid), in the final product.The dose strongly depends on the formulation and intended use of the product to which the preservative is added. Therefore, the user should determine dosage requirements for their specific matrix/system to be preserved. The lowest effective dose should be used.Assure that the final formulation does not exceed pH 6, since the preventive properties of the active substance against growth of microorganisms diminishes at pH above 7. The activity increases with decreasing pH and diminishes above pH 7, as the active substance is the protonated benzoic acid, and the ratio protonated/deprotonated increases at low pH.  |

### Risk mitigation measures

|  |
| --- |
| As a precaution to control dust explosion potential: eliminate ignition sources (e.g., sparks, static build-up, excessive heat, etc.), use spark-proof tools and equipment and prevent accumulation of dust (e.g., well-ventilated conditions, promptly vacuuming spills, cleaning overhead horizontal surfaces, etc.).Wash hands thoroughly after handling. Wear eye protection. Wear gloves during mixing and loading while adding Kalaguard® SB to the articles to be preserved (glove material to be specified by the authorisation holder within the product information). |

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

|  |
| --- |
| Likely direct or indirect adverse effects:• Eyes, mucosal, respiratory and gastrointestinal tract irritation.Description of first aid measures:General: If irritation or other symptoms occur or persist from any route of exposure, remove the affected individual from the area: get medical advice/attentionEye contact: Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention Ingestion: Never give anything by mouth to an unconscious person. Rinse out the mouth with water. Get medical advice/attentionEnvironmental precautions: Do not flush product into public sewer, water systems or surface waters.  |

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

|  |
| --- |
| Dispose of unused contents (incineration or landfill) in accordance with national and local regulations. Dispose of container in accordance with national and local regulations. Ensure the use of properly authorized waste management companies, where appropriate. |

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

|  |
| --- |
| Shelf-life: 2 years |

## Other information

|  |
| --- |
| - |

## 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)** |
| Bag | 25 kg | Polyethylene | n.a. | professional | Yes\* |
| Bag | 500 kg, 650 kg, 1000 kg | Polypropylene | Polypropylene straps fixed to the big bag | professional | Yes\* |
| *\* see section 2.2.2 for details on the assessment of packaging compatability* |

## Documentation

### Data submitted in relation to product application

Please refer to the reference list.

Sodium benzoate is an existing active substance included in Annex I of Regulation 528/2012/EC. As no active substance dossier on sodium benzoate has been submitted under the Review Programme, the available active substance data (Annex II of Regulation 528/2012/EC) have been submitted in the IUCLID format within the application. Thus two datasets have been included in the dossier: the product dataset according to the data requirements of Annex III of the BPR, and where relevant, data on the active substance according to the data requirements of Annex II of the BPR.

### Access to documentation

Please refer to the reference list. The data submitter is the data owner, except when indicated otherwise. For the studies for which the data submitter is not a data owner, the respective Letters of Access have been submitted with the dossier.

## Assessment of the biocidal product

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

The intended use reflects the use as originally proposed by the applicant, this can differ from the authorised use (see 2.1.4)

Table 2. Intended use # 1 – name of the use

|  |  |
| --- | --- |
| Product Type(s) | 6 |
| Where relevant, an exact description of the authorised use | The product Kalaguard® SB is intended to be used as an in-can preservative (PT6) in detergents, including dishwashing liquids, liquid laundry detergent and cleaners. The product is added to the articles needed to be preserved by either automated or manual dosing to achieve the resulting concentration of 0.25-2.5% (expressed as benzoic acid) in the final product.  |
| Target organism (including development stage) | Bacteria, yeasts, fungi |
| Field of use | In-can preservation of detergents (dishwashing liquids, laundry products, cleaners)  |
| Application method(s) | Automated or manual dosing |
| Application rate(s) and frequency | Filling of dosage systems is dependent on the production schedule and layout of the factory but typically in the range of once a week/month to multiple times per day. |
| Category(ies) of user(s) | Industrial |
| Pack sizes and packaging material | Bags 25 kg, polyethyleneBags 500 kg, 650 kg, 1000 kg, polypropylene |

## Physical, chemical and technical properties

Although the substance is included in Annex I of the Regulation (EU) 528/2012, a simplified procedure is not possible. Therefore, a full evaluation of the physical and chemical properties of the product is performed.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Not indicated | Not indicated; treated as 100% pure in the study.Batch 0950-1 | Solid (granules) | Ref no.2.2.2-01(xxxxx) |
| Colour at 20 °C and 101.3 kPa | Not indicated | Not indicated; treated as 100% pure in the study.Batch 0950-1 | White | Ref no.2.2.2-01(xxxxx) |
| Physical state at 20 °C and 101.3 kPa | EPA OPPTS 830.6303 | Sodium Benzoate, >99.9%Batch 1748-4>99.9% | Solid: granularEvaluations performed at 22 °C. | Ref no.2.2.2-02(xxxxx) |
| Colour at 20 °C and 101.3 kPa | EPA OPPTS 830.6302 | Sodium Benzoate, >99.9%Batch 1748-4>99.9% | WhiteEvaluations performed at 22 °C. | Ref no.2.2.2-02(xxxxx) |
| Odour at 20 °C and 101.3 kPa | EPA OPPTS 830.6304 | Sodium Benzoate, >99.9%Batch 1748-4>99.9% | Odourless Evaluations performed at 22 °C. | Ref no.2.2.2-02(xxxxx) |
| Acidity / alkalinity | - | - | Acidity/alkalinity is not required since the pH of a 1% aqueous solution of the biocidal product is in the range of 4-10 (pH = 7.21). Furthermore the product itself is not applied as aqueous solution. | - |
| pH | EPA OPPTS 830.7000 | Sodium Benzoate, >99.9%Batch 1748-4 | pH (25°C, 1% aqueous solution) = 7.21 | Ref no.2.2.2-02(xxxxx) |
| Relative density / bulk density | EC A3OECD 109gas comparison pycnometer | Not indicated; treated as 100% pure in the study.Batch 0950-1 | The density is 1.5 g/cm3 (1.5 x 103 kg/m3) at 20°C. The relative density (D204) is 1.5 at 20 °C. | Ref no.2.2.2-01(xxxxx) |
| Relative density / bulk density | EPA OPPTS 830.7300,ASTM E727, CIPAC MT 159 | Sodium Benzoate, >99.9%Batch 1748-4 | Bulk density: 811.6 g/L at 22 °C | Ref no.2.2.2-02(xxxxx) |
| Relative density / bulk density | Similar to OECD 109 (pour density) | Not indicated; regarded pure grade | Bulk density: 700 - 800 g/L | Ref no. 2.2.2-03(xxxxx) |
| **eCA remark**Acceptable. Considering the product is a solid, a bulk density determination should have been performed for the product. As the active substance is identical to the product, the eCA considers an additional determination not necessary. |
| Storage stability test – **accelerated storage** | OPPTS 830.6317 | Sodium Benzoate, >99.9%Batch 1748-4 | The formulation is stable when stored in HPDE containers at 54 ± 2 °C for 14 days. A.s. content(HPLC-UV, validated):Initial: 99.52%2w: 102.2%No physical changes observed (white, granular and no odour). No changes observed in the HDPE packaging. | Ref no.2.2.2-02(xxxxx) |
| Storage stability test – **accelerated storage** |  | Sodium benzoate>99.9%Batches 1828, 1829 | The formulation was stable for 14 days at 54 °C while stored in a glass jar.Content of a.s.: before storage: 100 % for both batchesafter storage: 100% for both batchespH 10% water solution: batch 1828: before and after 9.5batch 1829: before and after 9.2Colour and clarity were determined and no significant changes were observed.Particle size distribution was determined: Particle size distribution was determined: batch 1828: - before storage: the size of particles below 0.850 mm was 87.2 % and bellow 2.36 mm was 12.7 %- after storage: the size of particles below 0.850 mm was 86.5 % and bellow 2.36 mm was 13.5 %batch 1829:- before storage: the size of particles below 0.850 mm was 86.2 % and bellow 2.36 mm was 13.7 %- after storage: the size of particles below 0.850 mm was 84.8% and bellow 2.36 mm was 15.3 %. No significant changes observed after storage. | Ref no.2.2.2-04 (xxxxx) |
| Storage stability test – **long term storage at ambient temperature** | Not indicated (similar to GIFAP 17 procedure, 2009) | Sodium benzoate>99.9%Batches 1103, 1118, 1141 | The formulation is stable under laboratory conditions (21 °C and dry) for 4 years in 1L (HDPE) jar, white coloured, non-transparent.The content of a.s. (HPLC-UV, validated) determined in the three batches before and after storage is 99.99 %.Both colour and clarity of the product are not deteriorated.  | Ref no2.2.2-05(xxxxx) |
| Storage stability test – **long term storage at ambient temperature** | Not indicated, (silimar to GIFAP 17 procedure, (2009) | Sodium Benzoate, >99.9%Batch 1607 | The formulation is stable when stored in original packaging (i.e. 25 kg PE bags) under warehouse conditions (ambient temperature and dry) for approx. 18 months. The a.s content determined before and after storage is 99.99% w/w (HPLC-UV, validated).Colour and clarity of the product did not change over the period of storage. | Ref no2.2.2-06(xxxxx) |
| **eCA remark**Combining the four studies, it is expected the product is stable for 2 years in the proposed commercial packaging types. None of the studies fully address the requirements, but the composition of the product is simple, degradation does not occur and interaction with the packaging is also considered unlikely, although it was only tested during 18 months in PE bags. The other uncertainty left is the particle size distribution after real-time storage. Therefore, the eCA considers that a real-time shelf-life study should still be performed including all relevant parameters for this formulation (active substance content, pH, particle size, and the effects of stacking on the particle size as outlined in the BPR guidance) and in the worst-case packaging type (PE or PP bag). Considering the product’s simple composition, the eCA considers that a provisional authorization is acceptable. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Not relevant for solids. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **light** | - | - | Reference is made to the storage stability test. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | Humidity was not specifically addressed. The active substance / product is not prone to hydrolysis. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | Please refer to the storage stability conclusions. | - |
| Wettability | - | - | Not applicable, during use the product is not dispersed in water. | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not applicable, during use the product is not diluted in water. | - |
| Wet sieve analysis and dry sieve test | - | - | Wet sieve test: Not applicable, during use the product is not diluted with water.Dry sieve test:Refer to particle size distribution test. | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not applicable, during use the product is not diluted with water. | - |
| Disintegration time | - | - | Not applicable, during use the product is not dissolved in a solvent. | - |
| Particle size distribution, content of dust/fines, attrition, friability | Not indicatedSieve analysis followed by gravimetric determination | Not indicated  | Particle size distribution:100% < 2.36 mm85% < 0.85 mm43% < 0.43 mm8% < 0.21 mm5% < 0.18 mm1.4% < 0.125 mm | Ref no.2.2.2-07(xxxxx) |
| **eCA remark**AcceptableThe particle size of the product is rather large for a powder. The study does not address the amount of particles below 50µm. However, considering the human health assessment was based on the assumption the substance is a dusty powder, this information is not considered relevant. |
| Persistent foaming | - | - | Not applicable. During use the product is not applied with water.  | - |
| Flowability/Pourability/Dustability | - | - | Not applicable. | - |
| **eCA remark**AcceptableAlthough the eCA considers the product best represented by the product type DP (dustable powder), the product is not dusted during use, but applied to the product to be preserved directly. A dustability determination is therefore not considered necessary. |
| Burning rate — smoke generators | - | - | Not applicable, the product is not a smoke generator. | - |
| Burning completeness — smoke generators | - | - | Not applicable, the product is not a smoke generator. | - |
| Composition of smoke — smoke generators | - | - | Not applicable, the product is not a smoke generator. | - |
| Spraying pattern — aerosols | - | - | Not applicable, the product is not an aerosol. | - |
| Physical compatibility | - | - | There are no data that the product would be physically incompatible with other products.  | - |
| Chemical compatibility | - | - | There are no data that the product would be chemically incompatible with other products. | - |
| Degree of dissolution and dilution stability | - | - | Not applicable. The product is not used as a solution. | - |
| Surface tension | EC A5OECD 115OECD harmonised ring method | Not indicated; treated as 100% pure in the study.Batch 0950-1 | The surface tension of a 1 g/L aqueous solution of the product is 72.9 mN/m at 20°C. The product is therefore regarded as not surface active. | Ref no.2.2.2-01(xxxxx) |
| Viscosity | - | - | The study does not need to be conducted because the product is a solid. | - |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product is a 100% (w/w) formulation of sodium benzoate (>99.99 % (w/w) pure). At ambient conditions the product is an odourless, white solid (granules). The pH of a 1% aqueous solution of the product is 7.21 and of a 10% aqueous solution 9.2-9.5. Alkalinity/acidity determinations were therefore not relevant. The relative density (D204) of the product is 1.5 at 20°C. The size of ~98.6% of the particles was between 0.125 mm and 2.36 mm. ~1.4% of the particles were smaller than 0.125 mm. The product is not surface active. There are no data which would indicate that the product would be physically or chemically incompatible with other products.The content of the active substance in the product remained stable in all available storage stability studies. Data on the particle size distribution after real-time storage is not available and no 2 years data in PE bags is available. A provisional shelf-life is considered acceptable based on accelerated data. A real-time study, including relevant parameters for this formulation, should be provided as soon as possible, at the latest within six months post-authorisation. |

## Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | UN APP 6 | - | The product is regarded to be not explosive since the substance does not contain any group that is chemically unstable or highly energetic.(Statement) | Ref no.2.2.2-01 (xxxxx) |
| Flammable gases | - | - | Not applicable for a solid. | - |
| Flammable aerosols | - | - | Not applicable for a solid. | - |
| Oxidising gases | - | - | Not applicable for a solid. | - |
| Gases under pressure | - | - | Not applicable for a solid. | - |
| Flammable liquids | - | - | Not applicable for a solid. | - |
| Flammable solids | EC A.10UN N.1 | Not indicated; treated as 100% pureBenzoic acid, batch 0948-5  | Flammability: Not flammable.Result derived by read-across from benzoic acid. | Ref no.2.2.2-01(xxxxx) |
| Self-reactive substances and mixtures | - | - | The product does not contain alerts of specific and/or reactive groups which may have self-reactive properties. Furthermore the substance does not have explosive, oxidising or pyrophoric properties and is not an organic peroxide. Taking this into account and considering experience with the substance and its confirmed storage stability, it is very unlikely that the product is a self-reactive substance. | - |
| Pyrophoric liquids | - | - | Not applicable for a solid. | - |
| Pyrophoric solids | UN App 6 | - | From experience in use, and since the product does not contain specific structural alerts, the product is regarded to be not pyrophoric. (statement) | Ref no.2.2.2-01(xxxxx) |
| Self-heating substances and mixtures | - | - | Based on the structural formula of the active substance, the particle size of the product, and experience in use, the product is concluded to be not a self-heating substance. It will not react spontaneously with air when in larger amounts (kilograms) and after an extended period of time (hours or days). Testing for self-heating is therefore scientifically not necessary. | - |
| Substances and mixtures which in contact with water emit flammable gases | UN App 6 | - | Flammability in contact with water: From experience in use and since the product does not contain specific structural alerts, the product is regarded to be not highly flammable in contact with water. | Ref no.2.2.2-01(xxxxx) |
| Oxidising liquids | - | - | Not applicable for a solid. | - |
| Oxidising solids | UN App 6 | - | The product is regarded to be not oxidising since the substance does not contain any group that acts as an oxidizing agent. The oxygen atoms that are present are chemically bonded to carbon or hydrogen(Statement). | Ref no.2.2.2-01(xxxxx) |
| Organic peroxides | - | - | Not applicable. The substance is not an organic peroxide. | - |
| Corrosive to metals | - | - | There is no established suitable test method available for solid substances. Also, the pH of a 1% aqueous solution was determined to be 7.21 and no corrosive effect was evident on the skin. Therefore the product is not expected to be corrosive to metals, and a test with an aqueous solution has not been performed.  | - |
| **eCA remark**The substance is a (weak) base. Therefore, it can potentially be corrosive in aqueous solutions. No testing methods for corrosiveness of solids, nor information on corrosiveness of solids is available but it is not expected that the formulation would be corrosive to metals. Considering the provisions of Annex IV of the BPR, if no test method is available, a study should not be required. Considering the substance/product is also not severely classified based on the toxicological endpoints, the eCA accepts that the substance/product does not need to be classified as metal corrosive. |
| Auto-ignition temperatures of products (liquids and gases) | - | - | Not applicable for a solid. | - |
| Relative self-ignition temperature for solids | - | - | Reference is made to endpoint self-heating substances and mixtures. | - |
| Dust explosion hazard | - | - | Although the presence of dust in the product (granules) cannot be excluded, dust explosion hazard is not relevant for this product. Any dispersed dust will not ignite or explode when exposed to an ignition source. High concentrations of dust are not expected during normal use. | - |
| **eCA remark**The product is not classified as flammable or explosive by itself and the fact that sodium benzoate is a salt with a structure which is not easy to oxidise further, the risk of dust explosions is probably limited (expected to belong to Group A as described in the guidance on information requirements). The particle size of the product (<1mm) suggests however that dust explosions may occur and that explosive dust/air mixtures may be formed. Therefore, the applicant should include in their safety data sheet measures to prevent and/or limit the chance of dust explosions as no test was made available. Considering the above, the following risk mitigation measures are proposed by the applicant:*As a precaution to control dust explosion potential: eliminate ignition sources (e.g., sparks, static build-up, excessive heat, etc.), use spark-proof tools and equipment and prevent accumulation of dust (e.g., well-ventilated conditions, promptly vacuuming spills, cleaning overhead horizontal surfaces, etc.).*These measures are included in the SPC. |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is regarded to be not flammable, not explosive, not oxidizing and not flammable in contact with air or water. The product is not a self-reactive or self-heating substance. The product is not classified with regard to its physical characteristics. |

## Methods for detection and identification

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method**  | **Fortification range / Number of measurements** | **Linearity**  | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | V.C. |
| Sodium benzoate (detected as benzoic acid due to pH of the mobile phase)Batch1748-4 | HPLC-UV (a.s) | Not relevantHowever, 50:50 w/w (standard:product) spiking experiment (n = 3) resulted in the reported values (see column recovery rate) | Approx. 80.0-120.0 mg/L (80 – 120% purity)n=10R2 = 0.9981Slope0.6433 | no interference | 98.8-102 | 100 | Precision:1.23%(n=10) | Not relevant | Ref no. 2.2.3-01(xxxxx) |
| **method conditions and sample preparation:** HPLC-UV systemColumn: Luna C18(2), 250 mm x 4.6 mm i.d. Column temperature: 30 °C Injection volume: 10 μL Mobile phase: 30/70 (v/v) acetonitrile/monobasic potassium phosphate in water (pH ca. 2.4); vacuum filtered through 0.45-µm nylon Flow: 1 mL/min UV detection: 230 nmAccuracy samples: approximately 1 g of an approximately 10 g/kg sample stock solution and approximately 1 g of an approximately 10 g/kg standard stock solution were added into 100-mL volumetric flasks and dilutedto volume with deionized water. Triplicate sample stock solutions were prepared and used to prepare 3 fortified test solutions.  |

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| **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 |
| Waiver: The soil compartment is not a relevant environmental compartment for sodium benzoate in the current use (PT6).  There is no direct exposure to soil. Additionally, sodium benzoate has a low hazard (i.e. the substance is included on Annex I of BPR: low hazard profile substance) which makes an analytical method for soil matrix superfluous.  |

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| **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 |
| Waiver: The air compartment is not a relevant environmental compartment for sodium benzoate in the current use (PT6), as sodium benzoate is a solid substance with a negligible vapour pressure, and the product shall not be applied by spraying.  |

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| **Analytical methods for water** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method 1** | **Fortification range / Number of measurements** | **Linearity 2** | **Specificity 3** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Waiver:The water compartment is a relevant environmental compartment for sodium benzoate and its current use (PT6). There is indirect exposure to water via the treated product (dishwashing liquids, laundry products, cleaners). However, sodium benzoate has a low hazard which makes an analytical method for water matrix superfluous. |

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| **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 |
| Waiver: The matrices animal and human body fluids and tissues are directly exposed to sodium benzoate in its current use (PT6). However, according to ECHA BPR guidance on data requirements, an analytical method in animal and human tissues must be provided in case the substance is classified as toxic or highly toxic. Sodium benzoate is not classified as (highly) toxic. Furthermore sodium benzoate is an approved substance for use in food. This implies that exposures of animal and human tissues and body fluids are regarded to be acceptable. Based on these points of view, an analytical method for animal and human body fluids and tissues for monitoring purposes is not relevant. |

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| **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 |
| Waiver:No analytical methods for monitoring purposes in/on food of plant and animal origin or feeding stuffs is proposed for PT 6 uses although the active substance can indirectly come into contact with food of plant or animal origin, or feeding stuffs. Since sodium benzoate is an approved food additive, an analytical method for monitoring purposes is superfluous.  |

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| **Conclusion on the methods for detection and identification of the product** |
| A high performance liquid chromatographic method with spectrophotometric detection (HPLC-UV) for the quantitative analysis of sodium benzoate in the product, with acceptable validation parameters, is available. Validated parameters are precision, linearity, accuracy and limit of detection.Methods for the analysis of sodium benzoate for post-registration monitoring are deemed not to be relevant as sodium benzoate is an approved food additive.. |

## Efficacy against target organisms

### Function and field of use

Kalaguard® SB is an in-can preservative (PT6) based on 100% sodium benzoate (>99.99% (w/w) pure). The product is intended to be used for in-can preservation of detergents, such as dishwashing liquids, laundry products and cleaners. The product is intended for industrial application.

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

The product is used to prevent bacterial and yeast growth in detergents, including dishwashing liquids, laundry products and cleaners.

### Effects on target organisms, including unacceptable suffering

Kalaguard® SB decreases the number of viable bacteria and yeast. The activity increases with decreasing pH and diminishes above pH 7. The active substance sodium benzoate is also a well-known and widely used food preservative (E211) in the European Union. It is also used as a preservative in cosmetic products, as regulated by the EU Cosmetics Regulation (EC) No 1223/2009.

### Mode of action, including time delay

It is generally accepted that the protonated benzoic acid is the active antimicrobial agent. This is also the reason why the activity of sodium benzoate increases at lower pH, as the ratio of protonated (i.e. free) benzoic acid to ionized benzoic acid increases with the decrease of pH. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the benzoic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited (active substance assessment reports for benzoic acid for PT3 - <https://echa.europa.eu/documents/10162/f294be47-85b0-428f-2d71-430ef809c7d3>, and PT4 - <https://echa.europa.eu/documents/10162/40ead898-bda6-bf47-6cdc-d97911c3b54c>).

Benzoic acid is also believed to uncouple substance transport and oxidative phosphorylation from the election transport system by making the cytoplasmic membrane freely permeable to protons (Lou et al., 2007). Benzoates interfere with the utilization of acetate required for the function of energy rich compounds, which results in blockage of cell metabolism (Olutimayin et al., 2001).

### Efficacy data

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| In-can preservative | Preservation of dishwashing liquids | Sodium benzoate at 0.01, 0.025, 0.05, 0.25, 0.5, 1.0, 1.75, 2.0, 2.25 and 2.5 % in tryptic soy broth-based formulation | *E. coli* (ATCC 8739)*S. aureus* (ATCC 6538)*P. aeruginosa* (ATCC 9027)*C. albicans* (ATCC 10231)*A. brasiliensis* (ATCC 16404) | xxxxx procedure MCP 010 based on United States Pharmacopoeia (USP) 51 MethodFrequency or level of infestation / infection: single inoculation  Number of replicates: duplicates when platingTier 1 | Tryptic Soy Broth-based formulation pH 5.5 / 0 (unpreserved control) and 0.01, 0.025, 0.05, 0.25, 0.5, 1.0, 1.75, 2.0, 2.25 and 2.5 % sodium benzoate /0, 2, 7, 14 and 28 daysInitial inoculum:> 1.0x105 CFU/ml | LogR >2 (PASS) at 14 days:*E. coli*:1%*S. aureus*: 0.5%*P. aeruginosa*: 0.25%No increase at 14 days: *C. albicans*: 0.5%*A. brasiliensis*: 1%Untreated controls (0%) at 14 days:*E. coli*:increase - TNTC*S. aureus*: increase - TNTC*P. aeruginosa*: increase - TNTC*C. albicans*:increase - TNTC*A. brasiliensis*: decreaselogR >2 (PASS) at 28 days:*E. coli*:1%*S. aureus*: 0.25%*P. aeruginosa*: 0.25%No increase at 28 days: *C. albicans*: 0.5%*A. brasiliensis*: 1%Untreated controls (0%) at 28 days:*E. coli*:increase - TNTC*S. aureus*: increase - TNTC*P. aeruginosa*: increase - TNTC*C. albicans*:increase - TNTC*A. brasiliensis*: increase - TNTC | 2.2.5.5-1(xxxxx) |
| In-can preservative | Preservation of dishwashing liquids | Sodium benzoate at 0.5%, 0.65% and 1.0% in formulation | *Pool 1: Gram-negative bacteria (non-fermenters): environmental isolates**Pool 2: Gram-negative bacteria (fermenters): environmental isolates**Pool 3: Gram-positive bacteria: Staphylococcus aureus (ATCC 6538)**Pool 4: Yeast: C. alibicans (ATCC 10231)**Pool 5: Mould: A. brasiliensis (ATCC 16404)* | The study was performed by inoculating two hand dishwashing liquids containing different concentrations of sodium benzoate with five different pools of microorganisms into individual samples. Four repeat inoculations were performed in each sample with Pools 1, 2 & 3, a single inoculation was performed with Pools 4 and 5. The number of surviving microorganisms were investigated as total viable counts (TVC) at the set time points by total viable counts (2 days after each inoculation for Pools 1, 2 & 3, 2, 7, 14, 21 and 28 days post inoculations for Pools 4 & 5).  | Hand dishwashing liquid 1 (9.4% surfactant), pH 5.70-5.71 /0 (unpreserved control), 0.5%, 0.65% and 1.0% sodium benzoate/2 days after each inoculations for Pools 1, 2 & 3, 2, 7, 14, 21 and 28 days for Pools 4 and 5Initial inoculum:Bacteria: 5.0x106 CFU/mlYeast & fungi: 5.0x105 CFU/ml | Number of viable microorganisms for untreated controls, pH 5.86 (CFU/mL) 2 days after each inoculation (log reduction):Pool 1: > 30000 (<2) Pool 2: > 30000 (<2)S. aureus: < 50 (>4)Number of viable microorganisms for untreated controls, pH 5.68 (CFU/mL) at 7 and 28 days after inoculation (log reduction):C. albicans: < 100 (>3)A. brasiliensis: > 30000 (<1)Fungi and yeasts 0.5% After 7 and 28 daysLog RC. albicans: > 3A. brasiliensis: > 3Bacteria:1%2 days after each inoculationLog RPool 1: >4Pool 2: > 4S. aureus: > 4**Study is not valid** | 2.2.5.5-5(xxxxx) |
| In-can preservative | Preservation of dishwashing liquids | Sodium benzoate at 0.5%, 0.65% and 1.0% in formulation | *Pool 1: Gram-negative bacteria (non-fermenters): environmental isolates**Pool 2: Gram-negative bacteria (fermenters): environmental isolates**Pool 3: Gram-positive bacteria: Staphylococcus aureus (ATCC 6538)**Pool 4: Yeast: C. alibicans (ATCC 10231)**Pool 5: Mould: A. brasiliensis (ATCC 16404)* | The study was performed by inoculating two hand dishwashing liquids containing different concentrations of sodium benzoate with five different pools of microorganisms into individual samples. Four repeat inoculations were performed in each sample with Pools 1, 2 & 3, a single inoculation was performed with Pools 4 and 5. The number of surviving microorganisms were investigated as total viable counts (TVC) at the set time points by total viable counts (2 days after each inoculation for Pools 1, 2 & 3, 2, 7, 14, 21 and 28 days post inoculations for Pools 4 & 5).  | Hand dishwashing liquid 2 (18% surfactant), pH 5.52-5.70 / 0 (unpreserved control), 0.5%, 0.65% and 1.0% sodium benzoate / 2 days after each inoculations for Pools 1, 2 & 3, 2, 7, 14, 21 and 28 days for Pools 4 and 5Initial inoculum:Bacteria: 5.0x106 CFU/mlYeast & fungi: 5.0x105 CFU/ml | Number of viable microorganisms for untreated controls, pH 5.52 (CFU/mL) 2 days after each inoculation (log reduction):Pool 1: > 30000 (<2) Pool 2: > 30000 (<2)S. aureus: < 50 (>4)Number of viable microorganisms for untreated controls, pH 5.52 (CFU/mL) at days 7 and 28 after inoculation (log reduction):C. albicans: < 100 (>3)A. brasiliensis: > 30000 (<2) 0.5% After 7 and 28 daysLog R*C. albicans:* > 3*A. brasiliensis:* > 30.65%After 2 daysLog RPool 1: >4Pool 2: > 4*S. aureus*: > 4**Study is not valid** | 2.2.5.5-5(xxxxx) |
| In-can preservative | Preservation of non- ionic surfactant system | Sodium benzoate at 0.5% in formulation | *E. coli (ATCC 8739)**S. aureus (ATCC 6538)**P. aeruginosa (ATCC 9027)**C. albicans (ATCC 10231)**A. brasiliensis (ATCC 16404)* | xxxxx procedure MCP 010 based on United States Pharmacopoeia (USP) 51 MethodFrequency or level of infestation / infection: single inoculation  Number of replicates: duplicates when plating | Non-ionic surfactant-based formulation (see confidential annex for the details on composition), pH 5.5 / 0 (unpreserved control) and 0.5 sodium benzoate /14 (untreated controls and 0.5% sodium benzoate) and 28 days (0.5% sodium benzoate) | Number of viable microorganisms (CFU/mL) for untreated controls at day 14 after inoculation:E. coli: 1,012,200 S. aureus: 938,600P. aeruginosa: 414,180C. albicans: 416,520A. brasiliensis: 8050.5%LogRAfter 14 daysE. coli > 4S. aureus > 4P. aeruginosa > 4C. albicans > 4A. brasiliensis no passAfter 28 daysE. coli > 4S. aureus > 4P. aeruginosa > 4C. albicans > 4A. brasiliensis no pass | 2.2.5.5-6(xxxxx) |
| In-can preservative | Preservation of non-ionic surfactant system | Sodium benzoate at 0.26 (duplicate)% and 0.5% in formulation | *E. coli (ATCC 8739)**S. aureus (ATCC 6538)**P. aeruginosa (ATCC 9027)**C. albicans (ATCC 10231)**A. brasiliensis (ATCC 16404)* | xxxxx procedure MCP 010 based on United States Pharmacopoeia (USP) 51 MethodFrequency or level of infestation / infection: single inoculation 0.5%duplicate inoculation 0.26% Number of replicates: duplicate inoculation test with 0.26% sodium benzoate;duplicates when plating for both concentrations | Non-ionic surfactant-based formulation pH 5.5 / 0 (unpreserved control), 0.26 (2 tests) and 0.5 % sodium benzoate /0, 2, 7, 14 and 28 daysInitial inoculum:> 1.0x105 CFU/ml | LogR >2 (PASS) at 14 days:*E. coli*:0.5%*S. aureus*: 0.26%*P. aeruginosa*: 0.26%No increase at 14 days:*C. albicans*: 0.26%*A. brasiliensis*: 0.26%Untreated controls (0%) at 14 days:*E. coli*:increase*S. aureus*: increase*P. aeruginosa*: increase*C. albicans*: increase*A. brasiliensis*: decreaselogR >2 (PASS) at 28 days:*E. coli*: 0.5%*S. aureus*: 0.26%*P. aeruginosa*: 0.26%No increase at 28 days: *C. albicans*: 0.26%*A. brasiliensis*: 0.26%Untreated controls (0%) at 28 days:*E. coli*:increase*S. aureus*: increase*P. aeruginosa*: increase*C. albicans*: increase*A. brasiliensis*: regrowth after decrease**Note:***A. brasiliensis* is already suppressed by the non-ionic surfactant matrix itself, but inclusion of 5 g/L sodium benzoate does cause a significant additional reduction after 28 days. At 0% counts are 82.000 CFU/ml and at 0.5% it is 135 CFU/ml, which means an additional 600-fold (2.8 log) reduction due to the sodium benzoate. | 2.2.5.5-7(xxxxx) |

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| **Conclusion on the efficacy of the product by the applicant** |
| The biocidal product Kalaguard® SB is a 100% (w/w) formulation of sodium benzoate (>99.99 (w/w) pure), thus the studies conducted with sodium benzoate are applicable for the biocidal product and vice versa. The terms “biocidal product” and “sodium benzoate” are used interchangeably.In accordance with Guidance on the BPR: Volume II Parts B+C, v. 3.0 (April 2018), a tiered approach was followed to test the biocidal product. As a tier 1 (proof of principle) test the biocidal activity of sodium benzoate at different concentration levels was tested in a tryptic soy broth (Wanrooij, 2018), using a procedure based on United States Pharmacopoeia (USP) 51 Method. The formulations were inoculated with 5 microbial strains (bacterial strains *E. coli*, *S. aureus*, *P. aeruginosa*, yeast strain *C. albicans* and *A. brasiliensis*). The number of viable microorganisms was counted after 14 and 28 days contact time. Sodium benzoate at a concentration level of 1% and above was efficacious against all tested strains, resulting in a log reduction > 4 for all strains on day 28 after the inoculation. For tier 2, two hand dishwashing formulations varying in the concentration of the active detergent (surfactant) level (9.4% and 18%), preserved with sodium benzoate, were inoculated with 5 different pools of microorganisms: environmental isolates from Gram-negative non-fermenters and fermenters, *S. aureus*, *C. albicans* and *A. brasiliensis* (Jay and Ross, 2016). It should be noted that the samples containing sodium benzoate also contained 0.1% of the chelator ethylenediaminetetraacetic acid (EDTA), while no EDTA was included in the untreated controls. Antimicrobial activity of EDTA is known; however, literature sources suggest that this activity is not sufficient when EDTA is used on its own (Kabara, 1997). The exact bacterial strains in the used environmental isolates were not specified by the study authors; however, it was confirmed that these strains were commonly encountered in the dishwashing formulations of the manufacturer and therefore considered to be confidential (private communication with the study owner). For bacteria, four repeat inoculations were performed in each sample, while for yeasts and mould a single inoculation was performed. The numbers of surviving microorganisms were determined 2 days after each inoculation with bacteria, and 2, 7, 14, 21 and 28 days post-inoculation with moulds and yeasts as Total Viable Counts. All tested concentrations of sodium benzoate for the dishwashing formulation containing 18% surfactant caused an acceptable reduction in the number of viable microorganisms at 6.5 g sodium benzoate per L matrix (log 4 reduction two days after each inoculation for four consecutive inoculations for bacteria and at least log 3 reduction at 7 days with no increase thereafter up to 28 days for yeasts and moulds), while in the formulation containing 9.4% surfactant, only 10 g sodium benzoate per L matrix was sufficiently efficacious in all tested strains. In the untreated samples of both formulations, no microbiological growth could be demonstrated and no sufficient log reduction was observed in the samples inoculated with Gram-negative bacteria and mould (total viable counts > 30000 CFU/mL) and no microbial growth was observed after inoculation with Gram-positive bacteria and yeasts (< 50 and < 100 CFU/mL, respectively). **The study of Jay and Ross, 2016 is considered invalid by RMS and therefore not used for authorisation.**In the study of (Foster, 2016), performed according to the Microconsult Procedure MCP 010 based on United States Pharmacopoeia (USP) Method 51, a non-ionic surfactant formulation containing 5g sodium benzoate per L matrix was inoculated with 3 bacterial strains *E. coli*, *S. aureus*, *P. aeruginosa*, yeast strain *C. albicans* and fungi strain *A. brasiliensis*, and the numbers of viable microorganisms were determined 14 and 28 days past inoculation. The study also included an untreated control. In the samples preserved with 5g sodium benzoate per L matrix, a sufficient reduction in the total viable counts of microorganisms was demonstrated. In the untreated controls, the microbial growth at 14 days past inoculation was demonstrated in the strains *E. coli*, *S. aureus* and *P. aeruginosa*. A slight decrease in the number of viable organisms was observed in *C. albicans*, while in *A. brasiliensis* a significant decrease in the number of viable microorganisms was observed (log reduction 2.66). In the study of (Foster, 2018), performed by the same method, sodium benzoate was tested at concentrations of 2.6g and 5g per L matrix against *E. coli*, *S. aureus*, *P. aeruginosa*, *C. albicans* and *A. brasiliensis*. The study also included an untreated control. On day 14 after inoculation, sodium benzoate at 2.6 g per L matrix was sufficiently efficacious against *S. aureus* and *P. aeruginosa* (log reduction > 4) and it was efficacious against *E. coli* at 5g per L matrix. At 28 days post-inoculation, sufficient log reduction was demonstrated in all strains, except of *A. brasiliensis*. This demonstrates that sodium benzoate is already efficacious at concentration of 5g per L matrix against bacteria and yeasts. The non-ionic surfactant matrix itself already caused suppression of *A. brasiliensis* growth, but not of the other strains. However, this suppression of *A. brasiliensis* is significantly further reduced at the sodium benzoate inclusion levels of 5g per L matrix, with approximately an additional 600-fold or 2.8 log reduction compared to the untreated control.The overall composition of different types of liquid detergents is quite similar. They are usually water-based formulations and contain a surfactant as a major component, which is intended to remove soiling due to its amphiphilic properties. Further they may contain a number of additives, such as perfumes, dyes, builders to remove the hardness ions, pH controlling agents, viscosity controllers etc. Therefore efficacy results for sodium benzoate demonstrated in dishwashing liquids are considered to be applicable to other detergent matrices, such as laundry products and cleaners. The chosen strains are routinely used in the testing of cosmetic preparations and are considered to be the most relevant in the testing of formulations intended for routine use by general public. The efficacy of sodium benzoate was successfully demonstrated in the 28 days window. Considering sodium benzoate is a stable substance, which was demonstrated to remain stable for at least four years in a storage stability test, and considering the normal (i.e. indoors, room temperature, absence of direct sunlight etc.) expected storage conditions of the treated articles like dishwashing liquids, laundry products and cleaners, it can be expected with high amount of certainty that sodium benzoate shall remain efficacious during the whole shelf life of the treated articles. **Based on the outcome of the RCOM the RMS decided to remove the claim against fungi from the general conclusion and authorised use. The claims against fungi have been removed from the SPC. This has been concluded because no data demonstrating fungal growth in the control studies have been provided. In addition CFU counts are unsuitable on a fundamental level for growth evaluation of filamentous fungi like *A. brasiliensis.*** |

### Occurrence of resistance and resistance management

Many publications are available that report about resistance of micro-organisms against benzoic acid, mainly in the context of food spoilage (active substance assessment report for benzoic acid for PT3: <https://echa.europa.eu/documents/10162/f294be47-85b0-428f-2d71-430ef809c7d3>). A number of yeasts are known to be resistant to benzoates. It is suggested that the mechanism by which yeasts develop resistance to weak acidic antimicrobials, including benzoic acids, is related to membrane permeability and the ability of the cells to continuously pump antimicrobials out of the cell. Some micro-organisms on the other hand have innate resistance to benzoates because they metabolize the compounds. These bacteria and moulds degrade benzoic acid through either the ortho or the meta cleavage pathway. Few studies examine the potential for acquired resistance to benzoic acid in yeasts previously exposed to sub-inhibitory concentrations of benzoic acid. Pre-exposure to benzoic acid caused a 1.4 to 2.2 fold increase in MIC. The proposed resistance mechanism was increased cellular efflux (active substance assessment report for benzoic acid for PT3: <https://echa.europa.eu/documents/10162/f294be47-85b0-428f-2d71-430ef809c7d3>). There was neither any evidence of indicating increased resistance due to mutation nor any evidence that the resistance was stable. Further, there is little or no evidence in the literature of acquired bacterial resistance to benzoic acid.

Considering the length of time that benzoic acid has been applied to food products as a food additive it would seem, however, that the development of acquired resistance by spoilage and micro-organisms is very rare or non-existent (active substance assessment report for benzoic acid for PT3: <https://echa.europa.eu/documents/10162/f294be47-85b0-428f-2d71-430ef809c7d3>).

### Known limitations

The efficacy of Kalaguard® SB decreases at pH above 7. This is related to the fact that the ratio of protonated benzoic acid (which is considered to be the primary antimicrobial agent) to the benzoate ion decreases with the increasing pH.

### Evaluation of the label claims

The efficacy of sodium benzoate as in-can preservative in detergents was successfully demonstrated against bacteria and yeasts. The substance was shown to be efficacious at concentrations ≥5g sodium benzoate per L matrix and pH 5.5 - 5.7.

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

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

## Risk assessment for human health

### Assessment of effects on Human Health

The biocidal product Kalaguard® SB is a 100% (w/w) formulation of sodium benzoate (>99.99 (w/w) pure), thus the studies conducted with sodium benzoate are applicable for the biocidal product and vice versa. The terms “biocidal product” and “sodium benzoate” are used interchangeably.

As sodium benzoate is included in Annex I as Category 1 substance (substances authorized as food additives according to Regulation (EC) No. 1333/2008), in accordance with Art. 19, point 1a, the biocidal products containing this active substance are eligible for authorization, providing other conditions of Article 19 are met. Substances included in Annex I are considered to be approved under the Biocidal Product Regulation (EU) no. 528/2012, however, no assessment report of such substances is available. Data on the active substance in according with the data requirements of Annex II of Regulation (EU) No. 528/2012 were submitted where considered relevant.

***Skin corrosion and irritation***

No *in vitro* data are available.

|  |
| --- |
| **Summary table of animal studies on skin corrosion /irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle, Dose levels, Duration of exposure** | **Results***Average score**(24, 48, 72h)/**observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological**findings* | **Remarks** *(e.g. major deviations)* | **Reference**  |
| OECD Guideline 404, EU Method B.4, GLP, reliability 1 | Rabbit, New Zealand White, females, 3/group | Sodium benzoate, unchanged (no vehicle), 0.5 g 4 hours  | Average of 3 animals at 24, 48 and 72 hours:Erythema: 0Oedema: 0Weak erythema (score 1) was observed in 1 of the animals, which was fully reversible after 24 hours. No signs of systemic toxicity or mortality occurred.  | Observation period was 72 hours; however, in view of the absence of skin reactions this is considered acceptable.  | 2.2.6.1-1 (xxxxx) |

No human data are available.

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not irritating |
| Justification for the value/conclusion | No skin irritation was observed in a reliable guideline study with rabbits.  |
| Classification of the product according to CLP and DSD | Not classified |

NL CA remark: It was pointed out by a refMS that the negative results from animal study is not sufficient. In the RAC opinion on benzoic acid (25.11.2012) “industry representative considered Skin Irrit. 2 (H315) not to be justified because benzoic acid does not show skin irritating properties in any available animal studies according to EC or OECD guidelines.” However, RAC decided for Skin Irrit. 2, H315 based on human data. The ref MS DE considered, as the data basis is comparable to that of sodium benzoate the same classification should be the result. The refMS has considered that if read-across from benzoic acid to sodium benzoate is accepted, benzoic acid could be proposed for sodium benzoate, also considering human evidence and induction of pseudoallergic reaction of sodium benzoate.

However, NL CA has concluded H315 is not required for sodium benzoate. Sodium benzoate dissociates to benzoic acid in aqueous form, and both sodium benzoate and benzoic acid are present as benzoate anion when it is dissolved in water. It is reasonable to consider that the two substances share many common health effects and thus read-across is possible for systemic effects,. However, possible deviations from benzoic acid should be examined with care for local effects, as the exposure is to the undissolved form. The conclusion of non-classification of H315 for sodium benzoate was drawn by considering if the ground for classification of H315 for benzoic acid "Based on the positive results in human skin irritation studies and the underlying non-immunogenic irritant and inflammatory mechanism" (the CLH report, benzoic acid) is applicable for sodium benzoate.

1. Underling non-immunogenic irritant and inflammatory mechanism

According to the CLH report, “benzoic acid and its salts are capable of causing non-immune immediate contact reactions (NIICR) and non immunogenic contact urticarial (NICR), also known as peudoallergy”. NL CA follows this conclusion of the CLH report that sodium benzoate may cause NIICR and NICR, which per definition are considered irritant reactions.

2. Positive results in human skin irritation studies

For benzoic acid, there are many studies available with positive skin irritation reactions as listed in the CLH report (Table 5-9). For instance, xxxxx showed a considerable proportion of healthy volunteers reacted to benzoic acid diluted in petrolatum: 73.5% with erythema and 12.5% with oedema at 125 mM (ca 1.5% dilution), and 78.5% with erythema and 18% with oedema at 500 mM (ca. 6% dilution).

For sodium benzoate there are only two human studies presented in the CLH report: One study (xxxxx) is with dermatoses patients, and another one (xxxxx) is with urticarial patients. No study for healthy population is available. In the study by xxxxx dermatoses patients were exposed to 5% sodium benzoate diluted in petrolatum. The exposure level of 5% and solvent used are comparable to the study used by xxxxx for benzoic acid. In the study by Brasch only 0.2% of the tested patients showed skin irritation, indicates that sodium benzoate the irritant potency is much weaker than benzoic acid, if there is any. The second study by Warin showed that 11% (12/111) of patients showed positive result, after they are exposed to 50 or 500 mg sodium benzoate. However, the number of subjects is small and no healthy population was tested. Overall, the NL CA considered that these human data is not sufficient to assign H315 skin irritant for sodium benzoate.

3. The previous conclusions from authorities

The conclusion that sodium benzoate is not irritating to skin was reached by a number of authorities, including OECD SIDS (SIDS Initial Assessment Report on benzoates, 2001), WHO CICAD (2000) and Scientific Committee on Consumer Products (2005).

Based on WoE, NL CA has concluded H315 is not required for sodium benzoate, thus not for the biocidal product.

***Eye irritation***

No *in vitro* data are available.

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| **Summary table of animal studies on serious eye damage and eye irritation** |
| **Method,Guideline,** **GLP status, Reliability** | **Species,Strain,Sex,No/group** | **Test substance,Dose levels, Duration of exposure** | **Results***Average score (24, 48, 72h)/**observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference**  |
| OECD Guideline 405, EU method B.5, GLP, reliability 1 | Rabbit, New Zealand White, females, 3/group | Sodium benzoate, 60 +/- 1 mg (equivalent to 0.1 ml)/ animal, single instillation | Average of 3 animals at 24, 48 and 72 hours: Cornea: 0Iris: 0Conjunctivae: 2.47Chemosis: 0.7All effects were fully reversible within 14 days.  | Observation period was 14 days; however, considering all reactions were fully reversible within that time, this is considered acceptable.  | 2.2.6.1-2 (xxxxx) |

No human data are available.

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| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Irritating to eyes |
| Justification for the value/conclusion | Based on the observed effects on conjunctivae (average score 2.46) in the reliable guideline study with rabbits.  |
| Classification of the product according to CLP and DSD | Eye Irrit. 2, H319 |

***Respiratory tract irritation***

No data are available.

***Skin sensitization***

| **Summary table of animal studies on skin sensitisation** |
| --- |
| **Method,Guideline, GLP status, . Reliability** | **Species,Strain,Sex,No/group** | **Test substance, Vehicle,****Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)* | **Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks***(e.g. major deviations)* | **Reference**  |
| Modified LLNA Comparable to OECD guideline 429, no GLP, reliability 2 | Mouse, CBA, female, 5/group | Benzoic acid, 5%, 10% and 20% in acetone, four consecutive days, open application on both ears (total 25 µL/ear). 18 to 24 hours after last exposure animals were injected with 3H-methyl thymidine into the tail vein and after 5 hours euthanized.  | SI values: 5%: 0.810%: 0.920%: 0.8Vehicle (acetone): 1.0 | Benzoic acid was one of 17 chemicals tested in order to validate the LLNA method. The known sensitizers produced satisfactory response and can be considered as positive controls (e.g. DNCB had a SI of 21.1 at 0.1%).  | 2.2.6.1-3 (xxxxx) |

No human data are available.

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| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not sensitizing  |
| Justification for the value/conclusion | Based on the negative result in the study performed comparable to the LLNA guideline with the read-across substance benzoic acid. |
| Classification of the product according to CLP and DSD | Not classified |

***Respiratory sensitization (ADS)***

No data are available.

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| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not sensitizing  |
| Justification for the value/conclusion | Based on the lack of skin sensitizing properties of benzoic acid, respiratory sensitization is not expected. Sodium benzoate is a widely used (food) preservative, however, no reports were found in public databases on respiratory effects observed in animal studies or in humans (CAPLUS and MEDLINE via Scifinder). Evaluations by the WHO and the European Commission (published in 2000 and 2005, respectively) on benzoic acid and sodium benzoate do not mention respiratory sensitizing properties.  |
| Classification of the product according to CLP and DSD | Not classified |

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| --- |
| **Data waiving** |
| Information requirement | Respiratory sensitization  |
| Justification | Based on the lack of skin sensitizing properties of benzoic acid, respiratory sensitization is not expected. Furthermore, sodium benzoate is a widely used substance; however, no evidence of respiratory sensitization has been reported in the literature. |

***Acute toxicity***

*Acute toxicity by oral route*

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| **Summary table of animal studies on acute oral toxicity** |
| **Method Guideline****GLP status, Reliability**  | **Species,Strain,Sex,No/group** | **Test substance****Dose levelsType of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **ValueLD50** | **Remarks** *(e.g. major deviations)* | **Reference**  |
| Non-guideline, predates GLP, performed as a part of genotoxicity screening assay, oral gavage, limit test, 10 days observation period, gross necropsy performed, reliability 2 | Rat, unspecified strains, 2 and 10 males | Sodium benzoate, 5000 mg/kg bw as 0.85% in saline, gavage | There were no mortalities and no abnormal gross findings | LD50 > 5000 mg/kg bw |  | 2.2.6.1- 4 (xxxxx) |

It is of note that the World Health Organization concluded in 2000 that the acute oral toxicity of sodium benzoate was low, with an LD50 value between 2100–4070 mg /kg bw in rats. Furthermore it was concluded that the acute toxicity (and the symptoms) of sodium benzoate was similar to that of benzoic acid (3040 mg benzoic acid/kg bw in rats and 1940–2263 mg benzoic acid/kg bw in mice).

Human data:

Sodium benzoate is a well-known food additive with acceptable daily intake of 5 mg/kg bw/day, as set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1996, the EU Scientific Committee on Food (SCF) in 2002 and EFSA in 2016. In the United States, benzoic acid and sodium benzoate are on the FDA list of substances that are generally recognized as safe (GRAS) and may be used at a current maximum of 0.1% in food. There are no indications of acute toxicity of sodium benzoate in humans.

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| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | LD50 > 2000 mg/kg bw |
| Justification for the selected value | Based on the results of one acceptable acute toxicity study with rats, taking into account evaluations by WHO, JECFA, SCF, EFSA and FDA. |
| Classification of the product according to CLP and DSD | Not classified  |

*Acute toxicity by inhalation*

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| **Summary table of animal studies on acute inhalation toxicity** |
| **Method,Guideline,****GLP status , Reliability** | **Species,Strain,Sex,No/group** | **Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD)****Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LC50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Non-guideline, predates GLP, 1-hour exposure to 0.026 mg/L benzoic acid gross necropsy performed, study cited by two renowned scientific authorities, reliability 4 | Rat, strain and sex unspecified | Benzoic acid, dust, 0.026 mg/L  | No mortalities occurred, but generalized inactivity andlacrimation were noted. The gross autopsy gave nosignificant findings | LC50 > 0.026 mg/L/1 h  | The study is recovered as a secondary source only, but it was cited and used in the evaluations by two renowned scientific authorities. Based on the short exposure duration and the exposure concentration being below the concentration limit of 5 mg/L for classification for acute inhalation toxicity according to Regulation 1272/2008/EC, the study is considered to be not suitable for classification and labelling purposes and is provided as supporting information. | Ref no. 2.2.6.1- 5 (xxxxx), 2.2.6.1-6 (xxxxx) |
| Non-guideline, predates GLP, 4-hour exposure to 12.2 mg/L benzoic acid, 14 days observation, gross necropsy performed, clinical signs, body weight and histopathology, reliability 2 | Rat (Spartan, 5 males, 5 females) | Benzoic acid, dust, 12.2 mg/L (no MMAD reported), whole body exposure | No mortalities occurred, increased motor activity and slight erythema were observed during the 4 hour exposure period, after 24 hours all animals appeared normal. No effects seen on weight gain, no gross pathological or histopathological effects reported. | LC50 > 12.2 mg/L  | No MMAD was reported, this is not considered to influence the reliability of the study | Ref no. 2.2.6.1-7 (xxxxx) |

No human data are available.

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| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | LC50 > 12.2 mg/L (benzoic acid) |
| Justification for the selected value | Based on the results of acute inhalation toxicity study with rats with a read-across substance benzoic acid |
| Classification of the product according to CLP and DSD | Not classified |

*Acute toxicity by dermal route*

The World Health Organization concluded in 2000 that the acute dermal toxicity of benzoic acid and sodium benzoate was low, based on a study with rabbits which resulted in an LD50 value of benzoic acid above 10,000 mg/kg bw. As no original study report could be recovered, and the study was done with an analogue, the study has limited reliable and is only included as supporting evidence.

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| **Summary table of animal studies on acute dermal toxicity** |
| **Method, Guideline,****GLP status,****Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Non-guideline, predates GLP, limit test with rabbits, dermal application of 10000 mg/kg bw, gross autopsy performed, study cited by two renowned scientific authorities. Reliability 4 | Rabbits, sex and strain unspecified | Benzoic acid, 10000 mg/kg bw | No mortalities or signs of toxicity were noted | > 10000 mg/kg bw | The study is recovered as a secondary source only, but it was cited and used in the evaluations by two renowned scientific authorities. The study is provided as supporting information. | 2.2.6.1- 5 (xxxxx), 2.2.6.1- 6 (xxxxx) |

No human data are available.

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| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value |  No value available |
| Justification for the selected value | There is no necessity to address the dermal toxicity by testing and it can be concluded that Kalaguard® SB does not have to be classified for acute dermal toxicity based on the calculation rules. This conclusion is supported by the results of an acute dermal toxicity study with rabbits with a read-across substance benzoic acid. |
| Classification of the product according to CLP and DSD | Not classified |

***Information on dermal absorption***

No information on dermal absorption of sodium benzoate is available. Sodium benzoate is not corrosive to skin and the formulations are not skin corrosive. In accordance with EFSA guidance on dermal absorption (2012), the default values of 25% and 75%, respectively, shall be used in the risk assessment for formulations containing > 5% and ≤5% sodium benzoate, respectively. As oral absorption of sodium benzoate is considered to be 100%, no further refinement of dermal absorption values is possible.

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| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | Sodium benzoate > 5% | Sodium benzoate ≤5% |
| Value(s)\* | 25% | 75% |
| Justification for the selected value(s) | Default value according to the EFSA Guidance on dermal absorption (2012) | Default value according to the EFSA Guidance on dermal absorption (2012) |

NL CA remark: The approach to the toxicological evaluation of sodium benzoate that will be marketed as Kalaguard® SB is largely based on the data on a substance analogue (and precursor) of sodium benzoate, benzoic acid. Benzoic acid has been evaluated under the BPR Review Programme and the agreed EU conclusions the dermal absorption of benzoic acid should apply here. The PT 3 and PT4 CARs for benzoic acid concludes a dermal absorption range (including human data) of approximately 40 % in vivo in humans (14 - 43 %) and 70 % (53 - 99 %) in vitro in human skin. As there is no further justification presented, the NL CA applies a value of 75% to both the concentrate and the in-use dilution in the risk assessment.

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

Not applicable, the product does not contain substances of concern.

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

Not applicable, the product does not contain substances of concern.

***Other***

Benzoic acid has been evaluated under the BPR Review Programme. The relevant data are for the major part based on data on a substance analogue (and precursor) of sodium benzoate, benzoic acid. The data are submitted as a part of the IUCLID active substance dataset within the current application. Below a short summary is given on toxicity endpoints that have not been discussed.

**Genetic toxicity in vitro/in vivo**

Sodium benzoate does not induce mutations in assays with *Salmonella typhimurium* and *Escherichia coli* with and without metabolic activation (xxxxx).

*In vivo*, the test substance showed to be negative in a dominant lethal study, in an *in vivo* chromosome aberration test and a host mediated assay (xxxxx).

Taken all available data together, it is concluded that sodium benzoate is not mutagenic or clastogenic *in vivo*. This is further supported by the negative outcome of carcinogenicity studies in both rats and mice.

Human data:

Sodium benzoate is a well-known food additive with acceptable daily intake of 5 mg/kg bw/day, as set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1996, the EU Scientific Committee on Food (SCF) in 2002 and EFSA in 2016. In the United States, benzoic acid and sodium benzoate are on the FDA list of substances that are generally recognized as safe (GRAS) and may be used at a current maximum of 0.1% in food. There are no indications of genotoxicity of sodium benzoate in humans.

**Repeated dose toxicity**

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| **Summary table of key studies on repeated dose toxicity** |
| **Method Guideline****GLP status, Reliability**  | **Species,Strain,Sex,No/group** | **Test substance****Dose levelsType of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **ValueNOAEL** | **Remarks** *(e.g. major deviations)* | **Reference**  |
| Non-guideline (carcinogenicity), predates GLP, 2 | Rats, Fischer 344, test group: 50 males and 52 females per dose, control group: 25 males and 43 females | Sodium benzoate at 1% and 2% in feed (corresponds to appr. 141 and 280 mg/kg bw/day for males and 102 and 202 mg/kg bw/day, respectively), exposure duration 18 to 24 months | No differences in mortality, growth or food intake between treated and untreated rats, no toxicity or carcinogenicity attributed to sodium benzoate exposure observed | 280 and 202 mg/kg bw for males and females, respectively | Limited study summary. Minimal data provided on study design and results |  2.2.6.1-8 (xxxxx) |
| Carcinogenicity, non-guideline,non-GLP | Mouse,Swiss Albino,50 M + 50 F (control: 99 M + 99 F) | Oral (drinking water),2.5 yr0-20,000 ppm(~0-3000 mg/kg bw/d) | No effects on mortality and tumor incidence | 20,000 ppm |  | xxxxx 2.2.6.1-11 |
| Non-guideline (4 generation study), predates GLP, study performed with substance analogue, reliability 2 | Rat, unspecified strain, 20 rats/ sex/ dose | benzoic acid, as 0.5% and 1% in feed (corresponds to appr. 250 and 500 mg/kg bw | There were no adverse effects seen up to and including 500 mg/kg bw/day | 500 mg/kg bw (males and females) | Limited study summary. Minimal data provided on study design and results | Ref no. 2.2.6.1-9 (xxxxx), 2.2.6.1-10 (xxxxx) |

Human data:

Sodium benzoate is a well-known food additive with acceptable daily intake of 5 mg/kg bw/day, as set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1996, the EU Scientific Committee on Food (SCF) in 2002 and EFSA in 2016. In the United States, benzoic acid and sodium benzoate are on the FDA list of substances that are generally recognized as safe (GRAS) and may be used at a current maximum of 0.1% in food.

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| **Value used in the Risk Assessment – Repeated dose toxicity** |
| Value (NOAEL) | 500 mg/kg bw |
| Justification for the selected value | Based on the results of a multi-generation toxicity study with rats, performed with a substance analogue (benzoic acid); the study was assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1996, the EU Scientific Committee on Food (SCF) in 2002 and EFSA in 2016 and used to set the ADI for sodium benzoate. |
| Classification of the product according to CLP and DSD | Not classified  |

NL CA remark: For a structurally similar substance benzoic acid H372 STOT RE1 (lung) is assigned. According to the RAC opinion pulmonary toxicity of benzoic acid is attributed to the forms or physical states of the substance (powder form solid). In the key study to draw this conclusion rats were exposed to benzoic acid fine dust with mean aerodynamic diameter of 4.7 um. Although it is described to be powder, the biocidal product in the current PAR contains particles rather large for a powder:

Particle size distribution: 100% < 2.36 mm, 85% < 0.85 mm, 43% < 0.43 mm, 8% < 0.21 mm, 5% < 0.18 mm,1.4% < 0.125 mm

Due to the relatively large particle sizes sodium benzoate used in this biocidal product will not reach thoracic region. Therefore H372 STOT RE1 (lung) is not warranted for this biocidal product.

NL CA remark: It was pointed out by a refMS that there is a literature showing a possible positive correlation between worker exposure to a structurally similar compound, BCMBA and development of occupational asthma, rhinitis and urticarial, and it would be useful to include this information.

Reference of the study: 3-(Bromomethyl)-2-chloro-4-(methylsulfonyl)- benzoic acid: a new cause of sensitiser induced occupational asthma, rhinitis and urticarial (2017).

Suojalehto H1, Karvala K1, Ahonen S1,2, Ylinen K3, Airaksinen L1, Suuronen K1, Suomela S1, Lindström I1.

NL CA notes that the intolerance reactions to benzoic acid and its salts have been observed in sensitive population.

e.g. WHO CICADs (2000)

Cases of urticaria, asthma, rhinitis, or anaphylactic shock have been reported following oral, dermal, or inhalation exposure to benzoic acid and sodium benzoate. The symptoms appear shortly after exposure and disappear within a few hours, even at low doses

e.g. Scientific opinion EFSA ANS Panel (2016)

The Panel noted that intolerance reactions to benzoic acid and its salts have been reported in the literature, manifesting as gastrointestinal disturbances, skin reactions (urticaria, pruritus, etc.), bronchial hyper reactivity or asthmatic attacks, effects on the central nervous system or even anaphylaxis.

**Reproductive and developmental toxicity**

The studies available on repeated dose toxicity and carcinogenicity of sodium benzoate do not reveal effects on the reproductive organs/tissues in both male and female laboratory animals. In a 4-generation study with the analogue benzoic acid (xxxxx), no effects on reproductive performance and off-spring were reported up to 1% benzoic acid in feed (500 mg/kg bw).

**Carcinogenicity**

Two studies are available on the carcinogenicity of sodium benzoate.

The carcinogenicity of sodium benzoate was examined in Fischer 344 rats (xxxxx). The test substance was administered in the diet for 18 to 24 months at two dose levels (1% and 2%). No adverse clinical signs directly attributable to the compound were observed in treated animals. Differences in the average body weight, and mortality rates between treated and control groups were negligible. The results of the statistical test for dose-related trends were significant (p<0.05). Although a variety of tumours occurred among test and control rats of each sex, tumours appearing in treated rats were similar in type and number to those in controls. It was concluded that no evidence of carcinogenicity in rats from the test substance was demonstrated. The reliability of this study is considered to be 2 (reliable with restrictions, minimal data on study design, experimental results and study not performed following GLP guidelines).

This conclusion is supported by the outcome of a second carcinogenicity study, in which sodium benzoate was administered as a 2% solution in drinking water for life to randomly bred Swiss mice (xxxxx). Consumption of the test substance caused no detectable tumorigenic effect under the experimental conditions of this test. The reliability of this study was concluded to be 2 (reliable with restrictions; minimal data on study design and results, and study not performed following GLP guidelines).

#### Endocrine Disruptor Assessment

Not relevant because Kalaguard® SB only contains the active substance sodium benzoate, which has been approved for annex I inclusion, and no co-formulants.

### Exposure assessment

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

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

***List of scenarios***

|  |
| --- |
| **Summary table: scenarios** |
| **Scenario number** | **Scenario**(e.g. mixing/ loading) | **Primary or secondary exposure** **Description of scenario** | **Exposed group**(e.g. professionals, non-professionals, bystanders) |
| 1. | Mixing and loading (formulation of Kalaguard® SB into treated articles) | An industrial user adds the product to treated articles to be preserved, to the maximal concentration of 2.5% (expressed as benzoic acid), using either an automated dosing process or manual dosing.  | Industrial  |
| 2 | Use of laundry detergent liquids preserved with the product by professionals | A professional launderer loads a laundry detergent liquid preserved with the product into the washing machine 20 times per day.  | Professional  |
| 3 | Use of floor cleaner liquids preserved with the product for mopping the floor with a mop and a wringer bucket by professional users | A professional cleaner uses a floor cleaner liquid diluted in water to mop the floor with a mop and a wringer bucket for 110 minutes per day.  | Professional |
| 4 | Use of all-purpose cleaner liquids preserved with the product for surface wiping by professional users | A professional cleaner uses an all-purpose cleaner liquid to wipe surfaces for 220 minutes per day. | Professional |
| 5 | Surface cleaning by professional users using hand-held trigger cleaning spray preserved with the product | A professional user uses a hand-held trigger spray to clean surfaces for 30 minutes | Professional |
| 6 | Use of dishwashing liquids preserved with the product for cleaning dishes manually by professional users in the catering industry | A professional dishwasher uses a dishwashing liquid to wash dishes for 360 minutes per day | Professional |
| 7 | Use of dishwashing liquids preserved with the product by general public | A consumer uses a hand dishwashing liquid preserved with the product to do the dishes daily 3 times a day for 16 minutes.  |  Non-professional users (consumers) |
| 8 | Use of laundry detergent liquids preserved with the product by general public | A consumer uses a laundry detergent preserved with the product to do the hand-wash laundry once daily.  |  Non-professional users (consumers) |
| 9 | Use of all-purpose cleaners preserved with the product by general public | A consumer uses the liquid cleaner to clean 10 m2 of furniture such as tables and cupboards in the living room.  |  Non-professional users (consumers) |
| 10 | Exposure of general public to residues of the product in laundered clothing - adults | An adult consumer is exposed to the residues of the product in laundered clothes via contact with skin | General public |
| 11 | Exposure of general public to residues of the product in laundered clothing - children | A child is exposed to the residues of the product in laundered clothes via contact with skin | General public  |
| 12 | Exposure of general public to residues of dishwashing liquids preserved with the product on washed dinnerware - adults | An adult consumer is exposed to the residues of the product on the washed dinnerware via oral route. | General public  |
| 13 | Exposure of general public to residues of dishwashing liquids preserved with the product on washed dinnerware - children | A child is exposed to the residues of the product on the washed dinnerware via oral route. | General public |
| 14 | Exposure of general public to residues in food due to food contact with cleaned surfaces (e.g. kitchen tops) | A consumer is exposed via oral route to the residues of the product transferred into food from cleaned surfaces | General public |
| 15  | Exposure of toddlers to residues of all-purpose cleaners  | A secondary oral (hand-to-mouth) and dermal exposure of toddlers from cleaned surfaces concerning the use of all-purpose cleaners preserved with the biocidal product  | General public |

It should be noted that, although this list is not necessarily considered to be comprehensive, as other (secondary) exposure scenarios can be imagined (e.g. the use of spot removers), the scenarios reported above are considered to be representative of overall use of detergents and to cover the most realistic sources of exposure which are expected to occur on a daily basis.

***Industrial exposure***

*Scenario 1: Mixing and loading (formulation of Kalaguard® SB into treated articles)*

| **Description of Scenario 1** |
| --- |
| An industrial user adds solid sodium benzoate to the articles to be preserved to generate a maximal concentration of 2.5% by either automated or manual dosing |
|  | Parameters1 | Value |
| Tier 1 | Exposure to hands | 305 mg/min (mixing and Loading model 7, powder) |
| Respiratory exposure  | 7.2 mg/m3 (mixing and loading model 7, powder) |
| Exposure duration | 10 minutes x 3 times = 30 min |
| Inhalation rate | 1.25 m3/h |
| Dermal absorption | 75% (default) |
| Respiratory absorption | 100% (default) |
| Body weight | 60 kg |
| Tier 2 (gloves) | Exposure to hands (in gloves) | 3.05 mg/min (mixing and loading model 7, powder) |

***Calculations for Scenario 1***

An industrial user adds solid sodium benzoate to the articles to be preserved, e.g. dishwashing liquids, laundry products, cleaners, to generate the maximal concentration of 2.5% sodium benzoate (w/w, expressed as benzoic acid) in treated articles. The process occurs by either automated or manual dosing and is considered to take 10 minutes per operation (Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure on Methods and models to assess exposure to biocidal products in different product types, v.2, June 2016). As loading operation may occur several times per day, according to the use description, exposure duration of 30 min is assumed as the worst case. In accordance with HEEG Opinion 1 on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems on industrial scale (agreed at TM I 2008), a value of 305 mg/min for exposure to a powder during loading was applied in absence of PPE. When gloves are used, a value of 30.8 mg/min is used assuming gloves will reduce dermal exposure 10-fold.

The results of the calculations are presented below:

|  |
| --- |
| **Mixing and loading** |
| **Tier 1: No PPE** |
| **Dermal exposure (HEEG Opinion 1, Ispra, 06/04/2008)** |
| Exposure rate b.p. on hands (indicative value) | 305 mg/min |
| **Actual on hands sodium benzoate** | 9150 mg |
| **Internal dermal exposure** | 114.4 mg/kg bw/day |
| **Respiratory exposure (Mixing and Loading Model 7)** |
| External exposure concentration product | 7.2 mg/m3 |
| **External concentration sodium benzoate** | 7.2 mg/m3 |
| **Internal respiratory exposure** | 0.075 mg/kg bw/day |
| **Combined dermal and respiratory exposure** |  114.4 mg/kg bw/day |

|  |
| --- |
| **Mixing and loading** |
| **Tier 2: PPE (gloves)** |
| **Dermal exposure (HEEG Opinion 1, Ispra, 06/04/2008)** |
| Exposure rate b.p. on hands (indicative value) | 3.05 mg/min |
| **Actual on hands sodium benzoate** | 91.5 mg |
| **Internal dermal exposure** | 1.14 mg/kg bw/day |
| **Respiratory exposure (Mixing and Loading Model 7)** |
| **Internal respiratory exposure** | 0.075 mg/kg bw/day |
| **Combined dermal and respiratory exposure** |  1.12 mg/kg bw/day |

| **Summary table: estimated exposure from industrial uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 1 | Tier 1 /no PPE | 0.075 mg/kg bw/day | 114.4 mg/kg bw/day | - | 114.4 mg/kg bw/day |
| Tier 2 / PPE (gloves) | 0.075 mg/kg bw/day | 1.14 mg/kg bw/day | - | 1.12 mg/kg bw/day |

***Professional exposure***

The treated articles preserved with Kalaguard® SB can be used in professional settings, e.g. by professional launderers, cleaners etc. Laundering in professional settings are expected to occur by automated equipment and thus to not involve a direct contact with the treated articles. However, as a worst case, the exposure of a professional user during the loading of the treated article into the washing machine has been calculated for professional laundering. This scenario is also considered to be representative for professional dishwashing. For professional cleaning, two scenarios have been assessed: mopping of the floor using an all-purpose cleaner diluted in water, and wiping of surfaces using an all-purpose cleaner. The results of exposure estimates are presented below.

*Scenario 2: Use of laundry detergent liquids preserved with the product by professionals*

| **Description of Scenario 2** |
| --- |
| A professional launderer loads a laundry detergent liquid preserved with the product at a maximal concentration of 2.5% (w/w, expressed as benzoic acid) into the washing machine 20 times per day.The worst case for professional exposure by doing laundry using laundry detergent liquid, preserved with the product would be for those carrying out hand washing. This scenario 2 therefore represents not the worst case but the more realistic scenario. |
|  | Parameters1 | Value |
| Tier 1 | weight fraction sodium benzoate  | 2.5% (w/w, expressed as benzoic acid)  |
|  |  |
| product amount | 0.01 g |
| dermal absorption | 75% |
| events per day | 20 |
| Body weight | 60 kg |

***Calculations for Scenario 2***

Laundering in professional settings occurs in washing machines. According to TNsG Part 2 (2002), professional laundry equipment is effectively enclosed, thus no exposure is expected. However, as a worst case, the exposure for the scenario in which a professional user loads a laundry detergent liquid preserved with the product at a maximal concentration of 2.5% (expressed as benzoic acid) into a washing machine has been estimated. As a worst case, 20 events per day have been envisaged (expert judgement). The default exposure scenario from ConsExpo 4.1 was used to calculate the exposure per single loading event. As the vapour pressure of sodium benzoate is extremely low, its evaporation from aqueous solution is considered to be negligible; thus no respiratory exposure is expected. For dermal exposure, the body weight of the consumer was set to 60 kg according to HEEG Opinion 18 on Default human factor values for use in exposure assessments for biocidal products, endorsed at TM II 2013. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). The amount of the product which is considered to come into direct contact with hand during a single loading event is 0.01 g (default ConsExpo 4.1). The resulting exposure estimates are presented in Annex 3.2. The internal systemic exposure to sodium benzoate per single loading event is equal to 3.13 x 10-3 mg/kg bw/day. For 20 loading events per day, the exposure is calculated to be (3.13 x 10-3 x 20 =) 0.0626 mg/kg bw/day, respectively.

*Scenario 3: Use of floor cleaner liquids preserved with the product for the mopping of the floor with a mop and a wringer bucket by professional users*

| **Description of Scenario 3** |
| --- |
| A professional cleaner uses a floor cleaner liquid preserved with a product at a maximal concentration 2.5% (w/w, expressed as benzoic acid) diluted in water to mop the floor with a mop and a wringer bucket for 110 minutes per day. |
|  | Parameters1 | Value |
| Tier 1 |  |  |
| Exposure rate in-use b.p. on hands (75th percentile) | 1030 mg/min |
| Exposure rate in-use b.p. on the body (75th percentile) | 87.6 mg/min |
| Exposure duration | 110 minutes |
| Concentration sodium benzoate | 0.125% |
| Dermal absorption | 75% |
| Body weight | 60 kg |

***Calculations for Scenario 3***

Professional cleaners may use cleaning liquids diluted in water to mop the floors using a mop and a wringer bucket. According to HEAd hoc Recommendation no. 2 on professional mopping and wiping time used for cleaning hard surfaces (endorsed at the Human Health Working Group II on 24 March 2014), the estimated exposure duration for this activity is 110 minutes. According to the Cleaning Products Fact Sheet (RIVM report 320104003/2006), 250 g of the floor cleaning liquid is diluted in a bucket with 5 L water. The dilution fraction is then 20 times. Considering the maximal concentration of sodium benzoate in preserved products of 2.5% (w/w, expressed as benzoic acid), the resulting maximal concentration of sodium benzoate in the in-use solution is (2.5%/20 =)0.125%. The calculations have been performed with Surface Disinfection Model 1 for hand exposure and Surface disinfection Model 3 for body exposure (HEEG Recommendation no. 6 on methods and models to assess exposure to biocidal products in different product types, v.2). Both models include a mixing and loading stage, as well as the application. As the vapour pressure of sodium benzoate is extremely low, its evaporation from aqueous solution is considered to be negligible; thus no respiratory exposure is expected. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). The calculations are presented below.

|  |
| --- |
| **Floor mopping** |
| **Tier 1: No PPE** |
| **Dermal exposure to hands (Surface disinfection model 1)** |
| Exposure rate in-use b.p. on hands (75th percentile) | 1030 mg/min |
| Total b.p. on hands | 113300 mg |
| Concentration sodium benzoate | 0.125% |
| **Actual on hands sodium benzoate** | 141.6 mg |
| **Internal dermal exposure** | 1.77 mg/kg bw/day |
| **Dermal exposure to the body (Surface disinfection model 3)** |
| Exposure rate in-use b.p. on the body (75th percentile) | 87.6 mg/min |
| Total b.p. on the body | 9636 mg |
| Concentration sodium benzoate | 0.125% |
| **Actual on the body sodium benzoate** | 12.05 mg |
| **Internal dermal exposure** | 0.15 mg/kg bw/day |
| **Combined dermal exposure (hands and body)** | 1.92 mg/kg bw/day |

*Scenario 4: Use of all-purpose cleaner liquids preserved with the product for the wiping of surfaces by professional users*

| **Description of Scenario 4** |
| --- |
| A professional cleaner uses an all-purpose cleaner liquid preserved with a product at a maximal concentration 2.5% (w/w, expressed as benzoic acid) diluted in water to wipe the surfaces with a wrung cloth |
|  | Parameters1 | Value |
| Tier 1 | Exposure rate in-use b.p. on hands (75th percentile) | 1030 mg/min |
| Exposure rate in-use b.p. on the body (75th percentile) | 87.6 mg/min |
| Exposure duration  | 220 minutes |
| Concentration sodium benzoate | 0.031% |
| Dermal absorption |  75% |
| Body weight | 60 kg |

***Calculations for Scenario 4***

Professional cleaners may use cleaning liquids diluted in water to wipe the surfaces using a wrung cloth. According to HEAd hoc Recommendation no. 2 on professional mopping and wiping time used for cleaning hard surfaces (endorsed at the Human Health Working Group II on 24 March 2014), the estimated exposure duration for this activity is 220 minutes. According to the Cleaning Products Fact Sheet (RIVM report 320104003/2006), 63 g of an all-purpose cleaner liquid is diluted in a bucket with 5 L water. The dilution fraction is then 80 times. Considering the maximal concentration of sodium benzoate in preserved products of 2.5% (w/w, expressed as benzoic acid), the resulting maximal concentration of sodium benzoate in the in-use solution is (2.5%/80 =)0.031%. The calculations have been performed with Surface Disinfection Model 1 for hand exposure and Surface disinfection Model 3 for body exposure (HEEG Recommendation no. 6 on methods and models to assess exposure to biocidal products in different product types, v.2). Both models include also a mixing and loading stage, as well as the application. As the vapour pressure of sodium benzoate is extremely low, its evaporation from aqueous solution is considered to be negligible; thus no respiratory exposure is expected. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). The calculations are presented below.

|  |
| --- |
| **Surface wiping** |
| **Tier 1: No PPE** |
| **Dermal exposure to hands (Surface disinfection model 1)** |
| Exposure rate in-use b.p. on hands (75th percentile) | 1030 mg/min |
| Total b.p. on hands | 226600 mg |
| **Actual on hands sodium benzoate** | 70.25 mg |
| **Internal dermal exposure** | 0.88 mg/kg bw/day |
| **Dermal exposure to the body (Surface disinfection model 3)** |
| Exposure rate in-use b.p. on the body (75th percentile) | 87.6 mg/min |
| Total b.p. on the body | 19272 mg |
| **Actual on the body sodium benzoate** | 5.97 mg |
| **Internal dermal exposure** | 0.075 mg/kg bw/day |
| **Combined dermal exposure (hands and body)** | 0.95 mg/kg bw/day |

*Scenario 5: Use of hand-held trigger cleaning sprays preserved with the product for surface cleaning by professional users*

| **Description of Scenario 5** |
| --- |
| A professional cleaner uses a hand-held trigger spray preserved with a product at a maximal concentration 2.5% (w/w, expressed as benzoic acid) to clean surfaces for 30 minutes a day. |
|  | Parameters1 | Value |
| Tier 1 | Exposure rate in-use b.p. on hands  | 36 mg/min |
| External exposure concentration product | 10.5 mg/m3 |
| Exposure duration  | 30 minutes |
| Concentration sodium benzoate | 2.5% |
| Dermal absorption | 75% |
| Respiratory rate | 1.25 m3/hour |
| Respiratory absorption | 100% |
| Body weight | 60 kg |

***Calculations for Scenario 5***

Professional users may use ready to use hand-held trigger sprays to clean smaller washable areas. Usually, at first the product is sprayed onto the surface; then, it is left on the surface to soak in for several minutes; finally, the surface should be rinsed or taken off with a wet cloth. According to the HEEG Recommendation No. 6 on methods and models to assess exposure to biocidal products in different product type (v.2, June 2016), this activity lasts 30 minutes. The dermal and respiratory exposure has been calculated with Consumer Spraying and Dusting Model 2 according to the HEEG Recommendation No. 6. The product is used undiluted, thus the maximal concentration of sodium benzoate in the product is 2.5% (expressed as benzoic acid). Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). It should be noted that droplet particles generated by coarse spraying from a trigger spray, usually have a diameter > 100 µm and are thus are non-inhalable, but can deposit in the nasopharyngeal region and swallowed, thus becoming available for systemic absorption from gastro-intestinal tract. Therefore as a worst case, calculations considering 100% respiratory absorption were performed. The calculations are presented below.

|  |
| --- |
| **Surface spraying** |
| **Tier 1: No PPE** |
| **Dermal exposure to hands and forearms (Consumer Spraying and Dusting Model 2)** |
| Exposure rate in-use b.p. on hands  | 36 mg/min |
| Total b.p. on hands | 1080 mg |
| **Actual on hands sodium benzoate** | 27 mg |
| **Internal dermal exposure** | 0.3375 mg/kg bw/day |
| **Respiratory exposure (Consumer Spraying and Dusting Model 2)** |
| External exposure concentration product | 10.5 mg/m3 |
| **External concentration sodium benzoate** | 0.2625 mg/m3 |
|  |  |
| **Internal respiratory exposure** | 0.0027 mg/kg bw/day |
| **Combined dermal and respiratory exposure** | 0.340 mg/kg bw/day |

*Scenario 6: Use of dishwashing liquids preserved with the product for cleaning of dishes manually by professional users in the catering industry*

| **Description of Scenario 6** |
| --- |
| A professional dishwasher washes dishes manually with detergent liquid preserved with the product at a maximal concentration of 2.5% (w/w, expressed as benzoic acid) by hand daily 22 times a day for 16 minutes (approximately 6 hours per day) |
|  | Parameters1 | Value |
| Tier 1 | exposure area | 1961.2 cm2 (the area of palms and backs of both hands for an adult) |
| weight fraction sodium benzoate | 0.0035% |
| Events/day | 22 |
| Exposure period | 360 minutes (appr. 22 dish washes) |
| Dermal absorption | 75% |
| Body weight | 60 kg |

***Calculations for Scenario 6***

Dishwashing may be performed manually by professionals with dishwashing liquid preserved with sodium benzoate at a maximal concentration of 2.5% (expressed as benzoic acid) for maximum 6 hours per day. The default exposure scenario from ConsExpo 4.1 was used to perform the calculations. Application duration was considered to be 16 minutes (default ConsExpo 4.1), therefore a full time manual dishwasher is considered to perform approximately 22 dish washes per day.

The default scenario assumes that the consumer adds the dishwashing liquid to a sink filled with water with a total volume of 15 L. The amount of the dishwashing liquid added to water is assumed to be 7 g per 5000 mL water, which is equal to a dilution of ca. 714 times. Therefore the resulting weight fraction of sodium benzoate in the generated solution is calculated as (2.5%/714 =) 0.0035%. As the vapour pressure of sodium benzoate is extremely low, its evaporation from aqueous solution is considered to be negligible; thus no respiratory exposure is expected.

For dermal exposure, the exposed area was set to 1948.8 cm2 (the area of palms and backs of both hands, and forearms for an adult), while the body weight of the consumer was set to 60 kg according to HEEG Opinion 18 on Default human factor values for use in exposure assessments for biocidal products, endorsed at TM II 2013. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). It is considered that the water layer of 0.01 cm (default) comes into contact with the consumer skin; respectively, the amount of water containing product which can get absorbed through the skin, is calculated as (1948.8 cm2 x 0.01 cm x 1 g/cm3 =) 19.5 g (where 1 g/cm3 is taken as a default density of aqueous solution). ~~The resulting exposure estimates are presented in Annex 3.2~~. The internal systemic exposure to sodium benzoate is equal to 8.5x10-6 mg/kg bw per event ((19.5x0.0035%x75%);60), or, considering 22 applications per day, 1.9x10-4 mg/kg bw/day.

| **Summary table: systemic exposure from professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake\*** |
| Scenario 2 | Tier 1/no PPE | Negligible | 0.0626 mg/kg bw/day | Negligible | 0.0626 mg/kg bw/day |
| Scenario 3 | Tier 1/no PPE | Negligible | 1.92 mg/kg bw/day | Negligible | 1.92 mg/kg bw/day |
| Scenario 4 | Tier 1/no PPE | Negligible | 0.95 mg/kg bw/day | Negligible | 0.95 mg/kg bw/day |
| Scenario 5 | Tier 1/no PPE | 0.0027 mg/kg bw/day | 0.3375 mg/kg bw/day | Negligible | 0.340 mg/kg bw/day  |
| Scenario 6 | Tier 1/no PPE | Negligible | 1.9x10-4 mg/kg bw/day | Negligible | 1.9x10-4 mg/kg bw/day |

\* Expressed as benzoic acid

*Combined scenarios*

It is assumed that the same cleaners can perform both mopping and wiping tasks, as well as the surface cleaning using hand-held trigger sprays. Therefore a total combined systemic exposure for scenarios 3 (mopping), 4 (wiping) and 5 (trigger spraying) has been calculated.

| **Summary table: combined systemic exposure from professional uses** |
| --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios 3, 4 and 5 | 0.0027 mg/kg bw/day | 3.208 mg/kg bw/day | Negligible | 3.21 mg/kg bw/day |

***Non-professional exposure***

No non-professional exposure is envisaged. The use of treated articles preserved with the biocidal product is assessed as a secondary exposure of general public.

***Exposure of the non-professional users***

*Scenario 7: Use of dishwashing liquids preserved with the product by non-professional users (consumers) for hand dishwashing*

| **Description of Scenario 7** |
| --- |
| A consumer uses a hand dishwashing liquid preserved with the product at a maximal concentration of 2.5% (w/w, expressed as benzoic acid) to do the dishes daily 3 times a day for 16 minutes. |
|  | Parameters1 | Value |
| Tier 1 | exposed area,  | 1961.2 cm2 |
| weight fraction sodium benzoate | 0.0035% |
| Events/day | 3 |
| Dermal absorption | 75% |
|  | Body weight | 60 kg |

1 Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario 7**

A consumer uses a dishwashing liquid preserved with sodium benzoate at a maximal concentration of 2.5% (expressed as benzoic acid) to do the dishes manually three times a day. The default exposure scenario from ConsExpo 4.1 was used to perform the calculations. Application duration was considered to be 16 minutes (default ConsExpo 4.1). The default scenario assumes that the consumer adds the dishwashing liquid to a sink filled with water with a total volume of 15 L. The amount of the dishwashing liquid added to water is assumed to be 7 g per 5000 mL water, which is equal to a dilution of ca. 714 times. Therefore the resulting weight fraction of sodium benzoate in the generated solution is calculated as (2.5%/714 =) 0.0035%. As the vapour pressure of sodium benzoate is extremely low, its evaporation from aqueous solution is considered to be negligible; thus no respiratory exposure is expected. For dermal exposure, the exposed area was set to 1961.2 cm2 (the area of palms and backs of both hands, and forearms for an adult), while the body weight of the consumer was set to 60 kg according to HEEG Opinion 18 on Default human factor values for use in exposure assessments for biocidal products, endorsed at TM II 2013. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). It is considered that the water layer of 0.01 cm (default) comes into contact with the consumer skin; respectively, the amount of water containing product which can get absorbed through the skin, is calculated as (1961.2 cm2 x 0.01 cm x 1 g/cm3 =) 19.6 g (where 1 g/cm3 is taken as a default density of aqueous solution). The resulting exposure estimates are presented in Annex 3.2. The internal systemic exposure to sodium benzoate is equal to 0.0086 mg/kg bw per event, or, considering three applications per day, 0.026 mg/kg bw/day.

*Scenario 8: Use of laundry detergent liquids preserved with the product by non-professional users for handwash laundry*

| **Description of Scenario 8** |
| --- |
| A consumer uses a liquid laundry detergent preserved with the product at a maximal concentration of 2.5% (w/w, expressed as benzoic acid) to do the hand-wash laundry 1948.8 cm2 (the area of both hands and lower forearms) once daily.  |
|  | Parameters | Value |
| Tier 1 | exposure area | 1948.8 cm2 (the area of both hands and lower forearms) |
|  |  |
| weight fraction sodium benzoate  | 0.025% (w/w, expressed as benzoic acid) |
| dermal absorption  | 75% |
| Body weight | 60 kg |

**Calculations for scenario 8**

A consumer uses a laundry detergent liquid preserved with sodium benzoate at a maximal concentration of 2.5% (expressed as benzoic acid) to do the hand-wash laundry once daily. The default exposure scenario from ConsExpo 4.1 was used to perform the calculations. The default settings were applied, unless stated otherwise. As the vapour pressure of sodium benzoate is extremely low, its evaporation from aqueous solution is considered to be negligible; thus no respiratory exposure is expected. For dermal exposure the exposed area was set to 1948.8 cm2 (the area of both hands and lower forearms), while the body weight of the consumer was set to 60 kg according to HEEG Opinion 18 on Default human factor values for use in exposure assessments for biocidal products, endorsed at TM II 2013. It is assumed that not the total amount of diluted product is in contact with the skin but only a layer around the exposed skin. The TGD estimated the thickness of a product layer on the skin at 0.01 cm; thus, the amount of diluted product is 19.49 cm3, or 19.49 g. The weight fraction of the diluted laundry detergent in laundering solutions is 1%, thus the weight fraction of sodium benzoate in the in-use solution was calculated to be 0.025%. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). The resulting exposure estimates are presented in Annex 3.2. The internal systemic exposure to sodium benzoate is equal to 0.0609 mg/kg bw/day.

*Scenario 9: Use of all-purpose cleaners preserved with the product by non-professional users*

| **Description of Scenario 9** |
| --- |
| A consumer uses a liquid cleaner preserved with sodium benzoate at a maximal concentration of 2.5% (w/w, expressed as benzoic acid) to clean 10 m2 of furniture such as tables and cupboards in the living room. |
|  | Parameters | Value |
| Tier 1 | weight fraction sodium benzoate  | 0.031%(w/w, exposed as benzoic acid) |
| Dermal absorption | 75% |
| exposure area | 1948.8 cm2 (the area of both hands and lower forearms) |
| Body weight | 60 kg |

**Calculations for scenario 9**

A consumer uses a liquid cleaner preserved with sodium benzoate at a maximal concentration of 2.5% (w/w, expressed as benzoic acid) to clean 10 m2 of furniture such as tables and cupboards in the living room.The default exposure scenario from ConsExpo 4.1 was used to perform the calculations. As the vapour pressure of sodium benzoate is extremely low, its evaporation from aqueous solution is considered to be negligible; thus no respiratory exposure is expected. The application duration is considered to be 20 minutes (default ConsExpo 4.1). The default scenario assumes that 63 g of the product is diluted in 5 L water, which gives a dilution of 80 times. Therefore the resulting weight fraction of sodium benzoate in the generated solution is calculated as (2.5%/80 =) 0.031%. For dermal exposure, the exposed area was set to 1948.8 cm2 (the area of both hands and lower forearms), while the body weight of the consumer was set to 60 kg according to HEEG Opinion 18 on Default human factor values for use in exposure assessments for biocidal products, endorsed at TM II 2013. It is considered that the water layer of 0.01 cm comes into contact with the consumer skin; respectively, the product amount which can get absorbed through the skin, is calculated as (1948.8 cm2 x 0.01 cm x 1 g/cm3 =) 19.49 g (where 1 g/cm3 is taken as a default density of aqueous solution). Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). The resulting exposure estimates are presented in Annex 3.2. The internal systemic exposure to sodium benzoate is equal to 0.081 mg/kg bw/day ((19.49x0.031%x75%):60).

*Scenario 10: Exposure of general public to residues of the product in laundered clothing - adults*

| **Description of Scenario 10** |
| --- |
| An adult consumer is exposed to residues of sodium benzoate in laundered clothes via contact with skin. The total weight of the clothes is considered to be 1 kg.  |
|  | Parameters1 | Value |
| Tier 1 | leachable fraction (w/w, expressed as benzoic acid),  | 0.00575% |
| amount of clothes worn  | 1000 g |
| Dermal absorption  |  75% |
| Body weight | 60 kg |

**Calculations for Scenario 10**

After washing, residues of sodium benzoate from laundry detergents may remain on clothing and migrate from textile to skin, resulting in dermal exposure. As the vapour pressure of sodium benzoate is extremely low, its evaporation from fabric is considered to be negligible; thus no respiratory exposure is expected. The default exposure scenario from ConsExpo 4.1 was used to perform the calculations. It is assumed that a person wears clothes, e.g. underwear, nightclothes, blouses, trousers and socks 24 hours per day. The total weight of clothes that is worn per day, is assumed to be 1 kg (default ConxExpo 4.1). It is assumed that 115 g liquid laundry detergent is used per 5 kg laundry, and that 20% of the total product amount is remaining on the fabric (defaults ConsExpo 4.1). Based on this, the amount of liquid detergent that can adhere to the fabric, is calculated as (115/5 x 20%) = 4.6 g detergent/kg fabric. Because there are no data for the amount of detergent residues leaching from the textile, it is assumed that 50% is leachable (default ConsExpo 4.1). Respectively, the leachable weight fraction of sodium benzoate is calculated as (4.6 g/1000 g fabric x 2.5% x 50% =) 0.00575%. The amount of clothes that is worn by an adult is set to be 1000 g (RIVM Cleaning Product Fact Sheet, chap 4.3.3), and the body weight for an adult to 60 kg according to HEEG Opinion 18 on Default human factor values for use in exposure assessments for biocidal products, endorsed at TM II 2013. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). The internal systemic exposure to sodium benzoate is equal to (0.00575%x1000gx75%)= 43 mg/ day (0.72 mg/kg bw/day).

*Scenario 11: Exposure of general public to residues of the product in laundered clothing - infants*

| **Description of Scenario 11** |
| --- |
| The general public including a toddler and an infant (worst case) is exposed to residues of sodium benzoate in laundered clothes via contact with skin by wearing a pullover. The weight fraction transferred from the fabric to the skin is considered to be 1%.  |
|  | Parameters1 | Value |
|  | leachable fraction (w/w, expressed as benzoic acid),  | 0.00575% |
| Dermal absorption | 75% |
| Body weight  | 10 kg (toddler)8 kg (infant) |

**Calculations for Scenario 11**

After washing, residues of sodium benzoate from laundry detergents may remain on clothing and migrate from textile to skin, resulting in dermal exposure. As the vapour pressure of sodium benzoate is extremely low, its evaporation from fabric is considered to be negligible; thus no respiratory exposure is expected. In order to calculate the exposure of a child, the approach based on HERA Guidance Document Methodology (2005) was used in accordance with the HEEG Recommendation no. 6 on methods and models to assess exposure to biocidal products in different product types, v.2. The default exposure scenario of ConsExpo 4.1 is considered to be not representative for a child due to smaller clothes weight (i.e. it is considered unlikely that a toddler of 10 kg or an infant of 8 kg shall wear clothes weighing 1 kg). As the total body surface area (including the head) for an adult, toddler and infant is 16600 cm2 4800 cm2 and 4100 cm2, respectively, the expected clothes weight for a toddler and an infant will be 289 g and 247 g, respectively. It is assumed that 115 g liquid laundry detergent is used per 5 kg laundry, and that 20% of the total product amount is remaining on the fabric (defaults ConsExpo 4.1). Based on this, the amount of liquid detergent that can adhere to the fabric, is calculated as (115/5 x 20%) = 4.6 g detergent/kg fabric. Because there are no data for the amount of detergent residues leaching from the textile, it is assumed that 50% is leachable (default ConsExpo 4.1). Respectively, the leachable weight fraction of sodium benzoate is calculated as (4.6 g/1000 g fabric x 2.5% x 50% =) 0.00575%. The amount of clothes that is worn by a toddler and an infant is set to be 289 and 247 g. Dermal absorption of sodium benzoate was set at 75% in accordance with the EFSA Guidance on dermal absorption (2012). The internal systemic exposure to sodium benzoate is equal to

Toddler (0.00575%x289 gx75%)= 12.5 mg/day (1.24 mg/kg bw/day).

Infant (0.00575%x247 gx75%)= 10.7 mg/day (1.33 mg/kg bw/day).

*Scenario 12: Exposure of general public to residues of the product on washed dishware - adults*

| **Description of Scenario 12** |
| --- |
| An adult consumer is exposed to residues of sodium benzoate on washed dinnerware. The exposure is calculated in accordance with *Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017 - GUIDANCE ON ESTIMATING DIETARY RISK FROM TRANSFER OF BIOCIDAL ACTIVE SUBSTANCES INTO FOODS – NON-PROFESSIONAL USES*.  |
|  | Parameters | Value |
|  | Maximum percentage of sodium benzoate in dishwashing detergent | 2.5% |
| Concentration of detergent in dish wash solution  | 1400 mg/L |
| Amount of water left on dishes after rinsing (dilution factor for rinsing: 1/10 to be justified)  | 5.5 x 10-5 mL/cm2 |
| Area of dishes in daily contact with food  | 5400 cm2/d |
| Oral absorption | 100% |
| Body weight adult | 60 kg |

**Calculations for Scenario 12**

Oral exposure of adult consumers can occur because of residues on washed dinnerware. As the vapour pressure of sodium benzoate is extremely low, its evaporation from the residues on dinnerware is considered to be negligible; thus no respiratory exposure is expected. Dermal exposure is considered to be negligible in comparison to oral exposure. The calculations are performed based on “Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses” as included in the Guidance on BPR Vol III Part B+C, version 4.0 (Dec 2017). The value for amount of water left on dishes is 5.5 x 10-5 mL/cm2 and the value for the area of dishes in daily contact with food is 5400 cm2 (HERA guidance document Methodology, February 2005). It is considered that 7 g of dishwashing liquid are used per 5 L of water, thus the resulting dishwashing liquid concentration in water is 1.4 g/L. Subsequently, the total amount of ingested dishwashing liquid is calculated as (5.5 x 10-5 mL/cm2 x 5400 cm2 x 1.4 mg/mL =) 0.4158 mg. The maximal concentration of sodium benzoate in the dishwashing liquid is 2.5% (expressed as benzoic acid). Oral absorption of 100% is assumed for sodium benzoate. The body weight for an adult is set to 60 kg according to HEAd hoc recommendation no.14 on Default human factor values for use in exposure assessments for biocidal products. The resulting exposure estimates are presented in Annex 3.2. The internal systemic exposure to sodium benzoate is equal to 0.000175 mg/kg bw/day.

**Other information for scenario 12**

The guidance on estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses, establishes that the following points should be addressed:

- The possibility of degradation of sodium benzoate due to the elevated temperatures (70°C) and changes in pH (7 and 11) throughout a machine wash cycle of approximately 215 minutes.

- The potential degradation compounds (if any), its concentration and its toxicity.

The active substance is not prone to hydrolysis (PAR p.18). Therefore no exposure to degradation product of sodium benzoate is expected.

NL CA remark: Dietary exposure without rinsing should be considered as rinsing is not justified in the scenario description. Without rinisng, amount of water left on dishes is 5.5 x 10-4 mL/cm2, a factor 10 higher than the value used above. The internal systemic exposure to sodium benzoate is also 10 times higher without rinsing, i.e. 0.00175 mg/kg bw/day.

*Scenario 13: Exposure of general public to residues of the product on washed dishware - toddler*

| **Description of Scenario 13** |
| --- |
| A toddler is exposed to residues of sodium benzoate on washed dinnerware. The exposure is calculated in accordance with *Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017 - GUIDANCE ON ESTIMATING DIETARY RISK FROM TRANSFER OF BIOCIDAL ACTIVE SUBSTANCES INTO FOODS – NON-PROFESSIONAL USES*.  |
|  | Parameters1 | Value |
|  | Maximum percentage of sodium benzoate in dishwashing detergent | 2.5% |
| Concentration of detergent in dish wash solution  | 1400 mg/L |
| Amount of water left on dishes after rinsing (dilution factor for rinsing: 1/10 to be justified)  | 5.5 x 10-5 mL/cm2 |
| Area of dishes in daily contact with food  | 5400 cm2/d |
| Oral absorption | 100% |
| Body weight toddler | 10 kg |

**Calculations for Scenario 13**

Oral exposure of children can occur because of residues on washed dinnerware. The same default exposure scenario from “Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses” as included in the Guidance on BPR Vol III Part B+C, version 4.0 (Dec 2017) as for adults was used to perform the calculations, but the result was corrected for the body weight of 10 kg for a toddler. As the vapour pressure of sodium benzoate is extremely low, its evaporation from the residues on dinnerware is considered to be negligible; thus no respiratory exposure is expected. Dermal exposure is considered to be negligible in comparison to oral exposure. The total amount of ingested dishwashing liquid is calculated to be 0.4158 mg, the maximal concentration of sodium benzoate in the dishwashing liquid is 2.5% (expressed as benzoic acid). Oral absorption of 100% is assumed for sodium benzoate. The body weight for a toddler is set to 10 kg according to HEAd hoc recommendation no.14 on Default human factor values for use in exposure assessments for biocidal products. The resulting exposure estimates are presented in Annex 3.2. The internal systemic exposure to sodium benzoate is equal to 0.00105 mg/kg bw/day.

**Other information for scenario 13**

The guidance on estimating dietary risk from transfer of biocidal active substances into foods – non-professional uses, establishes that the following points should be addressed:

- The possibility of degradation of sodium benzoate due to the elevated temperatures (70°C) and changes in pH (7 and 11) throughout a machine wash cycle of approximately 215 minutes.

- The potential degradation compounds (if any), its concentration and its toxicity.

The active substance is not prone to hydrolysis (PAR p.18). Therefore no exposure to degradation product of sodium benzoate is expected.

NL CA remark: Dietary exposure without rinsing should be considered as rinsing is not justified in the scenario description. Without rinsing, amount of water left on dishes is 5.5 x 10-4 mL/cm2, a factor 10 higher than the value used above. The internal systemic exposure to sodium benzoate is also 10 times higher without rinsing, i.e. 0.0105 mg/kg bw/day.

*Scenario 15: Exposure of toddlers to residues of all-purpose cleaners*

| **Description of Scenario 15** |
| --- |
| A toddler is exposed to residues of sodium benzoate from all-purpose clearner applied on floor by crowling and hand-to-mouth ingestion. A toddler is assumed to stay on cleaned floor for 1 hour. |
|  | Parameters1 | Value |
|  | Concentration sodium benzoate | 0.031% |
| Indoor Transfer Coefficient  | 2100 cm2/h (HEAd hoc recommendation 12, child 1<2 yrs) |
| Exposure duration  | 1 h/day |
| Layer thickness of the applied cleaner on floor  | 0.01 cm |
| Transfer coefficient from floor  | 55% (TNsG 2007, White smooth glazed tile, dried fluid) |
| Amount of residue ingested by hand-to-mouth transfer | 10% of the total external exposure |
| Dermal absorption | 75% |
| Oral absorption | 100% |
| Body weight toddler | 10 kg |

**Calculations for Scenario 15**

As the vapour pressure of sodium benzoate is extremely low, its evaporation from the residues on dinnerware is considered to be negligible; thus no respiratory exposure is expected.

External exposure of a toddler is calculated as following:

2100 cm2/h x 1 h x 0.01 cm x55% transfer x 0.031% (expressed as benzoic acid)

= 3.58 mg external exposure

90% is exposed via skin and 10% is via oral route (hand-to-mouth)

Skin: 3.58 mg/day x 90% x 75% dermal absorption=2.42 mg/day = 0.24 mg/kg bw/day

Oral : 3.58 mg/day x 10% x 100% oral absorption = 0.36 mg/day = 0.04 mg/kg bw/day

Total 2.78 mg/day = 0.28 mg/kg bw/day for a toddler of 10 kg

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake\*** |
| Scenario 7 | Tier 1/no PPE | Negligible | 0.026 mg/kg bw/day  | Negligible | 0.026 mg/kg bw/day |
| Scenario 8 | Tier 1/no PPE | Negligible | 0.0609 mg/kg bw/day | Negligible | 0.0609 mg/kg bw/day |
| Scenario 9 | Tier 1/no PPE | Negligible | 0.081 mg/kg bw/day | Negligible | 0.081 mg/kg bw/day |
| Scenario 10 | Tier 1/no PPE | Negligible | 0.72 mg/kg bw/day | Negligible | 0.72 mg/kg bw/day |
| Scenario 11 | Tier 1/no PPE | Negligible | 1.24 mg/kg bw/day (toddler)1.33 mg/kg bw/day (infant) | Negligible | 1.24 mg/kg bw/day (toddler)1.33 mg/kg bw/day (infant) |
| Scenario 12 | Tier 1/no PPE | Negligible | Negligible | 0.00175 mg/kg bw/day | 0.00175 mg/kg bw/day |
| Scenario 13 | Tier 1/no PPE | Negligible | Negligible | 0.0105 mg/kg bw/day | 0.0105 mg/kg bw/day |
| Scenario 15 | Tier 1/no PPE | Negligible | 0.24 mg/kg bw/day | 0.04 mg/kg bw/day | 0.28 mg/kg bw/day |

\* Expressed as benzoic acid

*Combined scenarios*

It is assumed that the consumer can be exposed via all described exposure scenarios. Therefore a total combined systemic exposure for general public from all exposure scenarios has been calculated.

Furthermore, the combined exposure for a toddler from exposure to residues in laundered clothes, residues on the washed dinnerware and via cleaned surface has been calculated.

| **Summary table: combined systemic exposure from non-professional uses** |
| --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake\*** |
| Scenarios 7, 8, 9, 10, 12  | Negligible | 0.888 mg/kg bw/day | 0.00175 mg/kg bw/day | 0.890mg/kg bw/day |
| Scenarios 11, 13, 15 | Negligible | 1.48 mg/kg bw/day | 0.0505 mg/kg bw/day | 1.53 mg/kg bw/day |

\* Expressed as benzoic acid

Furthermore, industrial or professional users of the biocidal product may also be exposed to products preserved with sodium benzoate as consumers. Such worst case combined exposure for adults is calculated and presented in the table below.

| **Summary table: combined systemic exposure from industrial/professionals uses and exposure as the general public** |
| --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake\*** |
| Industrial workersScenarios 1 (Tier 2), 7, 8, 9, 10, 12  | 0.075 mg/kg bw/d | 2.03 mg/kg bw/day | 0.00175 mg/kg bw/day | 2.04 mg/kg bw/day |
| Professional workersScenarios 3, 4, 5, 7, 8, 9, 10, 12 | 0.0027 mg/kg bw | 4.10 mg/kg bw/day | 0.00175 mg/kg bw/day | 4.10 mg/kg bw/day |

***Monitoring data***

No monitoring data are available.

***Dietary exposure***

The exposure of general public to residues of the biocidal product on the washed dinnerware has been assessed in the previous section (Scenario 12 & 13).

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

| **Summary table of other (non-biocidal) uses** |
| --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s)** |
| 1. | Food additive | Sodium benzoate is used as a food preservative (E211) in the European Union | ADI = 5 mg/kg bw/day2 (expressed as benzoic acid) |
| 2. | Cosmetic products | Preservative in cosmetic products with a maximal concentration of 0.5%, as regulated by the EU Cosmetics directives 76/768/EEC | Full group ADI for benzoic acid and its salts of 0-5 mg/kg bw/day3  |
| 3 | Cosmetic products | Non-preservative purposes in cosmetic rinse-off products at a maximal concentration of 2.5%, in cosmetic oral-care products at a maximum concentration of 1.7%, and in leave-on products up to 0.5%.  | Full group ADI for benzoic acid and its salts of 0-5 mg/kg bw/day3 |
| 4 | Medicinal products | In oral medicines up to 0.5%, in parenterally administered drugs up to 0.5% | ADI = 5 mg/kg bw/day2 (expressed as benzoic acid) |

1 e.g. plant protection products, veterinary use, food or feed additives

2 EFSA Scientific Opinion on the re-evaluation of benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213) as food additives. EFSA Journal 2016, 14 (4) 4433

3Scientific Committee on Consumer Products (SCCP). Opinion on benzoic acid and sodium benzoate. SCCP/0891/05, adopted by the SCCP during the 4th plenary of 21 June 2005.

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

No livestock exposure is envisaged for PT6 applications.

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

**Scenario 14: Transfer of biocidal product residues into food as a result of cleaning of the surfaces which may come into contact with food**

A transfer of residues of the biocidal product into food may occur if the surfaces that are cleaned with treated articles that are preserved with the product, come into contact with food (e.g. kitchen tops). Professional users may use either cleaning liquids diluted in water to clean the surfaces with a wrung cloth, or hand-held trigger sprays to clean small surface areas. In the latter case, however, the cleaning liquids are sprayed on the surface and subsequently wiped off with a wet cloth, or washed with water, thus no residues of the product are expected to remain on the surface. In the first case, the dried residues of the cleaning solution may remain on the surface and come in contact with food, which will subsequently be consumed by general public.

The approach used to calculate the secondary exposure of general public to biocidal product residues in food is similar to the method used to calculate secondary oral exposure of general public to biocidal product residues on the washed dinnerware. According to the Cleaning Products Fact Sheet (RIVM report 320104003/2006), the surface of the kitchen top is 1.71 m2, or 17100 cm2. The amount of water left on the surface is considered to be the same as the amount of water left on the washed dinnerware, and is equal to 5.5 x 10-5 mL/cm2. According to the Cleaning Products Fact Sheet, 63 g of an all-purpose cleaner liquid is diluted in a bucket with 5 L water. The resulting cleaner concentration is thus 12.6 g/L, or 12.6 mg/mL. Subsequently, the total amount of the ingested cleaning liquid is calculated as (5.5 x 10-5 mL/cm2 x 17100 cm2 x 12.6 mg/mL =) 11.85 mg. Oral absorption of 100% is assumed for sodium benzoate. The body weight for an adult is set to 60 kg according to HEAd hoc recommendation no.14 on Default human factor values for use in exposure assessments for biocidal products. The resulting exposure estimates are presented in Annex 3.2. The resulting internal exposure to sodium benzoate is 0.00493 mg/kg bw/day.

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

This scenario is considered to be covered by Scenario 13 (Transfer of biocidal product residues into food as a result of cleaning of the surfaces which may come into contact with food).

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

The biocidal product Kalaguard® SB is 100% sodium benzoate (>99.9% pure). Thus exposure associated with production, formulation and disposal of the product is in fact identical to the exposure association with production and disposal of the active substance. This type of exposure is usually addressed at the active substance evaluation stage under the Review Programme. As sodium benzoate is included in Annex I of Biocidal Product Regulation, no specific assessment of exposure associated with its production and disposal is considered to be necessary. Furthermore, sodium benzoate is also an industrial substance registered under REACH, and its complete lifecycle, including the manufacture and disposal, is addressed under the REACH regulation.

***Aggregated exposure***

As currently no guidance is available on the estimation of aggregated exposure, this exposure was not assessed.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** |
| --- |
| **Scenario number** | **Exposed group****(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** |
| 1. Mixing and loading (formulation of Kalaguard® SB into treated articles) | Industrial users | 1/No PPE  | 114.4 mg/kg bw/day |
|  |  | 2/ PPE (gloves) | 1.12 mg/kg bw/day |
| 2. Use of laundry detergent liquids preserved with the product by professionals | Professionals | 1/No PPE | 0.0626 mg/kg bw/day |
| 3. Use of floor cleaner liquids preserved with the product for mopping the floor with a mop and a wringer bucket by professional users | Professionals | 1/No PPE | 1.92 mg/kg bw/day |
| 4. Use of all-purpose cleaner liquids preserved with the product for surface wiping by professional users | Professionals | 1/No PPE | 0.95 mg/kg bw/day |
| 5. Surface cleaning by professional users using hand-held trigger cleaning spray preserved with the product | Professionals | 1/No PPE | 0.340 mg/kg bw/day  |
| 6. Use of dishwashing liquids preserved with the product for cleaning of dishes manually by professional users in the catering industry | Professionals | 1/No PPE | 1.9x10-4 mg/kg bw/day |
| 7. Use of dishwashing liquids preserved with the product by general public | Consumers | 1/No PPE | 0.026 mg/kg bw/day |
| 8. Use of laundry detergent liquids preserved with the product by general public | Consumers | 1/No PPE | 0.0609 mg/kg bw/day |
| 9. Use of all-purpose cleaners preserved with the product by general public | Consumers | 1/No PPE | 0.081 mg/kg bw/day |
| 10. Exposure of general public to residues of products in laundered clothing - adults | General public | 1/No PPE | 0.72 mg/kg bw/day |
| 11. Exposure of general public to residues of products in laundered clothing – toddler and infant | General public | 1/No PPE | 1.24 mg/kg bw (toddler)1.33 mg/kg bw/day (infant) |
| 12. Exposure of general public to residues of dishwashing liquids preserved with the product on washed dinnerware - adults | General public | 1/No PPE | 0.00175 mg/kg bw/day |
| 13. Exposure of general public to residues of dishwashing liquids preserved with the product on washed dinnerware - toddler | General public | 1/No PPE | 0.0105 mg/kg bw/day |
| 14. Transfer of biocidal product residues into food as a result of cleaning of the surfaces which may come into contact with food | General public | 1/no PPE | 0.00493 mg/kg bw/day |
| 15. Exposure of toddlers to residues of all-purpose cleaners | General public | 1/no PPE | 0.28 mg/kg bw/day |
| Combined exposure Scenario 3, 4 and 5 | Professionals | 1/no PPE | 3.21 mg/kg bw/day |
| Combined exposure scenario 7, 8, 9, 10, 12 | General public (adults) | 1/no PPE | 0.890 mg/kg bw/day |
| Combined exposure scenario 11, 13, 15 | General public (toddler) | 1/no PPE | 1.53 mg/kg bw/day |
| Combined exposureScenario 1 (Tier 2), 7, 8, 9, 10, 12  | Industrial workers (including exposure as general public) | 2/gloves (scenario 1)1/no PPE(scenario 7-12) | 2.04 mg/kg bw/day |
| Combined exposure Scenario 3, 4, 5, 7, 8, 9, 10, 12 | Professional workers (including exposure as general public) | 1/no PPE | 4.10 mg/kg bw/day |

### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | Multigeneration study with rats; supported by available subacute and subchronic data | 500 mg/kg bw/day | 100 | None (100% oral absorption) | 5 mg/kg bw/day |
| AELmedium-term | Multigeneration study with rats; supported by available subacute and subchronic data | 500 mg/kg bw/day | 100 | None (100% oral absorption) | 5 mg/kg bw/day |
| AELlong-term | Multigeneration study with rats | 500 mg/kg bw/day | 100 | None (100% oral absorption) | 5 mg/kg bw/day |
| ARfD | - | - | - | - | Not derived |
| ADI | Multigeneration study with rats | 500 mg/kg bw/day | 100 | None (100% oral absorption) | 5 mg/kg bw/day |

1 Please explain background and reason for assessment factor.

For an analogue and a precursor of sodium benzoate, benzoic acid, the acute, medium- and long-term AEL of 5 mg/kg bw/day has been derived under the BPR Review Programme for benzoic acid for PT3 and 4, using the NOAEL of 500 mg/kg bw/day derived from a multi-generation study with rats (2.2.6.3-1). This study was submitted as a part of the IUCLID active substance dataset within the current application. It has been published in public literature and is no longer data-protected. In this study, no changes in body weight gain (data supplied only for up to 12/8 weeks for M/F) and histopathology of key organs performed after wk 16 were reported at the top dose of 500 mg/kg bw/day benzoic acid. Survival at this dose remained unaffected. NOAELs reported in other studies were between 500 and 1360 mg/kg bw/day (all other human toxicological studies included in the CAR of benzoic acid are publically available and are no longer data-protected). Mortalities and CNS effects observed at doses ≥ 1200 mg/kg bw/day are considered to be related to metabolic acidosis after saturation of glycine and glucuronate conjugation pathways. By setting a default assessment factor of 100, an acute and medium-term AEL of 5 mg/kg bw/day has been derived. Adverse toxic effects of benzoic acid were usually observed after repeated bolus doses within a short time. This can be explained by metabolic interference following saturation of the conjugation pathways and/or depletion of glycine/glucuronate. Thus, it appears unlikely that prolongation of exposure from subchronic to chronic aggravates benzoic acid toxicity. In addition, no additional target organs or adverse effects were reported after chronic exposure, neither in animals nor in humans from the use as food additive or therapeutic drug. Therefore, a NOAEL of 500 mg/kg bw/d is considered as the relevant basis for setting a systemic reference dose for long-term exposure to benzoic acid. By setting a default assessment factor of 100, a long-term AEL of 5 mg/kg bw/day has been derived for benzoic acid.

The EFSA Panel on Food Additives and Nutrient Sources has evaluated benzoic acid and a number of benzoate salts, including sodium benzoate, in 2016 (2.2.6.3-2) and derived the AEI of 5 mg/kg bw/day (expressed as benzoic acid) using the NOAEL of 500 mg/kg bw/day from the same study and applying the default assessment factor of 100.

Also, the a.s. sodium benzoate used in the biocidal product is intended to be produced as food quality product adhering to the requirements of Commission regulation (EU) No 213/2012 for sodium benzoate (E211) (see Confidential information for the statement).

Based on the above assessment of the toxicological data, the short-, medium- and long-term AEL and ADI of 5 mg/kg bw/day (expressed as benzoic acid) shall be used in the risk assessment of sodium benzoate in this PAR.

**Maximum residue limits or equivalent**

The maximum level (ML) for sodium benzoate as food additive E 211 is set to be 150 – 5000 mg/kg depending on food commodity, according to EU database on Food Additives (https://webgate.ec.europa.eu/foods\_system/main/).

**Specific reference value for groundwater**

Not derived.

***Risk for industrial users***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 1: addition of the biocidal product to the treated articles (mixing and loading) | Tier 1/no PPE | 500 | 5 | 114.4 | 2288 | no |
|  | Tier 2/ PPE (gloves) | 500  | 5 | 1.12 | 22.4 | yes |

**Combined scenarios**

No combined exposure scenarios are envisaged for industrial users.

**Local effects**

Sodium benzoate causes eye irritation; a qualitative risk assessment for this effect has been performed as summarized in the table below. The risk was concluded to be acceptable for all industrial uses. Considering the product will be used by trained professionals, risk of adverse effects is considered to be minimized by following the instructions carried on the label and good working practices.

|  |  |  |
| --- | --- | --- |
| Hazard | Exposure | Risk |
| Hazard category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk | Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓) |
| low | Eye irrit. Cat 2, H319 | - | 6 | industrial users | Mixing and loading (formulation of the product into treated articles) | skineye (splashes, hand to eye transfer) | 10 minutes per day | n.r. | labelling as eye irritantinstructions for use minimizing exposure for professionalspackaging reducing risk for eye exposure by splasheswashing of hands after useeye protector assigned in the labelling (P280g) | Acceptable: +Reversible effect +professionals following instructions for use +experience expected+appropriate PPE (eye protection) | Instructions for use and packaging as well as adherence to it, including washing of hands may vary (↑↓) |

**Conclusion**

Based on the results of the risk assessment, no adverse effects are expected for protected industrial users (gloves, eye protection) from exposure to sodium benzoate during automated or manual addition of the product Kalaguard® SB into the treated articles.

***Risk for professional users***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 2: use of laundry detergent liquids preserved with the product by professionals | 1 / no PPE | 500 | 5 | 0.0626 | 1.25 | Yes |
| Scenario 3: use of floor cleaner liquids preserved with the product for the mopping of the floor with a mop and a wringer bucket by professionals | 1 / no PPE | 500 | 5 | 1.92  | 38.4 | Yes |
| Scenario 4: use of all-purpose cleaner liquids preserved with a product to wipe surfaces with a wrung cloth | 1 / no PPE | 500 | 5 | 0.95 | 19 | Yes |
| Scenario 5: use of hand-held trigger cleaning sprays preserved with the product for surface cleaning | 1 / no PPE | 500 | 5 | 0.340 | 6.8 | Yes |
| Scenario 6: use of dishwashing liquids preserved with the product for cleaning of dishes manually by professional users in the catering industry | 1 / no PPE | 500 | 5 | 1.9x10-4 | <1 | Yes |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenarios 3, 4, 5 | Tier 1/no PPE | 500 | 5 | 3.21 | 64.2 | Yes |

**Local effects**

Sodium benzoate is classified as irritating to eyes; however, its maximal concentration of 2.5% (expressed as benzoic acid) in treated articles is below the classification limit for eye irritation according to Regulation 1272/2008/EC. Respectively, no adverse local effects due to exposure to sodium benzoate in treated articles is expected, and no risk assessment is necessary.

**Conclusion**

Based on the results of the risk assessment, no adverse effects are expected for unprotected professional users from exposure to sodium benzoate due to the use of treated articles preserved with the product, during loading of liquid laundry detergents into washing machines, mopping of the surfaces using a mop and a wringer bucket, wiping of the surfaces using a wrung cloth, and cleaning of the surfaces using a hand-held trigger spray.

No adverse effects are expected for unprotected professional users from combined exposure to sodium benzoate due to the use of treated articles preserved with the product from mopping of the surfaces using a mop and a wringer bucket, wiping of the surfaces using a wrung cloth, and cleaning of the surfaces using a hand-held trigger spray.

***Risk for the non-professional users (consumers) and general public***

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 7: use of dishwashing liquids preserved with the product by non-professional users | 1  | 500 | 5 | 0.026 | <1 | Yes |
| Scenario 8: use of laundry detergent liquids to do a hand-wash laundry by non-professional users | 1  | 500 | 5 | 0.0609 | 1.22 | Yes |
| Scenario 9: use of a liquid cleaner to clean 10 m2 furniture by non-professional users | 1  | 500 | 5 | 0.081 | 1.62 | Yes |
| Scenario 10: exposure to residues in laundered clothes via contact with skin, adults | 1  | 500 | 5 | 0.72 | 14.4 | Yes |
| Scenario 11: exposure to residues in laundered clothes via contact with skin, toddler and infant | 1  | 500 | 5 | 1.24 (toddler)1.33 (infant)  | 24.9(toddler)26.6 (infant) | Yes |
| Scenario 12: oral exposure to residues on the washed dinnerware, adults | 1 | 500 | 5 | 0.00175 | <1 | Yes |
| Scenario 13: oral exposure to residues on the washed dinnerware, toddler | 1 | 500 | 5 | 0.0105 | <1 | Yes |
| Scenario 15: Exposure of toddlers to residues of all-purpose cleaners | 1 | 500 | 5 | 0.28 | 5.6 | yes |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenarios 7, 8, 9, 10, 12 (adult) | 1 | 500 | 5 | 0.890 | 17.8 | Yes |
| Scenarios 11, 13, 15 (toddler) | 1 | 500 | 5 | 1.53 | 30.6 | Yes |
| Scenarios 1 (Tier 2), 7, 8, 9, 10, 12 (industrial workers) | 2 (scenario 1),1 (scenario 7-12) | 500 | 5 | 2.04 | 40.8 | Yes |
| Scenarios 3, 4, 5, 7, 8, 9, 10, 12 (professional workers) | 1 | 500 | 5 | 4.10 | 82 | Yes |

**Local effects**

Sodium benzoate is classified as irritating to eyes; however, its maximal concentration of 2.5% (expressed as benzoic acid) in treated articles is below the classification limit for eye irritation according to Regulation 1272/2008/EC. Respectively, no adverse local effects due to exposure to sodium benzoate in treated articles is expected, and no risk assessment is necessary.

**Conclusion**

Based on the results of the risk assessment, no adverse effects are expected for general public users from exposure to sodium benzoate due to the use of treated articles preserved with the product, during the use of dishwashing liquids, laundry detergents, and cleaners. No adverse effects are expected for general public, including children, from exposure to sodium benzoate residues on laundered clothes and on washed dinnerware.

No adverse effects are expected for general public from combined exposure to sodium benzoate due to the use of treated articles preserved with the product from the use of dishwashing liquids, laundry detergents, and cleaners, and residue exposure on the laundered clothes and washed dishware. No adverse effects are expected for children from combined exposure to sodium benzoate due to residue exposure on the laundered clothes and washed dishware.

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenario 14: exposure to residues in food due to transfer from cleaned surfaces (e.g. kitchen tops) | 13 | 500 | 5 | 0.00493 | 0.10 | Yes |

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

The biocidal product Purox® Clean contains 100% sodium benzoate (> 99.9% (w/w) pure). It does not contain any substances of concern and is not intended to use in combination with other active substances.

## Risk assessment for animal health

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There could also be animal exposure when using the biocidal product because animals could have contact to surfaces treated with all-purpose cleaners and to laundered bed clothes or other textiles. Cats seem to be more sensitive than other species (reports of sodium benzoate of WHO 2000, 2005). In cats, glucuronidation is generally very low. As glucuronidation is one of the detoxification routes for benzoic acid, cats may be sensitive to sodium benzoate than other species.

The exposure of animal including cats is however covered with a toddler dermal exposure and hand-to-mouth exposure (scenario 15). The LD50 for cats is reported to be 450 mg/kg bw, which is lower than LD50 for rodents that are reported to be >1940 mg/kg bw. The interspecies difference is 4.3-fold. As for the toddler risk assessment a safety factor of 100 was applied to derive the AEL of 5 mg/kg bw for human from the NOAEL 500 mg/kg bw for rats, and considering the exposure of toddler was calculated to be only 5.6% of the AEL, the exposure for domestic animals including cats to sodium benzoate is not expected to cause adverse effects from the use of Purox Clean.

## Risk assessment for the environment

The biocidal product Kalaguard® SB is a 100% (w/w) formulation of sodium benzoate (>99.99 (w/w) pure), thus the studies conducted with sodium benzoate are applicable for the biocidal product and vice versa. Respectively, the terms “biocidal product” and “sodium benzoate” are used interchangeably.

As sodium benzoate is an Annex I substance, for which no dossier has been submitted at the EU level, the active substance dataset in accordance with Annex II requirements of the BPR has been submitted as a part of the IUCLID dossier within the current application.

### Effects assessment on the environment

The following data were provided for the active substance sodium benzoate. As the product is identical to the active substance, the data can be considered product data.

|  |
| --- |
| **Summary table of further ecotoxicological studies** |
| **Method, Guideline, GLP status, Reliability** | Species/Inoculum | Endpoint | Exposure | Results | Remarks | Reference |
| Design | Duration | NOEC | EC10 | EC50 |
| **Fish** |
| EPA OPP 72-1; not GLP; reliability 2 | *Pimephales promelas* | Mortality | Flow-through | 96h | - | - | **484** | Key study; mean measured concentration of sodium benzoatea  | 9.2.1.1; xxxxx (Ref. no. 2.2.8-1) |
| OECD 203; not GLP; reliability 3 | *Pimephales promelas* | Mortality | Static | 96h | - | - | >100 | Supporting study; nominal concentration of sodium benzoate | 9.2.1.1; xxxxx (Ref. no. 2.2.8-2) |
| No guideline followed; not GLP; reliability 3 | *Danio rerio* | Malformations | Semi-static | 24h | 10 | - | - | Supporting study; nominal concentration of sodium benzoate | 9.2.1.6.1; xxxxx (Ref. no. 2.2.8-3) |
| **Aquatic invertebrates** |
| OECD 202; GLP; reliability 2 | *Daphnia magna* | Mobility | Semi-static | 48h | - | - | **>142** | Key study; read across benzoic acid; nominal concentration of benzoic acidb, c | 9.2.1.2; xxxxx (Ref. no. 2.2.8-4) |
| OECD 211 (1998); GLP; reliability 1  | *Daphnia magna* | Mortality and reproduction | Semi-static | 21d | **29.5** | - | **-** | Key study; read across benzoic acid; nominal concentration of benzoic acidc,d | 9.2.1.6.2; xxxxx (Ref no. 2.2.8-12) |
| OECD 202; not GLP; reliability 2 | *Daphnia magna* | Mobility | Static | 48h | - | - | 1015 | Supporting study; read across benzoic acid; nominal concentration of benzoic acidc | 9.2.1.2; xxxxx (Ref. no. 2.2.8-5) |
| OECD 202; not GLP; reliability 3 | *Daphnia magna* | Mortality | Static | 96h | - | - | >100 | Supporting study; nominal concentration of sodium benzoate | 9.2.1.2; xxxxx (Ref. no. 2.2.8-2) |
| No guideline followed; not GLP; reliability 4 | *Daphnia magna* | Mobility | Not specified | 48h | - | - | 650 | Supporting study; nominal concentration of sodium benzoate | 9.2.1.2; xxxxx (Ref. no. 2.2.8-6) |
| **Algae**  |
| OECD 201; GLP; reliability 2 | *Pseudokirchneriella subcapitata* | Growth rate | Static | 72h | - | - | **>30.5** | Key study; TWA concentration of sodium benzoatee | 9.2.1.3; xxxxx (Ref. no. 2.2.8-7) |
| **Microorganisms** |
| OECD 209; not GLP; reliability 2 | Activated sludge | Respiration inhibition | Static | 3h | - | - | **>1180** | Key study; read-across benzoic acid; nominal concentration of benzoic acidc,f | 9.2.1.5; xxxxx (Ref. no. 2.2.8-8) |
| No guideline followed; not GLP; reliability 4 | *Achromobacter* sp. | Growth inhibition | Not specified | 168h | - | - | >100 | Supporting study; nominal concentration of sodium benzoate | 9.2.1.5; xxxxx (Ref. no. 2.2.8-9) |

a Only mean measured concentrations were reported and therefore endpoint was based on mean measured.

b Chemical analysis was performed every 24 hours and measured concentrations were >80% throughout the study. Therefore mean measured concentrations were used to establish endpoints.

c Endpoint from toxicity studies performed with the structural analogue benzoic acid (pH adjusted), which is a precursor of sodium benzoate, were recalculated considering the difference in molecular weight (122.12 g/mol for benzoic acid and 144.11 /mol for sodium benzoate).

d As stated in the Assessment Report for benzoic acid (2013) the (initial) recovery rate in the test media was >90% and therefore the results were based on nominal concentrations.

e Chemical analysis was performed at 0, 24 and 72 hours after test start. After 24 hours the three lowest concentrations dropped below LOD (< 0.004 mg/L) and after 72 hours all concentrations were below LOD. As statistically significant effects on growth rate and yield were only observed at the two highest test concentrations, TWA concentrations were used to establish 72-hour endpoints.

f No chemical analysis was performed. However, for this three hour test the nominal test concentrations are considered sufficient.

Various studies with aquatic organisms are available as part of the product data. Part of the studies are considered supporting data.

In the study by xxxxx various organisms, including *Pimephales promelas* and *Daphnia magna*, were exposed under static conditions for 96 hours, after which survival, condition and behaviour were assessed. Results were based on nominal concentrations, as a chemical analysis was not performed. However, decline of the concentration of the test substance may be expected, as indicated by the algae study by xxxxx discussed below. Moreover, the number of replicates and test organisms (one replicate with ten organisms) was lower than recommended for *Daphnia magna* in OECD 202. Hence, the study was not considered reliable.

The key study by xxxxx is a flow-through test with *Pimephales promelas* exposed to sodium benzoate. The study is considered reliable and the endpoint is based on mean measured concentrations.

The study by xxxxx presents the exposure of zebrafish embryos (48 hours post fertilization) to sodium benzoate (1-2000 mg/L) for a period of 24 hours, under static conditions, after which survival and motility were assessed. This study also does not include chemical analysis of test substance concentrations. No guideline was followed, but when considering relevant guidelines (OECD 212 and 236) the embryos used in the test are older than recommended (both OECD GDs recommend to use embryos as soon as possible after fertilization) and exposure is shorter than discussed in these OECD GDs (3-5 days and 96 hours in OECD 212 and 236, respectively). Moreover, both guidelines state that short-term testing with embryos may be used to assess acute toxicity to fish or as a screening for chronic toxicity, but that any reduced exposure with respect to life stages may reduce the sensitivity and thus underestimate the chronic toxicity. Reduction of the exposure duration to 24 hours reduces the sensitivity further. Moreover, mortality was only tested at one concentration (1000 mg/L) for a prolonged period of 144 hours, which demonstrated that mortality rates followed a time-dependent manner, with mortality increasing over time to 100% mortality at 144 hours. Hence, it was not possible to obtain a reliable NOEC from this study.

Data are lacking on controls, dissolved oxygen concentrations and chemical analysis for the study by Kamaya et al. (2005). Hence, the study is not considered reliable for PNEC derivation.

The study by xxxxx only presents an endpoint for daphnids acutely exposed to sodium benzoate when added to Lake Erie water. No other details (applied guideline, test conditions, test concentrations, number of replicates and animals per test concentration etc.) were provided. Hence, the study is not considered reliable for the PNEC derivation.

A study by xxxxx with *Daphnia magna* acutely exposed to benzoic acid is available from the Assessment Report for benzoic acid (2013). The agreed endpoint is also considered relevant for the assessment of sodium benzoate.

One long-term test with *Daphnia magna* (xxxxx) exposed to benzoic acid is available. This study was evaluated in the Assessment Report for benzoic acid (2013) and the agreed endpoint for this study is also considered relevant for this assessment.

In the *Pseudokirchneriella subcapitata* study by xxxxx measured concentrations declined rapidly; below the limit of detection within 24 hours for the lowest test concentrations. Therefore, it is considered that the study is sufficient to obtain an ErC50 value (higher than the highest test concentration), but that it is not possible to obtain reliable NOEC or EC10 values.

A study with activated sludge exposed to benzoic acid (xxxxx) is available from the Assessment Report for benzoic acid (2013). The agreed endpoint is also considered relevant for the assessment of sodium benzoate.

The study by xxxxx describes bacteria species found in rotten canned herring and their behavior towards salt and preservatives. The study does not provide information on the microbial degradation of sodium benzoate in sewage sludge. Hence, the study is not considered relevant for the PNEC derivation.

The PNEC was derived using only data from studies with reliability 1 or 2. The endpoints in bold in the table above were considered most relevant to derive the PNEC. Acute aquatic toxicity data are available for all of the 3 trophic levels fish, aquatic invertebrates and algae. The L(E)C50 values derived from the key studies are 484 mg/L for fish, and above the highest tested concentration in daphnids (>142 mg/L) and algae (>30.5 mg/L). One chronic key study is available for daphnids (29.5 mg/L).

All key acute toxicity values are based on measured concentrations, but the key chronic study is based on nominal concentrations (based on evaluation in the Assessment Report for benzoic acid (2013)). Various toxicity studies were performed with the structural analogue benzoic acid (pH adjusted), which is a precursor of sodium benzoate. The benzoic acid based endpoints were recalculated, considering the difference in molecular weight (122.12 g/mol for benzoic acid and 144.11 /mol for sodium benzoate).

As the acute data do not clearly indicate that one trophic level is more sensitive (lowest values are higher-than-values), a test with invertebrates is considered sufficient for PNEC derivation. Based on an assessment factor of 100, the PNEC freshwater is 0.30 mg sodium benzoate/L.

For microorganisms, a 3-h IC50 value of >1180 mg sodium benzoate/L was determined in a study with the structural analogue benzoic acid. Based on an assessment factor of 100 for such available data, the PNECstp is 11.8 mg sodium benzoate/L.

No experimental data on the toxicity to sediment and soil species is available for the substance and therefore PNECs are calculated using the equilibrium partitioning method (EPM) and the PNEC for freshwater. The PNEC for freshwater sediment is 0.23 mg/kg sediment ww (1.1 mg/kg dw) and the PNEC for soil 0.035 mg/kg ww (0.039 mg/kg dw). The Koc of 0.0172 L/kg is used in the equations (see also section 2.2.8.2 Exposure assessment).

All relevant PNECs for sodium benzoate are presented in the table below:

|  |
| --- |
| **Hazard assessment conclusion for the environment** |
| **Compartment** | **Hazard conclusion** | **Remarks/Justification** |
| Freshwater | PNEC: 0.30 mg/L | Acute toxicity data are available at 3 trophic levels and one chronic study is available. The chronic endpoint is a NOEC of . Based on the available information, the assessment factor is 100. |
| Marine water | - | The marine environment is not considered relevant for the exposure due to the intended use. |
| Sediments (freshwater) | PNEC:0.23 mg/kg sediment ww | No experimental data on sediment organisms is available. Therefore the PNEC for freshwater sediment is derived using the equilibrium partitioning method. In the calculation the PNEC for freshwater of 0.30 mg/L and the adsorption coefficient (Koc) of 0.018 L/kg are used. Related to dry weight, the PNEC sediment is 1.1 mg/kg dw.As both the PNEC for sediment and the PEC for sediment need to be derived by using equilibrium partitioning with freshwater data, the risk assessment for freshwater also covers the risks for the sediment compartment.  |
| Sediments (marine water) | - | The marine environment is not considered relevant for the exposure due to the intended use. |
| Sewage treatment plant (STP) | PNEC: 11.8 mg/L | In an activated sludge respiration inhibition test an EC50 value of >1000 mg benzoic acid/L was determined. The assessment factor is 100. This value was converted to sodium benzoate, based on molecular weights |
| Soil | PNEC: 0.035 mg/kg soil ww | No experimental data on soil organisms are available. Therefore the PNEC for soil is derived using the equilibrium partitioning method. In the calculation the PNEC for freshwater of 0.30 mg/L, the adsorption coefficient (Koc) of 0.018 L/kg, and the Henry's law constant of 3.76E-05 Pa·m³/mol (at 12 °C as calculated by EUSES) are used. Related to dry weight, the PNEC for soil is 0.040 mg/kg dw. |
| Air | - | Not assessed (no hazard identified) |
| Secondary poisoning | - | Not assessed (low potential for bioaccumulation; log Kow value is ‑2.27) |

***Further Ecotoxicological studies***

Further data are not available.

|  |
| --- |
| **Data waiving** |
| Information requirement | No further data needed. |
| Justification | Data on fish (acute), daphnia (acute), algae and sewage sludge are available. |

***Endocrine disruption***

Not relevant because Kalaguard® SB only contains the active substance sodium benzoate, which has been approved for annex I inclusion, and no co-formulants.

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

No data are available.

|  |
| --- |
| **Data waiving** |
| Information requirement | Data not needed |
| Justification | The primary receiving compartment is the sewage treatment plant (STP), after which the aquatic compartment may be exposed. The bioaccumulation potential of the substance is expected to be low, as the Kow and Koc are very low, and therefore the risk assessment for the aquatic compartment is considered to also be protective of the sediment compartment. The soil compartment may also be exposed when sewage sludge is applied to the soil and a PNEC can be calculated using the equilibrium partitioning method. Hence, the available data on toxicity to activated sludge and aquatic organisms are sufficient for the risk assessment. |

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

No data are available.

|  |
| --- |
| **Data waiving** |
| Information requirement | Data not needed |
| Justification | The preserved product is not bait or granular formulation, and is intended for use indoors. Therefore, direct exposure to non-target organisms under field conditions is not expected. |

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

No data are available.

|  |
| --- |
| **Data waiving** |
| Information requirement | Data not needed |
| Justification | The preserved product is not bait or granular formulation and is intended for use indoors. Therefore, direct exposure to non-target organisms is not expected. |

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

No data are available.

|  |
| --- |
| **Data waiving** |
| Information requirement | Data not needed |
| Justification | The preserved product is intended for indoor use only. The primary receiving compartment is the sewage treatment plant (STP), after which the aquatic and soil compartments may be exposed. The substance is not expected to bioaccumulate, as the Kow and Koc are very low. Hence, the available data on toxicity to activated sludge and aquatic organisms are sufficient for the risk assessment.  |

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

Kalaguard® SB is intended for use as an in-can preservative in dishwashing liquids, laundry liquids and cleaners. Release to the environment will be via waste water only and therefore the primary receiving compartment is the sewage treatment plant (STP). Discharge of water from the STP to freshwater may occur, so the aquatic compartment and sediment compartment may be exposed. The soil compartment may also be exposed when sewage sludge is applied to the soil and therefore risks to soil organisms and groundwater are also assessed.

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

Data are included with the product dossier on biodegradation of the active substance; xxxxx 10.1.1.2 (Ref. no 2.2.8-10)) and xxxxx 10.1.1.2 (Ref. no 2.2.8-11)). These studies present screening for ready biodegradability according to OECD 301D for ammonium containing substances and OECD 301B for surfactants, respectively. The studies are regarded as supporting data (reliability 4), but it should be considered that sodium benzoate is used as a reference compound that meets the criteria for ready biodegradability in OECD 301 (1992). Hence, sodium benzoate is considered to be ready biodegradable.

***Leaching behaviour (ADS)***

No data are available as the product is not a treated article.

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

No data are available.

|  |
| --- |
| **Data waiving** |
| Information requirement | Data not needed |
| Justification | The primary receiving compartment is the sewage treatment plant (STP). The soil compartment may also be exposed when sewage sludge is applied to the soil. The active substance is ready biodegradable and has a very low log Koc. Default values for distribution and dissipation will be used in the risk assessment and no further data are required. |

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

No data are available.

|  |
| --- |
| **Data waiving** |
| Information requirement | Data not needed |
| Justification | The fate of the active substance is covered by the data provided for the active substance (it is well-soluble in water, ready biodegradable and has a low Koc value (0.018 L/kg)), as the product is identical to the active substance.  |

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

No data are available.

|  |
| --- |
| **Data waiving** |
| Information requirement | Data not needed |
| Justification | Sodium benzoate is well soluble in water and ready biodegradable. Furthermore, its vapour pressure is low. Moreover, the preserved product is intended for indoor use. Therefore, transformation in air is not relevant.  |

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

No data available.

|  |
| --- |
| **Data waiving** |
| Information requirement | No data needed |
| Justification | The preserved product is not intended for spraying near surface waters. |

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

No data available.

|  |
| --- |
| **Data waiving** |
| Information requirement | No data needed |
| Justification | The preserved product is not intended for spraying outside and there is no potential for formation of dust as the products are used in aqueous solutions. |

### Exposure assessment

The application of detergents and cleaning fluids (from here on referred to as ‘cleaning products’) takes place mainly in professional and non-professional settings. Use of cleaning products will generally be indoors (surface cleaning, dishwashing, laundry), and the primary receiving compartment is the sewage treatment plant (STP).

The formulation step is not assessed because the product is identical to the active substance i.e. no formulation takes place. Service life is not assessed because it is limited to the shelf life of the end-product in the can. Finally, the waste stage is not assessed because it is assumed that cleaning product containers are disposed of as domestic waste and will usually be incinerated.

The local release to wastewater is calculated as described in the ESD PT 6 (UBA, 2018). A single tonnage-based scenario is calculated and compared to the aggregated exposure of several consumption-based scenarios for both professional and non-professional uses. The most critical of these two approaches, i.e. the scenario with the highest local release to wastewater, is used for calculations of predicted environmental concentrations (PECs).

The PECs are calculated according to the Guidance on the Biocidal Product Regulation Volume IV: Environment - Part B+C (ECHA, 2017) by means of EUSES v2.1.2. The fate and emission of chemicals in STP is modelled using SimpleTreat v4.0 (RIVM, 2014), and the results of Simpletreat transferred to EUSES as described in the Technical Agreements for Biocides (TAB) v1.3 (ECHA, 2017). All values for parameters are based on defaults unless otherwise noted.

**General information professional and non-professional use**

Uses of in-can preservatives are typically wide dispersive. Professional uses and non-professional uses are assessed together which is in line with the approach presented in ESD PT 6.

In the ESD PT 6 a total of six scenarios are distinguished for both professional and non-professional uses.

First, a general *tonnage*-based scenario is defined for use of cleaning products in professional areas. This scenario also covers the non-professional areas when the entire EU volume is used in the equation (worst-case approach). Also, use of the entire EU volume in this scenario automatically covers aggregated exposure.

Second, two professional *consumption*-based scenarios are defined, one for surface cleaning (institutional areas) and one for large-scale laundry (washing streets in hospitals).

Finally, three non-professional *consumption*-based scenarios are defined for surface cleaning, fabric washing, and dish washing.

Releases from all the different consumption-based scenarios must be anticipated to end up in a single local STP, and therefore need to be summed in order to assess aggregated exposure.

|  |  |
| --- | --- |
| Assessed PT | PT 6 (Preservatives for Products during Storage) |
| Assessed scenarios | Scenario 1: Tonnage based; total EU volumeScenario 2: Consumption-based; all uses summed |
| ESD(s) used | PT 6 (UBA, 2018) |
| Approach | **Scenario 1:**Release to wastewater calculated based on total EU tonnage**Scenario 2:**Release to wastewater calculated based on aggregated exposure from both professional uses, and all three non-professional uses.Only the scenario with the highest local release to STP is further assessed. |
| Distribution in the environment | Calculated based on: BPR guidance Vol. IV; Part B+C, v2.0 (ECHA, 2017) |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenarios 1 and 2:Production: no**Formulation: yes****Use : yes**Service-life: noWaste-stage: no |
| Remarks | - |

The maximum concentration of sodium benzoate in the cleaning product is 2.95% (equivalent to 2.5% benzoic acid). Assuming a density of 1 kg/L, this relates to 0.0295 kg sodium benzoate/L.

***Emission estimation***

Direct releases from different use scenarios take place only via wastewater to the STP. The emissions are calculated based on the calculation tables presented in ESD PT 6 (UBA, 2018). For the tonnage scenario, the emission data (formulation step and use/application step) are presented in the confidential annex (Section 3.6). For the consumption scenarios, the outcome of the calculations is shown below.

**Consumption-based scenario [2]**

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Scenario 2-1: professional use in surface cleaning |
| Scenario 2-2: professional use in large-scale laundry |
| Scenario 2-3: non-professional use in surface cleaning |
| Scenario 2-4: non-professional use in fabric washing |
| Scenario 2-5: non-professional use in dish washing |
| Concentration of active substance in the product | 0.0295 | kg/L | Or kg/kg under assumption of density of 1 kg/L. |

Calculations for consumption-based scenarios

| **Resulting local emissions to relevant environmental compartments** |
| --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| professional use in surface cleaning | 0.059 | - |
| professional use in large-scale laundry | 4.25 | - |
| non-professional use in surface cleaning | 1.48 | - |
| non-professional use in fabric washing | 3.06 | - |
| non-professional use in dish washing | 0.43 | - |
| **STP aggregated exposure** | **9.27** | The total local emission calculated for consumption-based scenarios is worst-case compared to the tonnage-based approach. Therefore the consumption-based scenarios are used as input for further calculations (i.e. PECs and PEC/PNEC values) |

***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 | Other |
| Tonnage-based scenario 1 | Yes | Yes | No | No | Yes | No | Yes | Yes | Not relevant |
| Consumption-based scenario 2 | Yes | Yes | No | No | Yes | No | Yes | Yes | Not relevant |

|  |
| --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Molecular weight | 144.11 | g/mol | 4.4; xxxxx (Ref. no. 2.2.2-01)  |
| Vapour pressure  | 0.11 | Pa | 4.4; xxxxx (Ref. no. 2.2.2-01) |
| Water solubility | 556 | g/L | 8.5.2; xxxxx (Ref. no. 2.2.6.1-05) |
| Log Octanol/water partition coefficient | -2.27 | Log 10 | 8.5.2; xxxxx (Ref. no. 2.2.6.1-05) |
| Organic carbon/water partition coefficient (Koc) | 0.018 | L/kg | Calculated in Simpletreat (‘neutral substance’) |
| Biodegradability | Ready biodegradable  |  | 10.1.1.2; OECD 301 (1992) |
| Coefficient for sorption on organic matter (Kom) | 0.0106 | L/kg | Calculated using the Koc |
| Half-life in soil | 30 | d | Default value based on biodegradability |

Note: for further detail on input parameters, see IUCLID active substance dossier

|  |
| --- |
| **Calculated fate and distribution in the STP (Simpletreat v4.0)** |
| **Compartment** | **Percentage [%]** | **Remarks** |
| All scenarios |
| Air | 0.00 | SimpleTreat v4.0 with note 1 |
| Water | 8.02 |
| Sludge | 1.70x10-4 |
| Degraded in STP | 92.0 |

Note 1: SimpleTreat input and settings based on guidance in TAB v1.3 (ENV9)

***Calculated PEC values***

PEC values for surface water were calculated using equations from the BPR guidance Vol. IV; Part B+C, v2.0 (ECHA, 2017) and according to relevant exposure scenario documents (ESDs, release to the environment). For both professional and non-professional uses, the local emission value from scenario 2 (consumption-based – aggregated exposure) is entered as input for calculation of PECs. The PECs presented in the following sections are those based on aggregated exposure only, as this represents a worst-case approach.

|  |
| --- |
| **Summary table on calculated PEC values** |
| Scenario | **STP** | **Freshwater\*** | **Soil** | **Groundwater** |
| [mg/L] | [mg/L] | [mg/kg dw] | [µg/L] |
| Consumption-based aggregated exposure | 0.371 | 0.0371 | 2.97E-05 | 0.21 |

\* The risk assessment for the freshwater compartment also covers the risk to the (freshwater) sediment compartment

***Primary and secondary poisoning***

Primary poisoning

Not applicable as the product is intended for indoor use, and is not a rodenticide or pesticide.

Secondary poisoning

No data available. Sodium benzoate is unlikely to bioaccumulate in aquatic or terrestrial environment according to the BPR guidance Vol. IV; Part B+C, v2.0 (ECHA, 2017), as its log Kow value is low (‑2.27), the substance is not highly adsorptive, does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features do not indicate accumulation and the substance is readily biodegradable. The bioconcentration factor for fish is 0.0024 L/kg and the bioconcentration factor for earthworms is 0.841 L/kg as determined with EUSES v2.1.2. No further assessment of secondary poisoning via the food chain is therefore considered necessary.

### Risk characterisation

***Atmosphere***

Not a relevant receiving compartment, considering the indoor use of the product and the low vapour pressure of the active substance.

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

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECSTP** |
| Consumption-based aggregated exposure\* | 0.031 |

\*The assessment was based on the worst-case scenario, with the highest emission

Conclusion: The PEC/PNEC ratio based on aggregated exposure of all professional and non-professional uses is <1. The risk to micro-organisms in the STP is acceptable.

***Aquatic compartment***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECwater\*\*** |
| Consumption-based aggregated exposure\* | 0.12 |

\*The assessment was based on the worst-case scenario, with the highest local emission

\*\* The risk assessment for the freshwater compartment also covers the risk to the sediment compartment

Conclusion: The PEC/PNEC, based on aggregated exposure of all professional and non-professional uses, is 0.12. The risk to aquatic organisms and sediment organisms is considered acceptable.

***Terrestrial compartment***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECsoil** |
| Consumption-based aggregated exposure\* | <0.001 |

\*The assessment was based on the worst-case scenario, with the highest local emission

Conclusion: The PEC/PNEC based on aggregated exposure of all professional and non-professional uses is <1. The risk to terrestrial organisms is acceptable.

***Groundwater***

The local PEC for groundwater is 0.21 µg/L. This is above the cut-off of 0.1 µg/L and therefore afurther assessment is needed. Recently it was agreed at WG that only a worst case Pearl calculation is needed. These calculations were performed in different seasons for the grassland and arable land (winter cereals) on Jokionen soil, which is the most sensitive soil for leaching. For input parameters please refer to the table with input parameters in Section 2.2.8.2 and the used dosage in PEARL was as 1.43E-07 kg/ha/y for both soil types. The results showed that all PEC groundwater values are <0.0001 µg/L, below the cut-off of 0.1 µg/L. Therefore emission to groundwater is negligible.

***Primary and secondary poisoning***

Primary poisoning

Not relevant (see justification above).

Secondary poisoning

Not relevant (see justification above).

***Mixture toxicity***

Not applicable, the product contains one active substance and does not contain substances of concern.

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

Aggregated exposure is relevant based on the different professional and non-professional uses being wide dispersive uses with possible overlap in time and space. Following ESD PT 6 (UBA, 2018), the aggregated use of all five consumption-based sub-scenarios was assessed as a worst-case approach.

## Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of biocidal product

Store cool and dry, under well-ventilated conditions. Store this material away from incompatible substances (strong acids and oxidizing agents). Avoid contact with iron salts. Do not store in open, unlabelled or mislabelled containers. Keep container closed when not in use. Do not reuse empty container without commercial cleaning or reconditioning. Product will absorb water vapor (hygroscopic).

Recommended methods and precautions concerning handling

Wash hands thoroughly after handling. Wear eye protection. IF IN EYES: Rince cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: get medical advice/attention.

Particulars of likely direct or indirect adverse effects

Most important symptoms and effects, both acute and delayed:

Coughing, irritation. Preexisting sensitization, skin and/or respiratory disorders or diseases may be aggravated.

First aid instructions, antidotes

General: If irritation or other symptoms occur or persist from any route of exposure, remove the affected individual from the area: see a physician/get medical attention.

Eye contact: Immediately flush eyes with plenty of clean water for an extended time, not less than fifteen (15) minutes. Flush longer if there is any indication of residual chemical in the eye. Ensure adequate flushing of the eyes by separating the eyelids with fingers and roll eyes in a circular motion. If eye irritation persists: Get medical advice/attention.

Skin contact: Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.

Inhalation: If affected, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Call a POISON CENTER or doctor/physician if you feel unwell.

Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse out the mouth with water. Get medical attention immediately

Recommended methods and precautions concerning protection of the environment

No specific measures are needed to protect the environment, as the risk to the environment was concluded to be acceptable.

##  Assessment of a combination of biocidal products

Not applicable.

##  Comparative assessment

Not applicable.

# Annexes

**3.1 List of studies of the biocidal product**

**3.2 Output tables from exposure assessment tools**

**3.3 New information on the active substance**

**3.4 Residue behaviour**

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

**3.6 Confidential annex**

**3.7 Other**

## List of studies for the biocidal product

| **Data point** | **Author(s)** | **Year** | **Title** | **Company Report No.**  | **Source** | **GLP** **Y/N** | **Published** **Y/N** | **Vertebrate study****Y/N** | **Data protection claimed****Y/N** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2.2.2-01 | xxxxx | 2010 | Determination of physico-chemical properties of Natriumbenzoaat (Purox® S) | xxxxx | xxxxx | Y | N | N | Y | Emerald Kalama Chemical(DSM Special Products) |
| 2.2.2-02 | xxxxx | 2018 | Physical and Chemical Characteristics of Purox SColor, Physical State, Odor, Oxidation/Reduction, Storage Stability,Corrosion Characteristics, pH and Bulk Density | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical |
| 2.2.2-03 | xxxxx | 2015 | Determination of the bulk density of sodium benzoate | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical BV |
| 2.2.2-04 | xxxxx | 2018 | Excellerated stability study of purox/kalaguard sodium benzoate | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical BV |
| 2.2.2-05 | xxxxx | 2016 | Stability study of Purox® sodium benzoate, Laboratorium Emerald Kalama Chemicals BV, (rev. 21-11-2016) | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical(DSM Special Products) |
| 2.2.2-06 | xxxxx | 2018 | Stability study of Purox® sodium benzoate, Laboratorium Emerald Kalama Chemicals BV, (04-07-2018) | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical |
| 2.2.2-07 | xxxxx | 2015 | Determination of the particle size distribution of Sodium Benzoate | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical(DSM Special Products) |
| 2.2.3-01 | xxxxx | 2018 | Purox S:Preliminary Analysis and Enforcement Analytical Method | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical |
| 2.2.5.4-1 | xxxxx | 2007 | Mitochondrial uncouplers with an extraordinary dynamic range | xxxxx | xxxxx | N | Y | N | N | Data published |
| 2.2.5.4-1 | xxxxx | 2001 | The Surface Charge of theBacterial Isolates from Orange Drinks.  | xxxxx | xxxxx | N | Y | N | N | Data published |
| 2.2.5.5-1 | xxxxx | 2018 | Efficacy study of Purox/Kalaguard® SB sodium benzoate in tryptic soy broth | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical |
| 2.2.5.5-5 | xxxxx | 2016 | Unilever Research & Development – Supporting Evidence of the Preservative Efficacy of Sodium Benzoate in Hand Dish Wash Liquid (HDWL) Using Unilever Challenge Test Method | xxxxx | xxxxx | N | N | N | Y | Unilever U.K. Central Resources Limited |
| 2.2.5.5-6 | xxxxx | 2016 | Efficacy study of Purox® sodium benzoate in non-ionic surfactant system | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical  |
| 2.2.5.5-7 | xxxxx | 2018 | Efficacy study of Purox/Kalaguard® SB sodium benzoate in non-ionic surfactant system | xxxxx | xxxxx | N | N | N | Y | Emerald Kalama Chemical  |
| 2.2.5.5-8 | xxxxx | 1997 | Preservative-free and self-preserving cosmetics and drugs: principles and practices | xxxxx | xxxxx | N. | N.  | N.  | N.  | Data published |
| 2.2.6.1-1 | xxxxx | 1989 | Primary skin irritation/corrosion study with natrium benzoate in rabbits | xxxxx | xxxxx | Y | N | Y | Y | Emerald Kalama Chemical |
| 2.2.6.1-2 | xxxxx | 1989 | Acute eye irritation/corrosion study with Natrium benzoate in rabbits | xxxxx | xxxxx | Y | N | Y | Y | Emerald Kalama Chemical |
| 2.2.6.1-3 | xxxxx | 1992 | Examination of the local lymph node assay for use in contact sensitization risk assessment  | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.6.1-4 | xxxxx | 1974 | Mutagenic evaluation of compound FDA 71-37, sodium benzoate |  | xxxxx | N | Y | Y | N | Data published |
| 2.2.6.1-5 | xxxxx | 2005 | Opinion on benzoic acid and sodium benzoate | xxxxx |  | N | Y | Y | N | Data published |
| 2.2.6.1-6 | xxxxx | 2000 | Benzoic acid and sodium benzoate | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.6.1-7 | xxxxx | 1974 | Benzoic acid. Acute toxicity studies in rats and rabbits | xxxxx | xxxxx | N | N | Y | Y | Eastman Chemical Company |
| 2.2.6.1-8 | xxxxx | 1979 | Report of carcinogenesis bioassay of sodium benzoate in rats: absence of carcinogenicity of sodium benzoate in rats | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.6.1-9 | xxxxx | 1960 | Die Verträglichkeit dir Benzoesäure im chronischenFütterungversuch.  | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.6.1-10 | xxxxx | 2016 | Scientific Opinion on the re-evaluation of benzoic acid (E 210), sodiumbenzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213)as food additives | xxxxx | xxxxx | N | Y | N | N | Data published |
| 2.2.6.1-11 | xxxxx | 1984 | Lack of Tumorigenicity of Sodium Benzoate in Mice | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.8-1 | xxxxx | 1985 | Acute toxicity of organic chemicals to fathead minnows (*Pimephales promelas*) | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.8-2 | xxxxx | 1986 | Simultaneous evaluation of the acute effects of chemicals on seven aquatic species | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.8-3 | xxxxx | 2007 | Treatment with sodium benzoate leads to malformation of zebrafish larvae | xxxxx | xxxxx | N | Y | Y | N | Data published |
| 2.2.8-4 | xxxxx | 1998 | Acute Immobilisation Test on Daphnia magna (Semi static Test Procedure) | xxxxx | xxxxx | Y | N | N | Y | Menno Chemie-Vertrieb GmbH |
| 2.2.8-5 | xxxxx | 2005 | Acute toxicity of benzoic acids to the crustacean Daphnia magna | xxxxx | xxxxx | N | Y | N | N | Data published |
| 2.2.8-6 | xxxxx | 1945 | The toxicity thresholds of various sodium salts determined by the use of Daphnia magna | xxxxx | xxxxx | N | Y | N | N | Data published |
| 2.2.8-7 | xxxxx | 2010 | Fresh water algal growth inhibition test with natriumbenzoaat (Purox S) | xxxxx | xxxxx | Y | N | N | Y | Emerald Kalama Chemical |
| 2.2.8-8 | xxxxx | 1985 | Evaluation of the OECD activated sludge, respiration inhibition test | xxxxx | xxxxx | N | Y | N | N | Data published |
| 2.2.8-9 | xxxxx | 1955 | In verdorbenen Heringspräserven vorkommende Bakterie-Arten und ihr Verhalten gegenűber Salz und Konservierungsmittel | xxxxx | xxxxx | N | Y | N | N | Data published |
| 2.2.8-10 | xxxxx | 1989 | Prevention of nitrification-caused erroneous biodegradablitiy data in the closed bottle test | xxxxx | xxxxx | N | Y | N |  | Data published |
| 2.2.8-11 | xxxxx | 1991 | Influence of hydrophobe type and extent of branching on environmental response factors of nonionic surfactants | xxxxx | xxxxx | N | Y | N |  | Data published |
| 2.2.8-12 | xxxxx | 2004 | Influence of Benzoic Acid to Daphniamagna in a Reproduction Test | xxxxx | xxxxx | Y | N | N | Y | Menno Chemie-Vertrieb GmbH |

## Output tables from exposure assessment tools

**human toxicological RISK ASSESSMENT**

**Exposure scenario 2: loading of liquid laundry detergent into the washing machine by professionals, ConsExpo 4.1**

**ConsExpo 4.1 report**

Report date: 6-12-2016

**Product**

Sodium benzoate

**Compound**

Compound name : Sodium benzoate

CAS number : 532-32-1

molecular weight 122 g/mol

vapour pressure 0,001 Pascal

KOW -2,27 10Log

**General Exposure Data**

exposure frequency 365 1/year

body weight 60 kilogram

**Dermal model: Direct dermal contact with product : instant application**

weight fraction compound 2,5 %

exposed area 205 cm2

applied amount 0,01 gram

**Uptake model: fraction**

uptake fraction 75 %

**Output**

**Dermal : point estimates**

dermal load : 0,00122 mg/cm2

dermal external dose : 0,00417 mg/kg

dermal acute (internal) dose : 0,00313 mg/kg

dermal chronic (internal) dose : 0,00312 mg/kg/day

**Integrated (point estimates)**

total external dose: 0,00417 mg/kg

total acute dose (internal): 0,00313 mg/kg

total chronic dose (internal): 0,00312 mg/kg/day

**~~Exposure scenarios 6 and 7: Use of dishwashing liquids by professionals in the horeca and by consumers (calculation per single event), ConsExpo 4.1~~**

**~~ConsExpo 4.1 report~~**

**Exposure scenario 8: Use of laundry products by non-professional users**

**ConsExpo 4.1 report**

file name:

Report date: 4-10-2016

**Product**

Sodium benzoate

**Compound**

Compound name : Sodium benzoate

CAS number : 532-32-1

molecular weight 122 g/mol

vapour pressure 0,001 Pascal

KOW -2,27 10Log

**General Exposure Data**

exposure frequency 104 1/year

body weight 60 kilogram

**Dermal model: Direct dermal contact with product : instant application**

weight fraction compound 0,025 %

exposed area 1,95E3 cm2

applied amount 19,5 gram

**Uptake model: fraction**

uptake fraction 75 %

**Output**

**Dermal : point estimates**

dermal load : 0,0025 mg/cm2

dermal external dose : 0,0812 mg/kg

dermal acute (internal) dose : 0,0609 mg/kg

dermal chronic (internal) dose : 0,0173 mg/kg/day

**Integrated (point estimates)**

total external dose: 0,0812 mg/kg

total acute dose (internal): 0,0609 mg/kg

total chronic dose (internal): 0,0173 mg/kg/day

**Exposure scenario 9: Use of all-purpose cleaners by non-professional users**

**ConsExpo 4.1 report**

Report date: 27-9-2016

**Product**

Sodium benzoate

**Compound**

Compound name : Sodium benzoate

CAS number : 532-32-1

molecular weight 122 g/mol

vapour pressure 0,001 Pascal

KOW -2,27 10Log

**General Exposure Data**

exposure frequency 104 1/year

body weight 60 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0,031 %

exposure duration 240 minute

room volume 58 m3

ventilation rate 0,5 1/hr

applied amount 400 gram

release area 1E5 cm2

application duration 20 minute

mol weight matrix 18 g/mol

mass transfer rate 3,38E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 1,25 m3/hour

**Dermal model: Direct dermal contact with product : instant application**

weight fraction compound 0,031 %

exposed area 1,95E3 cm2

applied amount 1,95 gram

**Uptake model: fraction**

uptake fraction 75 %

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 2,29E-6 mg/m3

inhalation mean concentration on day of exposure: 3,82E-7 mg/m3

inhalation air concentration year average : 1,09E-7 mg/m3/day

inhalation acute (internal) dose : 1,91E-7 mg/kg

inhalation chronic (internal) dose : 5,43E-8 mg/kg/day

**Dermal : point estimates**

dermal load : 0,00031 mg/cm2

dermal external dose : 0,0101 mg/kg

dermal acute (internal) dose : 0,00756 mg/kg

dermal chronic (internal) dose : 0,00215 mg/kg/day

**Integrated (point estimates)**

total external dose: 0,0101 mg/kg

total acute dose (internal): 0,00756 mg/kg

total chronic dose (internal): 0,00215 mg/kg/day

**Exposure scenario 12: Oral exposure to residues of sodium benzoate on washed dinnerware - adults**

**ConsExpo 4.1 report**

file name:

Report date: 27-9-2016

**Product**

Sodium benzoate

**Compound**

Compound name : Sodium benzoate

CAS number : 532-32-1

molecular weight 122 g/mol

vapour pressure 0,001 Pascal

KOW -2,27 10Log

**General Exposure Data**

exposure frequency 365 1/year

body weight 60 kilogram

**Oral model: Oral exposure to product : direct intake**

weight fraction compound 2,5 %

amount ingested 0,00042 gram

**Uptake model: Fraction**

uptake fraction 1 fraction

**Output**

**Oral : point estimates**

oral external dose : 0,000175 mg/kg

oral acute (internal) dose : 0,000175 mg/kg

oral chronic (internal) dose : 0,000175 mg/kg/day

**Integrated (point estimates)**

total external dose: 0,000175 mg/kg

total acute dose (internal): 0,000175 mg/kg

total chronic dose (internal): 0,000175 mg/kg/day

**Exposure scenario 13: Oral exposure to residues of sodium benzoate on washed dinnerware - toddlers**

**ConsExpo 4.1 report**

**Product**

Sodium benzoate

**Compound**

Compound name : Sodium benzoate

CAS number : 532-32-1

molecular weight 122 g/mol

vapour pressure 0,001 Pascal

KOW -2,27 10Log

**General Exposure Data**

exposure frequency 365 1/year

body weight 10 kilogram

**Oral model: Oral exposure to product : direct intake**

weight fraction compound 2,5 %

amount ingested 0,00042 gram

**Uptake model: Fraction**

uptake fraction 1 fraction

**Output**

**Oral : point estimates**

oral external dose : 0,00105 mg/kg

oral acute (internal) dose : 0,00105 mg/kg

oral chronic (internal) dose : 0,00105 mg/kg/day

**Integrated (point estimates)**

total external dose: 0,00105 mg/kg

total acute dose (internal): 0,00105 mg/kg

total chronic dose (internal): 0,00105 mg/kg/day

**Exposure scenario 14: Oral exposure to residues of sodium benzoate due to transfer into food from cleaned surfaces**

**ConsExpo 4.1 report**

file name:

Report date: 17-10-2016

**Product**

**Compound**

Compound name : sodium benzoate

CAS number : 532-32-1

molecular weight 122 g/mol

vapour pressure 0,001 Pascal

KOW -2,27 10Log

**General Exposure Data**

exposure frequency 365 1/year

body weight 60 kilogram

**Oral model: Oral exposure to product : direct intake**

weight fraction compound 2,5 %

amount ingested 11,9 milligram

**Uptake model: Fraction**

uptake fraction 100 %

**Output**

**Oral : point estimates**

oral external dose : 0,00494 mg/kg

oral acute (internal) dose : 0,00494 mg/kg

oral chronic (internal) dose : 0,00493 mg/kg/day

**Integrated (point estimates)**

total external dose: 0,00494 mg/kg

total acute dose (internal): 0,00494 mg/kg

total chronic dose (internal): 0,00493 mg/kg/day

**ENVIRONMENTAL RISK ASSESSMENT**

**SIMPLETREAT (v4.0)**





**LOCAL EMISSIONS RATES TO WASTEWATER (ESD PT6)**

ESD PT6: Emission scenario for calculating the release of preservatives used in professional detergents for surface cleaning in industrial areas



ESD PT6: Emission scenario for calculating the releases of preservatives used in detergents for sanitary purposes based on average consumption



ESD PT6: Emission scenario for calculating the release of preservatives used in professional detergents used for laundry from hospitals in washing streets

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Symbol** | **Value** | **Unit** | **Origin** |
| **Input** |  |  |  |  |
| Number of washing tubes (with disinfectant) | Nm | 3 | - | D |
| Capacity of washing tube (laundry) | Cap | 8000 | kg/d | D |
| Amount of detergent per kg laundry | Vproduct | 6 x 10-3 | L/kg | D |
| Concentration of active substance in detergent | Cdetergent | 0.0295 | kg/L | S |
| Concentration reduction in washing process | Fred | 0 | - | D |
| Market penetration factor | Fpenetr | 1 | - | D |
| **Output** |  |  |  |  |
| Local release to wastewater | Elocalwater | 4.25 | kg/d | O |

ESD PT6: Emission scenario for calculating the release of preservatives used in non-professional detergents for fabric washing



ESD PT6: Emission scenario for calculating the release of preservatives used in non-professional detergents for dish washing



## New information on the active substance

Not applicable, as the active substance is included in Annex I of Regulation 528/2012/EC and no active substance dossier has previously been provided.

## Residue behaviour

The maximum level (ML) for sodium benzoate as food additive E 211 is set to be 150 – 5000 mg/kg depending on food commodity, according to EU database on Food Additives (https://webgate.ec.europa.eu/foods\_system/main/).

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

**Please refer to the IUCLID file of the biocidal product.**

## Confidential annex

**We refer to the separate document.**

## Other

Not applicable.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)