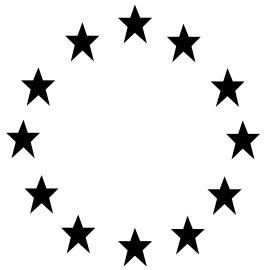
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

# PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



BELOX

Product types 2, 3, 4, 5

Hydrogen peroxide as included in the Union list of approved active substances

Case Number in R4BP: [BC-KC029711-56]

Evaluating Competent Authority: SI

Date: February 2020

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# 1 CONCLUSION

The biocidal product family BELOX (hereinafter as: BELOX) consists of 4 products containing 35 % to 49.9% of the active substance hydrogen peroxide and are divided into two *meta* SPCs. The products do not contain any substance of concern.

The following uses within product types 2, 3, 4 and 5 have been assessed:
- surface disinfection in enclosed spaces by VHP process,
- disinfection of non-porous surfaces in animal housing,
- aseptic packaging,
- cork stoppers disinfection,
- surface disinfection in enclosed spaces by VHP process in food and feed area,
- disinfection of inner surfaces of drinking water piping and tanks,
- disinfection of piping and tanks for beverages by CIP,
- disinfection at the drinking water suppliers and their water distribution systems,
- disinfection of water in reservoirs,
- disinfection of water for animals.

**Phys-chem**

Products included in BELOX are colourless liquid with characteristic odour of hydrogen peroxide. The products in the family are acidic.

Products included in BELOX are stable according to accelerated storage test (at 40°C for 8 weeks) and long-term storage test at ambient temperature at 20 °C for 2 years.

With regard to physical and chemical hazards, only the biocidal product BELOX 50 is classified as an Oxidising Liquid category 3, but products included in BELOX biocidal products family are not flammable, auto-flammable, explosive or corrosive to metals.

**Efficacy**

The BELOX products are effective against bacteria, bacterial spores, fungi and viruses under the claimed use conditions and when strictly following the instructions of authorized use.

The efficacy of *meta* SPC 1 and *meta* SPC 2 were proven using BELOX 35 and INTEROX ST50. INTEROX ST50 and products from BPF BELOX are all stabilised hydrogen peroxide solutions. Since stabilisers do not affect efficacy, the efficacy results made on INTEROX ST50 can also be used to prove the efficacy of BELOX products.

For PT2 and PT4, the surface disinfection in enclosed spaces by VHP process was demonstrated by EN phase 2 step 1 tests performed with bacteria (EN1276), fungi (EN1650) and spores (EN13704) and phase 2 step 2 test according to French norm NF T 72-281. Effective concentration of hydrogen peroxide should reach 360 ppm – 400 ppm. The disinfection should last minimum of 90 minutes.

For PT3, disinfection of non-porous surfaces in animal housing by spraying was demonstrated by EN phase 2 step 1 tests performed with bacteria (EN1656) and fungi (EN1657) and by EN phase 2 step 2 tests for bacteria (EN14349) and fungi (EN16438). The products are diluted to the concentration 17.3 % of hydrogen peroxide. The contact time is 30 minutes.

Several uses are claimed within PT4:
- Disinfection of aseptic packaging was shown by EN phase 2 step 1 tests performed with bacteria (EN1276), fungi (EN1650) and spores (EN13704, clean conditions only). In addition to suspension tests, the semi field study proved activity of the product against spores of heat resistant bacterium *Geobacillus stearothermophilus*. The effective concentrations 35 % $H_2O_2$ at ≥ 70 °C for at least 15 seconds.
- Cork stoppers disinfection was demonstrated by already mentioned EN phase 2 step 1 tests and additional surface test (EN13697). The effective concentration ranges from 10 to 35 % $H_2O_2$ for at least 15 min. When using the lowest concentration 10% $H_2O_2$ cleaning prior the disinfection is necessary.
- For disinfection of inner surfaces of drinking water piping and tanks and for piping and tanks for beverages by CIP, the same EN phase 2 step 1 tests were used. For CIP suspension tests are sufficient to demonstrate efficacy, EN phase 2 step 2 are not required. But cleaning prior to disinfection is necessary. Concentration of hydrogen peroxide is 9.88 % and the contact time is 15 to 60 minutes for deposits and 3 hours for pipes.

Within PT5 disinfection of water at the drinking water suppliers and their water distribution systems, disinfection of water in reservoirs and water for animals was demonstrated by suspension test against bacteria (EN1276) and viruses (EN14476) and quantitative determination of the efficacy of drinking water disinfectants 2013/12. Hydrogen peroxide in drinking water has an initial concentration of 25 mg/L to maintain 5 mg/L residual at the final point. The treatment is carried out in the deposit to assure that the product has enough contact time (15 h).

**Human health**

Eight proposed uses and 18 scenarios have been assessed for industrial/professional user. All uses are considered acceptable if technical and organizational risk mitigation measures as proposed are respected and appropriate PPE (long sleeved gloves, safety goggles with side shields, rubber boots and apron) and RPE (full face mask with gas/vapour filter) are worn where required.
Professional inhalation exposure during disinfection of animal housing by spraying (PT3) is acceptable only when wearing RPE (RPE with gas/vapour filter: APF = 10) and assuming at least 3 air exchanges per hour in Tier 2 refinement. It should be considered at the national level if all proposed RMM can be applied/respected.
Secondary exposure to hydrogen peroxide from proposed uses of BELOX is considered negligible and therefore no adverse effects are expected for bystanders due to the use of BELOX. In pipes and tanks disinfected by BELOX, disinfected subjects are flushed with fresh water prior to use for drinking water and beverages. Hydrogen peroxide residues on food wrapping materials are expected to evaporate prior to wrapping of the food due to heating

before use. Residues in drinking water for human consumption are estimated to be very low (MOS> 1000) and do not present risk to human health.
There are no relevant residues of hydrogen peroxide expected in food and feeding stuff due to the rapid degradation of hydrogen peroxide to water and oxygen in the environment. The exposure to hydrogen peroxide in disinfected drinking water shows a sufficient margin of safety for a substance with local effects at the site of contact. Additionally, minimal residues of the application solution in food or feed are unlikely to cause local effects due to the expected high dilution rate in food.
No specific need to set MRL was identified for biocidal products of BELOX family.

**Environment**

A risk assessment for the environment has been carried out for all intended uses (see chapter 1.2.1 Intended use(s) as applied for by applicant). Based on the environmental risk assessment it is unlikely that assessed uses cause any unacceptable risk for the environment if the directions for use are to be followed. However, for the disinfection of inner surfaces of drinking water piping and tanks the $PEC/PNEC_{water}$ is greater than the trigger value of 1. To resolve the indicated risk to the aquatic compartment from the respective use, it should be noted that distribution systems for drinking water are disinfected only intermittently and that risk assessment relies on the conservative assumption (reduction of only 25 % at discharge into sewer was assumed). Furthermore, permission or consent for disposal of any wastewater generated to a sewer must be obtained from the relevant water service company or environmental authority, as appropriate. Consequently, the risk to the aquatic compartment is assumed acceptable also for disinfection of inner surfaces of drinking water piping and tanks.

**Overall conclusion**

In opinion of the Slovenian CA, the BELOX biocidal product family meets the conditions laid down in Article 19(1) and may also be expected to fulfil the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore can be authorised for the specified uses. The detailed grounds for the overall conclusion are described in the PAR.

# 2 ASSESSMENT REPORT

## 2.1 Summary of the product assessment

### 2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

| **Identifier**[1] | **Country (if relevant)** |
|---|---|
| BELOX | Slovenia, Austria, Bulgaria, Croatia, Czech Republic, Greece, Hungary, Italy, Poland, Romania, Slovakia, Spain, Switzerland |

2.1.1.2 Authorisation holder

| | | |
|---|---|---|
| **Name and address of the authorisation holder** | **Name** | Belinka Perkemija kemična industrija, d.o.o. |
| | **Address** | Zasavska cesta 95, 1231 Ljubljana – Črnuče, Slovenia |
| **Authorisation number** | SI-0017971-0000 | |
| **Date of the authorisation** | 1.7.2020 | |
| **Expiry date of the authorisation** | 30.6.2030 | |

2.1.1.3 Manufacturer(s) of the products of the family

| | |
|---|---|
| **Name of manufacturer** | Belinka Perkemija kemična industrija, d.o.o |
| **Address of manufacturer** | Zasavska cesta 95, 1231 Ljubljana – Črnuče, Slovenia |
| **Location of manufacturing sites** | Zasavska cesta 95, 1231 Ljubljana – Črnuče, Slovenia |

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

| | |
|---|---|
| **Active substance** | Hydrogen peroxide |
| **Name of manufacturer** | Belinka Perkemija kemična industrija, d.o.o. |
| **Address of manufacturer** | Zasavska cesta 95, 1231 Ljubljana – Črnuče, Slovenia |
| **Location of manufacturing sites** | Zasavska cesta 95, 1231 Ljubljana – Črnuče, Slovenia |

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

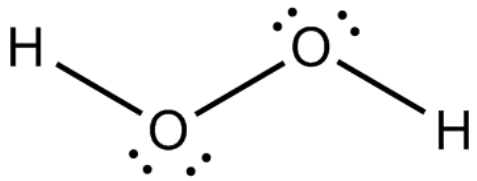
## 2.1.2 Product (family) composition and formulation

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

Do the products 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

### 2.1.2.1 Identity of the active substance

| **Main constituent(s)** | |
|---|---|
| **ISO name** | Hydrogen peroxide |
| **IUPAC or EC name** | Hydrogen peroxide |
| **EC number** | 231-765-0 |
| **CAS number** | 7722-84-1 |
| **Index number in Annex VI of CLP** | 008-003-00-9 |
| **Minimum purity / content** | < 70 % Aqueous solution<br>> 99,5 % Calculated hydrogen peroxide |
| **Structural formula** |  |

### 2.1.2.2 Candidate for substitution

Hydrogen peroxide is not candidate for substitution in accordance with Article 10 of BPR. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 258/2012.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
|---|---|---|---|---|---|---|
| | | | | | **Min** | **Max** |
| Dihydrogen dioxide, hydrogen dioxide | Hydrogen peroxide | Active substance | 7722-84-1 | 231-765-0 | 35 | 49.9 |

The full product family formulation composition details are contained within the Confidential Annex of this PAR.

The BELOX (BPF) consists of in total 4 products whereas one is concentrated and the others are its dilutions. All products are based on the active substance hydrogen peroxide. In total, the family is divided in 2 meta-SPCs based on differences in hazard classification:

- Meta - SPC 1 – BELOX 35: BELOX 35 SB, BELOX 35 FP, BELOX 35 E,
- Meta – SPC 2 – BELOX 50: BELOX 50.

#### 2.1.2.4 Information on technical equivalence

The RMS FI concluded that manufacturing location listed in the section 2.1.1.4 complies with the reference specification presented in the CAR for hydrogen peroxide (PTs 1-6) based on post-approval data. No technical equivalence assessment is needed.

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

Products belonging to the BELOX do not contain any substance of concern.

#### 2.1.2.6 Type of formulation

| |
|---|
| SL - soluble liquid |

### 2.1.3 Hazard and precautionary statements

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

#### 2.1.3.1 BELOX 35

| **Classification** | |
|---|---|
| Hazard category | Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; STOT SE 3; Aquatic Chronic 3 |
| Hazard statement | H302 Harmful if swallowed.<br>H315 Causes skin irritation.<br>H318 Causes serious eye damage.<br>H332 Harmful if inhaled.<br>H335 May cause respiratory irritation.<br>H412 Harmful to aquatic life with long lasting effects. |
| | |
| **Labelling** | |
| Hazard pictograms | GHS05  GHS07  |
| Signal words | Danger |

| | |
|---|---|
| Hazard statements | H302 Harmful if swallowed.<br>H315 Causes skin irritation.<br>H318 Causes serious eye damage.<br>H332 Harmful if inhaled.<br>H335 May cause respiratory irritation.<br>H412 Harmful to aquatic life with long lasting effects. |
| Precautionary statements (all P statements triggered by the CLP legislation) | P261 Avoid breathing vapours/spray.<br>P270 Do not eat, drink or smoke when using this product.<br>P271 Use only outdoors or in a well-ventilated area.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/protective clothing/eye protection/face protection.<br>P301 + P312 IF SWALLOWED: Call a POISON CENTRE / doctor/…if you feel unwell.<br>P302 + P352 IF ON SKIN: Wash with plenty of water.<br>P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P310 Immediately call a POISON CENTER<br>P330 Rinse mouth.<br>P332 + P313 If skin irritation occurs: Get medical advice/ attention.<br>P362 + P364 Take off contaminated clothing and wash it before reuse.<br>P403 + P233 Store in a well-ventilated place. Keep container tightly closed.<br>P501 Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers. |

#### 2.1.3.2 BELOX 50

| **Classification** | |
|---|---|
| Hazard category | Ox. Liq. 3; Acute Tox. 4; Skin Irrit. 2; Eye Dam. 1; STOT SE 3; Aquatic Chronic 3 |
| Hazard statement | H272 May intensify fire; oxidiser.<br>H302 Harmful if swallowed.<br>H314 Causes severe skin burns and eye damage.<br>H332 Harmful if inhaled.<br>H335 May cause respiratory irritation.<br>H412 Harmful to aquatic life with long lasting effects. |
| | |
| **Labelling** | |
| Hazard pictograms | |

| | |
|---|---|
| | GHS03  GHS05  GHS07  |
| Signal words | Danger |
| Hazard statements | H272 May intensify fire; oxidiser.<br>H302 Harmful if swallowed.<br>H314 Causes severe skin burns and eye damage.<br>H332 Harmful if inhaled.<br>H335 May cause respiratory irritation.<br>H412 Harmful to aquatic life with long lasting effects. |
| Precautionary statements (all P statements triggered by the CLP legislation) | P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>P260 Do not breathe vapours/spray<br>P270 Do not eat, drink or smoke when using this product.<br>P271 Use only outdoors or in a well-ventilated area.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/protective clothing/eye protection/face protection.<br>P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.<br>P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.<br>P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P310 Immediately call a POISON CENTER<br>P362 + P364 Take off contaminated clothing and wash it before reuse.<br>P403 + P233 Store in a well-ventilated place. Keep container tightly closed.<br>P501 Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers |

## 2.1.4 Authorised uses

### 2.1.4.1 Surface disinfection in enclosed spaces by VHP process

Table 1. Use of the product for surface disinfection in enclosed spaces by VHP process

| | |
|---|---|
| **Product Type** | PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria, fungi and bacterial spores |
| **Field of use** | Surface disinfection in enclosed spaces by VHP process - private and public health area |
| **Application method(s)** | Disinfection with vaporized hydrogen peroxide - VHP process |
| **Application rate(s) and frequency** | Concentration of hydrogen peroxide should reach 360 ppm – 400 ppm. The disinfection phase lasts minimum of 90 minutes. |
| **Category(ies) of users** | Industrial, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE |

Use-specific instructions for use

| |
|---|
| Prepare the area to disinfect by removing standing liquids and visible soils by wiping down and installing biological and chemical indicators to control the disinfection process. Follow the VHP machine manufacturer's instructions. Insert the bottle with the product as delivered into a VHP machine, seal the enclosed space or room, which should be up to 30 $m^2$ in size, and initiate the decontamination cycle. Concentration of hydrogen peroxide should reach 360 ppm – 400 ppm. Prevent entry during disinfection process. The disinfection phase lasts minimum of 90 minutes. After decontamination cycle, aeration of the room is mandatory until the hydrogen peroxide level is below 1 ppm (1.25 mg/$m^3$). |

Use-specific risk mitigation measures

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|---|
| During mixing and loading personal protective equipment (safety goggles with side shields, long sleeved gloves, apron and rubber boots) must be worn.<br>RPE (half mask/full face mask with gas/vapour filter) must be worn when re-entry in space after treatment, if the concentrations are above 1.25 mg/$m^3$. |

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

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

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

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### 2.1.4.2 Disinfection of animal housing

Table 2. Use of the product for disinfection of animal housing

| | |
|---|---|
| **Product Type** | PT 3 - Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | |
| **Target organism (including development stage)** | Bacteria and yeast |
| **Field of use** | Disinfection of non-porous surfaces in animal housing |
| **Application method(s)** | The disinfectants are applied by spraying. |
| **Application rate(s) and frequency** | Concentration of hydrogen peroxide used is 17.29 % diluted from 35 or 49.9 % $H_2O_2$ (BELOX) in water. Usual application rate is 0.15 L/$m^2$.<br>Frequency of treatment is usually every 5-8 weeks. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE<br>21 kg, drum, HDPE |

Use-specific instructions for use

| |
|---|
| Dilute the product to concentration 17.29 % of hydrogen peroxide. Wet the surfaces by spraying and leave it to dry (min. 30 min). When stables are completely dry, animals can be resettled. |

Use-specific risk mitigation measures

| |
|---|
| PPE (impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields) and RPE (full face mask with gas/vapour filter: APF = 10) must be worn during mixing and loading, application (spraying) and cleaning phase. Beside that operational RMM must be in place (at least 3 air exchanges per hour) during spraying. |

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

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

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

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#### 2.1.4.3 Aseptic packaging

Table 3. Use of the product in aseptic packaging

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | Disinfection of packaging in specially designed machines (closed system) |
| **Target organism (including development stage)** | Bacteria, fungi and bacterial spores |
| **Field of use** | Aseptic packaging |
| **Application method(s)** | A wetting system and an immersion bath system |
| **Application rate(s) and frequency** | The packaging material is immersed in a bath or sprayed with ≥ 35 % $H_2O_2$ at ≥ 70 °C for at least 15 seconds |
| **Category(ies) of users** | Industrial, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE<br>21 kg, plastic drum, HDPE<br>32 kg, plastic drum, HDPE<br>65 kg, plastic drum, HDPE<br>225 kg, plastic drum, HDPE<br>1100 kg, IBC container, HDPE<br>Bulk transport, steel, SS316 |

Use-specific instructions for use

| |
|---|
| Follow the machine manufacturer's instructions. For each disinfecting line, individual tests are necessary to determine the appropriate dose and time. The packaging material is immersed in a bath or sprayed with ≥ 35 % $H_2O_2$ at ≥ 70 °C for at least 15 seconds. |

Use-specific risk mitigation measures

| |
|---|
| During loading personal protective equipment (safety goggles with side shields, apron, long sleeved gloves and rubber boots) must be worn. During the maintenance work personal protective equipment (waterproof coverall, long sleeved gloves and rubber boots) and RPE (full face mask with gas/vapour filter) must be worn. |

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

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

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

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#### 2.1.4.4 Cork stoppers disinfection

Table 4. Use of the product for cork stoppers disinfection

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | Disinfection of cork stoppers in specially designed machines (closed system) |
| **Target organism (including development stage)** | Bacteria and fungi |
| **Field of use** | Cork stoppers disinfection |
| **Application method(s)** | A wetting system |
| **Application rate(s) and frequency** | The cork stoppers are wetted with 10 (clean conditions) – 35 % $H_2O_2$ at ≥ 20 °C for at least 15 minutes |
| **Category(ies) of users** | Industrial, professional |
| **Pack sizes and packaging material** | 21 kg, plastic drum, HDPE<br>32 kg, plastic drum, HDPE<br>65 kg, plastic drum, HDPE<br>225 kg, plastic drum, HDPE<br>1100 kg, IBC container, HDPE |

Use-specific instructions for use

| |
|---|
| Follow the machine manufacturer's instructions. Hydrogen peroxide is automatically pumped in to the machine and mixed with water to achieve desired concentration (10-35 %). For each disinfecting line, individual tests are necessary to determine the appropriate dose and time. The cork stoppers should be wetted by spraying in a bath with 10 – 35 % $H_2O_2$ at ≥ 20 °C for at least 15 min. The lowest concentration 10% $H_2O_2$ should be used under clean conditions only. |

Use-specific risk mitigation measures

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|---|
| During loading personal protective equipment (safety goggles with side shields, apron, long sleeved gloves and rubber boots) must be worn. During the maintenance work |

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| personal protective equipment (waterproof coverall, long sleeved gloves and rubber boots) and RPE (full face mask with gas/vapour filter) must be worn. |

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

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

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

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#### 2.1.4.5 Surface disinfection in enclosed spaces by VHP process

Table 5. Use of the product for surface disinfection in enclosed spaces by VHP process

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria, fungi and bacterial spores |
| **Field of use** | Surface disinfection in enclosed spaces by VHP process - food and feed area |
| **Application method(s)** | Disinfection with vaporized hydrogen peroxide - VHP process |
| **Application rate(s) and frequency** | Concentration of hydrogen peroxide should reach 360 ppm – 400 ppm. The disinfection phase lasts minimum of 90 minutes |
| **Category(ies) of users** | Industrial, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE |

Use-specific instructions for use

| |
|---|
| Follow the VHP machine manufacturer's instructions. Insert the bottle with the product into to a VHP machine, seal the enclosed space or room, which should be up to 30 $m^2$ in size, and initiate the decontamination cycle. Concentration of hydrogen peroxide should reach 360 ppm – 400 ppm. The disinfection phase lasts minimum of 90 minutes. After decontamination cycle, aeration of the room is mandatory until the hydrogen peroxide level is below 1 ppm (1.25 $mg/m^3$). |

Use-specific risk mitigation measures

| |
|---|
| During mixing and loading personal protective equipment (safety goggles with side shields, apron, long sleeved gloves and rubber boots) must be worn.<br>RPE (full face mask with gas/vapour filter) must be worn when re-entry in space after treatment, if the concentrations are above 1.25 mg/m$^3$. |

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

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

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

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#### 2.1.4.6 Disinfection of inner surfaces of drinking water piping and tanks

Table 6. Use of the product for disinfection of inner surfaces of drinking water piping and tanks

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria, yeasts and bacterial spores |
| **Field of use** | Disinfection of inner surfaces of drinking water piping and tanks |
| **Application method(s)** | For the application CIP technologies are used. Hydrogen peroxide solution is prepared with CIP machine and filled into the pipes and tanks. The insides of large tanks are sprayed automatically through spray balls and rotating jets. |
| **Application rate(s) and frequency** | Disinfection of drinking water reservoirs or drinking water pipes is performed at start-up or restart-up after a longer period of standstill. Cleaning prior to disinfection is necessary. The distribution and storing systems get disinfected by either automatic spraying or injecting 9.88 % hydrogen peroxide in container or in pipes. After 60 minutes contact time for |

| | |
|---|---|
| | deposits and 3 hours for pipes, the surface has to be rinsed with clean drinking water. |
| **Category(ies) of users** | Industrial, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE<br>21 kg, plastic drum, HDPE<br>32 kg, plastic drum, HDPE<br>65 kg, plastic drum, HDPE<br>225 kg, plastic drum, HDPE<br>1100 kg, IBC container, HDPE |

Use-specific instructions for use

| |
|---|
| Cleaning prior to disinfection is needed. Pre-rinse cleaning container and all lines with tap water. A CIP machine that pumps hydrogen peroxide solution through the piping system is attached. A detector that indicates when the disinfection process is complete is set up at the outlet. CIP machine mixes the biocidal product with water to concentration 9.88 % of hydrogen peroxide. The distribution and storing systems get disinfected by either automatic spraying or injecting 9.88 % (w/w) hydrogen peroxide in container or in pipes. After 60 min contact time for tanks and 3h for pipes, tanks and pipes have to be rinsed with clean drinking water. Waste water must be collected separately. |

Use-specific risk mitigation measures

| |
|---|
| PPE (impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields) and RPE (full face mask with gas/vapour filter: APF = 10) must be worn during mixing and loading. |

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

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

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|---|
| Waste water must be collected separately after required contact time. Permission or consent for disposal of any wastewater generated to a sewer must be obtained from the relevant water Service Company or environmental authority, as appropriate. |

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

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| - |

#### 2.1.4.7 CIP of piping and tanks for beverages

Table 7. Use of the product for disinfection of piping and tanks for beverages

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria and fungi |
| **Field of use** | Disinfection of piping and tanks for beverages |
| **Application method(s)** | Hydrogen peroxide solution is prepared with CIP machine and filled into the pipes and tanks. The insides of large tanks are sprayed automatically through spray balls and rotating jets. |
| **Application rate(s) and frequency** | Cleaning prior to disinfection is necessary. Disinfection of piping and tanks for beverages is performed by filling tap with 9.88 % hydrogen peroxide BELOX. After 15 min contact time the tap has to be rinsed. |
| **Category(ies) of users** | Industrial, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE<br>21 kg, plastic drum, HDPE |

Use-specific instructions for use

| |
|---|
| Cleaning prior to disinfection is needed. Pre-rinse cleaning container and all lines with tap water.<br>Connect the CIP machine with the piping and tanks. CIP machine mixes the product with water to concentration 9.88% of hydrogen peroxide and the solution is then filled into the cleaning container. Tap head must be cleaned and connected with cleaning container. The tap is then opened, and the lines are filled with the disinfecting solution. The disinfection solution is left to act for at least 15min. The insides of the large tanks are automatically sprayed for at least 15 min. After prescribed contact time, tap the remaining cleaning solution. The piping and tanks should be rinsed with clean drinking water. Wastewater must be collected separately. |

Use-specific risk mitigation measures

| |
|---|
| PPE (impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields) and RPE (full face mask with gas/vapour filter: APF = 10) must be worn during mixing and loading. |

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

| |
|---|
| - |

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

| |
|---|
| Waste water must be collected separately after required contact time. |

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

| |
|---|
| - |

#### 2.1.4.8 Drinking water disinfectant

Table 8. Use of the product as drinking water disinfectant

| | |
|---|---|
| **Product Type** | PT 5 Drinking water disinfectants |
| **Where relevant, an exact description of the authorised use** | / |
| **Target organism (including development stage)** | Bacteria and viruses |
| **Field of use** | Group 1. Disinfection at the drinking water suppliers and their water distribution systems<br>Group 4. Disinfection of water in reservoirs<br>Group 6. Disinfection of water for animals |
| **Application method(s)** | The product is added continuously to the drinking water by a dosing system. |
| **Application rate(s) and frequency** | The product is added continuously to the drinking water by a dosing system which applies the product according to a signal received from a pulsing counter depending on the amount of water consumed. Hydrogen peroxide in drinking water for disinfection has an initial concentration of 25 mg/L to maintain 5 mg/L residual at the final point. The treatment is carried out in the deposit to assure that the product has enough contact time (15 h) with the water. Drinking water is checked daily for of hydrogen peroxide concentration at the outlet of the drinking water treatment plant and at the final-end-tap to assure that national limit values for hydrogen peroxide are not exceeded. |
| **Category(ies) of users** | Industrial, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE<br>21 kg, plastic drum, HDPE<br>32 kg, plastic drum, HDPE<br>65 kg, plastic drum, HDPE<br>225 kg, plastic drum, HDPE<br>1100 kg, IBC container, HDPE<br>Bulk transport, steel, SS316 |

Use-specific instructions for use

| |
|---|
| The product is added manually or continuously by a dosing system to the drinking water. Follow the dosing system manufacturer's instructions. Initial concentration of hydrogen peroxide in drinking water should be 25 mg/L and 5 mg/L the final point. The treatment should be carried out in the deposit to assure that the product has enough contact time (15 h) with the water. Drinking water should be checked daily for hydrogen peroxide concentration at the outlet of the drinking water treatment plant and at the final-end-tap to assure that national limit values for hydrogen peroxide are not exceeded. |

Use-specific risk mitigation measures

| |
|---|
| PPE (impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields) and RPE (full face mask with gas/vapour filter: APF = 10) must be worn during mixing and loading. |

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

| |
|---|
| - |

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

| |
|---|
| - |

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

| |
|---|
| - |

## 2.1.5 General directions for use

### 2.1.5.1 Instructions for use

| |
|---|
| See specific instruction for each use. |

### 2.1.5.2 Risk mitigation measures

| |
|---|
| Wear protective long-sleeved gloves, protective clothing (waterproof coverall, apron), safety goggles with side shields/RPE (full face mask with gas/vapour filter) and rubber boots. |

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

| |
|---|
| Likely direct or indirect adverse effects:<br>- Irritation to severe chemical burns of the eyeys, mucosae, respiratory and digestive tract, with risk of rupture of colon, gastrointestinal embolism (vessel blockage caused by air bubbles) |

| |
|---|
| - Convulsion, coma, cardiac arrest and pulmonary oedema.<br>IF SWALLOWED: Rinse mouth. Do NOTinduce vomiting.<br>IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water<br>IF INHALED: Remove person to fresh air and keep comfortable for breathing.<br>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |

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

| |
|---|
| Remaining application solutions and biocidal product should be collected and left to authorized collector of hazardous waste.<br>Completely emptied containers leave to aproved waste disposal. |

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

| |
|---|
| **Storage:** Tanks and packaging must be made of suitable materials, such as passivated metals (pure aluminium (min. 99.5% Al)), stainless steel (F. 4574, SS 316L, 304L SS), polyethylene - PE, high density polyethylene - HDPE, Teflon, PTFE.<br>**Shelf-life:** 2 year |

### 2.1.6 Other information

| |
|---|
| Application codes |

### 2.1.7 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) |
|---|---|---|---|---|---|
| Bulk transport | | steel, SS316 | steel, SS316 | professional | Yes |
| IBC Container | 1100 kg | HDPE | HDPE | professional | Yes |
| Plastic drum | 225 kg | HDPE | HDPE | professional | Yes |
| Plastic drum | 65 kg | HDPE | HDPE | professional | Yes |
| Plastic drum | 32 kg | HDPE | HDPE | professional | Yes |

| | | | | | |
|---|---|---|---|---|---|
| Plastic drum | 21 kg | HDPE | HDPE | professional | Yes |
| Plastic bottle | 1 kg | HDPE | HDPE | professional | Yes |

### 2.1.8 Documentation

#### 2.1.8.1 Data submitted in relation to product application

See Annex 3.1 List of studies for the biocidal product family

#### 2.1.8.2 Access to documentation

Belinka Perkemija d.o.o. is producer of hydrogen peroxide listed on the Article 95 List and co-owner of the data in the active substance dossier - hydrogen peroxide (CAS 7722-84-1; EC 231-765-0) for product-types 1, 2, 3, 4, 5, 6, 11 & 12[2].

## 2.2 Assessment of the biocidal product (family)

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

Table 1. Use of the product for surface disinfection in enclosed spaces by VHP process

| | |
|---|---|
| **Product Type** | PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria, viruses, fungi and bacterial spores |
| **Field of use** | Surface disinfection in enclosed spaces by VHP process - Private and public health area disinfection |
| **Application method(s)** | Disinfection with vaporized hydrogen peroxide - VHP process |
| **Application rate(s) and frequency** | Concentration of hydrogen peroxide should reach 300 ppm – 400 ppm. The succeeding sterilisation phase lasts min. 90 min. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE |

[2] CEFIC Peroxygens Sector group, 2016

Table 2. Use of the product for disinfection of animal housing

| | |
|---|---|
| **Product Type** | PT 3 - Veterinary hygiene |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria |
| **Field of use** | Disinfection of non-porous surfaces in animal housing |
| **Application method(s)** | The disinfectants are applied by spraying. |
| **Application rate(s) and frequency** | Concentration of hydrogen peroxide used is 7.41 % diluted from 35 or 49.9 % $H_2O_2$ (BELOX) in water. Usual application rate is 0.15 L/$m^2$.<br>Frequency of treatment is usually every 5-8 weeks. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE<br>21 kg, drum, HDPE |

Table 3. Use of the product in aseptic packaging

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | Disinfection of packaging in specially designed machines (closed system). |
| **Target organism (including development stage)** | Bacteria |
| **Field of use** | Aseptic packaging |
| **Application method(s)** | A wetting system and an immersion bath system. |
| **Application rate(s) and frequency** | The packaging material is immersed in a bath or sprayed with ≥ 35 % $H_2O_2$ at ≥ 70 °C for at least 15 seconds. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | Please see section 2.1.7. |

Table 4. Use of the product for cork stoppers disinfection

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | Disinfection of cork stoppers in specially designed machines (closed system). |

| | |
|---|---|
| **Target organism (including development stage)** | Bacteria, yeasts |
| **Field of use** | Cork stoppers disinfection |
| **Application method(s)** | A wetting system |
| **Application rate(s) and frequency** | The packaging material is sprayed with 10 – 35 % $H_2O_2$ at ≥ 20 °C for at least 15 minutes. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | Please see section 2.1.7. |

Table 5. Use of the product for surface disinfection in enclosed spaces by VHP process

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria, viruses, fungi and bacterial spores |
| **Field of use** | Surface disinfection in enclosed spaces by VHP process - Food and feed area disinfectants |
| **Application method(s)** | Disinfection with vaporized hydrogen peroxide - VHP process |
| **Application rate(s) and frequency** | Concentration of hydrogen peroxide should reach 300 ppm – 400 ppm. The succeeding sterilisation phase lasts min. 90 min. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | 1 kg, plastic bottle, HDPE |

Table 6. Use of the product for disinfection inner surfaces of drinking water piping and tanks

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria, yeasts and bacterial spores |
| **Field of use** | Disinfection of drinking water piping and tanks |
| **Application method(s)** | The solution is filled into the pipes, while the inside of large tanks is sprayed. |

| | |
|---|---|
| **Application rate(s) and frequency** | Disinfection of drinking water reservoirs or drinking water pipes is performed at start-up or restart-up after a longer period of standstill. The distribution and storing systems get disinfected by either spraying or injecting 7.41 % hydrogen peroxide in container or in pipes. After 15 min contact time for deposits and 3 h for pipes the surface has to be rinsed. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | Please see section 2.1.7. |

Table 7. Use of the product for disinfection of piping and tanks for beverages

| | |
|---|---|
| **Product Type** | PT 4 - Food and feed area |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Bacteria, yeasts, fungi |
| **Field of use** | Disinfection of piping and tanks for beverages |
| **Application method(s)** | The solution is filled into the pipes and tanks |
| **Application rate(s) and frequency** | Disinfection of piping and tanks for beverages is performed by filling tap with 4 % BELOX 35 or 2.4 % BELOX 50 (1,2 % $H_2O_2$) at 40 ˚C. After 15 min contact time the tap has to be rinsed. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | Please see section 2.1.7. |

Table 8. Use of the product as drinking water disinfectant

| | |
|---|---|
| **Product Type** | PT 5 Drinking water disinfectants |
| **Where relevant, an exact description of the authorised use** | Drinking water in collective systems |
| **Target organism (including development stage)** | Bacteria |
| **Field of use** | Disinfection of drinking water |
| **Application method(s)** | The product is added continuously to the drinking water by a dosing system. |
| **Application rate(s) and frequency** | The product is added continuously to the drinking water by a dosing system which applies the product according to a signal received from a pulsing counter depending on the amount of water |

| | |
|---|---|
| | consumed. Hydrogen peroxide in drinking water for disinfection has an initial concentration of 25 mg/L to maintain 5 mg/L residual at the final point. The treatment is carried out in the deposit to assure that the product has enough contact time (15 h) with the water. Drinking water is checked daily for of hydrogen peroxide concentration at the outlet of the drinking water treatment plant and at the final-end-tap to assure that national limit values for hydrogen peroxide are not exceeded. |
| **Category(ies) of users** | Industrial, Trained professional, Professional |
| **Pack sizes and packaging material** | Please see section 2.1.7. |

## 2.2.2 Physical, chemical and technical properties

**Meta SPC 1**

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Physical state at 20 °C and 101.3 kPa | Visual | BELOX 35 (35 % $H_2O_2$, batch #155884) | Liquid<br>SI CA comment: Acceptable | Benetka 2017 |
| Colour at 20 °C and 101.3 kPa | Visual | BELOX 35 (35 % $H_2O_2$, batch #155884) | Colourless<br>SI CA comment: Acceptable | Benetka 2017 |
| Odour at 20 °C and 101.3 kPa | Organoleptic | BELOX 35 (35 % $H_2O_2$, batch #155884) | typical odour<br>SI CA comment: Acceptable | Benetka 2017 |
| pH | CIPAC method MT 75.3, 1999 | BELOX 35 (35 % $H_2O_2$, batch #155884) | 2.4 at 22.3 °C<br>SI CA comment: Acceptable | Schlegl 2017 |
| Acidity | - | - | Read across from BELOX 50.<br><br>Since acidity of BELOX 50, which has lower pH, is extremely low, any difference in acidity would be lower than analytical error – study not necessary.<br>SI CA comment: Acceptable | - |
| Relative density / bulk density | OECD Test Guideline 109 | BELOX 35 (35 % $H_2O_2$, | 1.128 at 20.0 °C<br>SI CA comment: Acceptable | Schlegl 2017 |

<table>
<tr><td></td><td></td><td>batch #155884)</td><td></td><td></td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC method MT 46.3 (storage at 54 ℃ for two weeks)</td><td>BELOX 35 (35 % $H_2O_2$, batch #155884)</td><td>Storage in 1L plastic container at a temperature mean of 54.6 °C for 14 days. $H_2O_2$ determined titrimetrically before and after storage.
<table>
<tr><td></td><td colspan="2">% $H_2O_2$ (w/w)</td></tr>
<tr><td></td><td>Container 1</td><td>Container 2</td></tr>
<tr><td>Before storage</td><td>35.9</td><td>35.9</td></tr>
<tr><td>After storage</td><td>36.1</td><td>36.1</td></tr>
</table>
The decrease of concentration of hydrogen peroxide was less than 10 %. Products BELOX 35 SB, BELOX 35 FP and BELOX 35 are stable according to accelerated storage test.<br>SI CA comment:<br>Acceptable.</td><td>Benetka 2017</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>GIFAP (Croplife International) monograph no. 17</td><td>BELOX 35 (35 % $H_2O_2$, batch #155884)</td><td>Storage in 1L plastic container at a temperature mean of 25.2 °C for 2 years. $H_2O_2$ determined titrimetrically before storage and after 2 years.
<table>
<tr><td></td><td colspan="2">% $H_2O_2$ (w/w)</td></tr>
<tr><td></td><td>Container 1</td><td>Container 2</td></tr>
<tr><td>Before storage</td><td>35.9</td><td>35.9</td></tr>
<tr><td>After 2Y storage</td><td>35.3</td><td>34.9</td></tr>
</table>
The concentration for both parallels was 35.9% w/w $H_2O_2$ before, and 35.3% (#1) and 34.9% (#2) w/w after 2 year of storage at ambient temperature. Products BELOX 35 SB, BELOX 35 FP and BELOX 35 are stable according to accelerated storage test.<br>SI CA comment:<br>Results (decrease of a.s. content for average 0.8%) justify the storage stability of 2 years at room temperature. The study is acceptable according to the stability of active substance,</td><td>Benetka 2019</td></tr>
</table>

| | | | | |
|---|---|---|---|---|
| | | | but data about the packaging stability is not available. | |
| Storage stability test – **low temperature stability test for liquids** | BPR Guidance, Volume I, point 3.4.1.3 | | **In the instructions for use it is stated:** Store in a ventilated, cool (0–25°C) location protected against frost and direct sunlight and away from heat sources and flammable substances.<br>SI CA comment: Acceptable, since the label state 'Store in a location protected against frost'. | Instructions for use |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | BPR Guidance, Volume I, point 3.4.2 | | **In the instructions for use it is stated:** Store in a ventilated, cool (0 - 25 °C) location protected against frost and direct sunlight and away from heat sources and flammable substances.<br>SI CA comment: Acceptable, since the label state 'Store in a location protected against direct sunlight'. | Instructions for use |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | BPR Guidance, Volume I, point 3.4.2 | | **In the instructions for use it is stated:** Store in a ventilated, cool (0 – 25°C) location protected against frost and direct sunlight and away from heat sources and flammable substances.<br>SI CA comment: Acceptable, since the label state 'Store in a ventilated, cool (0–25°C) location protected against frost and direct sunlight and away from heat sources and flammable substances.' Since the products are water-based, access of humidity would be irrelevant. | Instructions for use |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | GIFAP (Croplife International) monograph no. 17 | BELOX 35 (35 % $H_2O_2$, batch #155884 | Storage in 1L plastic container at a temperature mean of 25.2°C for 2 years. Statement about the condition of container material before and after storage is not available.<br>SI CA comment: Acceptable. | Benetka 2019 |

| | | | | |
|---|---|---|---|---|
| Wettability | BPR Guidance, Volume I, point 3.5.1 | | Not applicable, the products are supplied as liquids.<br>The data is required only for solid preparations which are to be dispersed in water.<br>SI CA comment: Acceptable. | |
| Suspensibility, spontaneity and dispersion stability | BPR Guidance, Volume I, point 3.5.2 | | Not applicable, product does not contain any insoluble substance.<br>The data is required only for products that contain insoluble active substance and form suspensions or dispersions.<br>SI CA comment: Acceptable. | |
| Wet sieve analysis and dry sieve test | CIPAC MT 179, CIPAC MT 41.1 | BELOX 50 (49.9% H2O2), Batch # 209983 | BELOX 50 was diluted in water and inverted 15 times in a graduated cylinder. After a standing time of 5 minutes, it was filtered through a 75 µm sieve. After 18 hours, it was filtered again. No residue was left on either sieve – it can be concluded that BELOX 50 has total degree of dissolution and total dilution stability. Since BELOX 35 contains lower concentrations of all ingredients than BELOX 50, the results of this test apply to BELOX 35 as well.<br>SI CA comment: Acceptable, no residues. | Radulović 2018a |
| Emulsifiability, re-emulsifiability and emulsion stability | BPR Guidance, Volume I, point 3.5.4 | | Not applicable, preparation does not form emulsion.<br>The data is required only for the products that form emulsions.<br>SI CA comment: Acceptable. | |
| Disintegration time | BPR Guidance, Volume I, point 3.5.5 | | Not applicable, the products are supplied as liquids.<br>The data is required only for products that are tablets.<br>SI CA comment: Acceptable. | |
| Particle size distribution, content of dust/fines, attrition, friability | BPR Guidance, Volume I, point 3.5.6 | | Not applicable, the products are supplied as liquids.<br>The data is required only for biocidal products supplied as powders or granules.<br>SI CA comment: Acceptable. | |

| | | | | |
|---|---|---|---|---|
| Persistent foaming | CIPAC method 47.2: Determination of the foaming of suspension concentrates | | No foam was produced of sample BELOX 50 at level 70% (35 % of $H_2O_2$ - the highest in use concentration) and BELOX 50 at level 2.4 % (1.2% of $H_2O_2$ - the lowest in use concentration). Since BELOX 35 contains lower concentrations of all ingredients than BELOX 50 and the highest and lowest in use concentrations are the same, the results of this test apply to BELOX 35 as well.<br>SI CA comment:<br>Read across from BELOX 50.<br>Acceptable. | Fröschl 2019 |
| Flowability/Pourability/ Dustability | BPR Guidance, Volume I, point 3.5.8 | | Not applicable, the products are supplied as liquids.<br>The data is required only for the preparations supplied as granules, suspension concentrates, capsule suspensions, suspoemulsions or powder.<br>SI CA comment: Acceptable. | |
| Burning rate — smoke generators | BPR Guidance, Volume I, point 3.5.9 | | Not applicable, the products are supplied as liquids.<br>The data is required only for smoke generators.<br>SI CA comment: Acceptable. | |
| Burning completeness — smoke generators | BPR Guidance, Volume I, point 3.5.10 | | Not applicable, the products are supplied as liquids.<br>The data is required only for smoke generators.<br>SI CA comment: Acceptable. | |
| Composition of smoke — smoke generators | BPR Guidance, Volume I, point 3.5.11 | | Not applicable, the products are supplied as liquids.<br>The data is required only for smoke generators.<br>SI CA comment: Acceptable. | |
| Spraying pattern — aerosols | BPR Guidance, Volume I, point 3.5.12 | | Not applicable, the products are supplied as liquids.<br>The data is required only for preparations sold as aerosols.<br>SI CA comment: Acceptable. | |

| | | | | |
|---|---|---|---|---|
| Physical compatibility | BPR Guidance, Volume I, point 3.6 | | Not applicable, not intended to be used with other products. The data is required only when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products.<br>SI CA comment: Acceptable. | |
| Chemical compatibility | BPR Guidance, Volume I, point 3.6 | | Not applicable, not intended to be used with other products.<br>The data is required only when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products.<br>SI CA comment: Acceptable. | |
| Degree of dissolution and dilution stability | CIPAC method MT 179 | | Test performed under normal conditions (25 °C). After dilution, rotation in a cylinder and filtration on a sieve, no residue was detected. Sample was left to stand for 18 hours and filtered again, with no resulting residue.<br><br>BELOX 50 has a total degree of dissolution, total solution stability and total dilution stability.<br><br>Since BELOX 35 has a lower peroxide content than BELOX 50, it is considered to possess same degree of dissolution and solution stability. No further studies necessary.<br>SI CA comment:<br>Read across from BELOX 50. Acceptable. | Blagojević, 2018 |
| Surface tension | EU Method A.5 (Surface Tension) | BELOX 35 (35 % $H_2O_2$, batch #155884) | 60.8 mN/m at 20 °C<br>SI CA comment: Acceptable. | Schlegl 2017 |
| Viscosity | ISO 2431 | | 0.7 $mm^2/s$ at 23°C | |

| | | | | |
|---|---|---|---|---|
| | | BELOX 35 (35 % $H_2O_2$, batch #155884) | SI CA comment: $0.7*10^{-6}$ $m^2/s$ at 23 °C Viscosity at 40 °C is missing; the measured viscosity is not at exactly 20 °C. Since the product contains <10% hydrocarbons, we find the study acceptable. | Schlegl 2017<br><br>Schlegl 2017a |

**Meta SPC 2**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
|---|---|---|---|---|
| Physical state at 20 °C and 101.3 kPa | Visual | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | Liquid<br>SI CA comment: Acceptable. | Benetka 2017a |
| Colour at 20 °C and 101.3 kPa | Visual | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | Colourless<br>SI CA comment: Acceptable. | Benetka 2017a |
| Odour at 20 °C and 101.3 kPa | Organoleptic | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | Typical odour<br>SI CA comment: Acceptable. | Benetka 2017a |
| pH | CIPAC method MT 75.3, 1999 | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | 1.6 at 22.3 °C<br>SI CA comment: Acceptable. | Schlegl 2017a |
| Acidity | CIPAC method MT 31 | BELOX 50 (49.9 % $H_2O_2$, batch #209983) | 0.017 % at 23 °C, calculated as concentration of sulfuric acid | Radulović 2018 |
| Relative density / bulk density | OECD Test Guideline 109 | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | 1.189 at 20.0 °C<br>SI CA comment: Acceptable. | Schlegl 2017a |
| Storage stability test – **accelerated storage** | CIPAC method MT 46.3 (storage at 54 ℃ for two weeks) | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | Storage in 1L plastic container at a temperature mean of 54.6°C for 14 days. $H_2O_2$ determined titrimetrically before and after storage. Measurement for the first parallel was 50.5% w/w $H_2O_2$ before, 50.75 after test period, and 50.4% w/w before and 50.3% after for the second parallel. Product | Benetka 2017a |

<table>
<tr><td></td><td></td><td></td><td>BELOX 50 is stable according to accelerated storage test.<br>SI CA comment: Acceptable.</td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>GIFAP (Croplife International) monograph no. 17</td><td>BELOX 50 (49.9 % $H_2O_2$, batch #155885)</td><td>Storage in 1L plastic container at a temperature mean of 25.2°C for 2 years. $H_2O_2$ determined titrimetrically before storage and after 2 years.
<table>
<tr><td></td><td colspan="2">% $H_2O_2$ (w/w)</td></tr>
<tr><td></td><td>Container 1</td><td>Container 2</td></tr>
<tr><td></td><td>50.5</td><td>50.4</td></tr>
<tr><td>After 2Y storage</td><td>48.8</td><td>48.4</td></tr>
</table>
The concentration of the first parallel was 50.5% w/w $H_2O_2$ before, and 49.2% w/w after 1 year of storage. For parallel #2, it was 50.4% before and 48.4% after, which is average 1.85 %. Product BELOX 50 is stable according to accelerated storage test. The data about the packing material condition change before and after storage is missing.<br>SI comment:<br>Results (decrease of a.s. content for average 1.85 %) justify the storage stability of 2 years at room temperature. The study is acceptable according to the stability of active substance. Data about the packaging stability is not available.</td><td>Benetka 2019a</td></tr>
<tr><td>Storage stability test – low temperature stability test for liquids</td><td>BPR Guidance, Volume I, point 3.4.1.3</td><td></td><td>In the instructions for use it is stated: Store in a ventilated, cool (0–25°C) location protected against frost and direct sunlight and away from heat sources and flammable substances.<br>SI CA comment: Acceptable, since the label state ‘Store in a location protected against frost’.</td><td>Instructions for use</td></tr>
</table>

| | | | | |
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| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | BPR Guidance, Volume I, point 3.4.2 | | **In the instructions for use it is stated:** Store in a ventilated, cool (0–25°C) location protected against frost and direct sunlight and away from heat sources and flammable substances.<br>SI CA comment: Acceptable, since the label state 'Store in a location protected against direct sunlight'. | Instructions for use |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | BPR Guidance, Volume I, point 3.4.2 | | **In the instructions for use it is stated:** Store in a ventilated, cool (0–25°C) location protected against frost and direct sunlight and away from heat sources and flammable substances.<br>SI CA comment: Acceptable, since the label state 'Store in a ventilated, cool (0–25°C) location protected against frost and direct sunlight and away from heat sources and flammable substances.' Since the products are water-based, access of humidity would be irrelevant. | Instructions for use |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | GIFAP (Croplife International) monograph no. 17 | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | Storage in 1L plastic container at a temperature mean of 25.2°C for 2 years. $H_2O_2$ determined titrimetrically before storage and after 2 years (the study is still ongoing). The concentration of the first parallel was 50.5% w/w $H_2O_2$ before, and 49.2% w/w after 2 years of storage. For parallel #2, it was 50.4% before and 48.4% after. Since there were no significant changes to active substance content.<br>No explicit statement about the condition of packing material before and after storage is available. and no visible changes to the container material, it can be concluded that BELOX 35 | Benetka 2019a |

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| | | | products are not reactive to container material.<br>SI CA comment:<br>Additional data on the state of packing material before and after storage was not provided. | |
| Wettability | BPR Guidance, Volume I, point 3.5.1 | | Not applicable, the products are supplied as liquids.<br>The data is required only for solid preparations which are to be dispersed in water.<br>SI CA comment:<br>Acceptable. | |
| Suspensibility, spontaneity and dispersion stability | BPR Guidance, Volume I, point 3.5.2 | | Not applicable, product does not contain any insoluble substance.<br>The data is required only for products that contain insoluble active substance and form suspensions or dispersions.<br>SI CA comment:<br>Acceptable. | |
| Wet sieve analysis and dry sieve test | CIPAC MT 179, CIPAC MT 41.1 | BELOX 50 (49.9% H2O2), Batch # 209983 | BELOX 50 was diluted in water and inverted 15 times in a graduated cylinder. After a standing time of 5 minutes, it was filtered through a 75 µm sieve. After 18 hours, it was filtered again. No residue was left on either sieve – it can be concluded that BELOX 50 has total degree of dissolution and total dilution stability.<br>SI CA comment:<br>Acceptable. | Radulović 2018a |
| Emulsifiability, re-emulsifiability and emulsion stability | BPR Guidance, Volume I, point 3.5.4 | | Not applicable, preparation does not form emulsion.<br>The data is required only for the products that form emulsions.<br>SI CA comment:<br>Acceptable. | |
| Disintegration time | BPR Guidance, Volume I, point 3.5.5 | | Not applicable, the products are supplied as liquids.<br>The data is required only for products that are tablets.<br>SI CA comment:<br>Acceptable. | |

| | | | | |
|---|---|---|---|---|
| Particle size distribution, content of dust/fines, attrition, friability | BPR Guidance, Volume I, point 3.5.6 | | Not applicable, the products are supplied as liquids.<br>The data is required only for biocidal products supplied as powders or granules.<br>SI CA comment:<br>Acceptable. | |
| Persistent foaming | CIPAC method 47.2: Determination of the foaming of suspension concentrates | | No foam was produced of sample BELOX 50 at level 70% (35 % of H2O2 - the highest in use concentration) and BELOX 50 at level 2.4 % (1.2 % of H2O2 - the lowest in use concentration).<br>Results are:<br>2.4 % BELOX w/w in CIPAC C water:<br>Time Volume of foam<br>10s 0 ml<br>1 min 0 ml<br>3 min 0 ml<br>12 min 0 ml<br><br>70 % BELOX w/w in CIPAC C water:<br>Time Volume of foam<br>10s 0 ml<br>1 min 0 ml<br>3 min 0 ml<br>12 min 0 ml<br><br>No foaming was observed at both concentrations.<br>Acceptable study. | Fröschl 2019 |
| Flowability/Pourability/ Dustability | BPR Guidance, Volume I, point 3.5.8 | | Not applicable, the products are supplied as liquids.<br>The data is required only for the preparations supplied as granules, suspension concentrates, capsule suspensions, suspoemulsions or powder.<br>SI CA comment:<br>Acceptable. | |
| Burning rate — smoke generators | BPR Guidance, Volume I, point 3.5.9 | | Not applicable, the products are supplied as liquids.<br>The data is required only for smoke generators.<br>SI CA comment:<br>Acceptable | |

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| Burning completeness — smoke generators | BPR Guidance, Volume I, point 3.5.10 | | Not applicable, the products are supplied as liquids.<br>The data is required only for smoke generators.<br>SI CA comment:<br>Acceptable | |
| Composition of smoke — smoke generators | BPR Guidance, Volume I, point 3.5.11 | | Not applicable, the products are supplied as liquids.<br>The data is required only for smoke generators.<br>SI CA comment:<br>Acceptable | |
| Spraying pattern — aerosols | BPR Guidance, Volume I, point 3.5.12 | | Not applicable, the products are supplied as liquids.<br>The data is required only for preparations sold as aerosols.<br>SI CA comment:<br>Acceptable | |
| Physical compatibility | BPR Guidance, Volume I, point 3.6 | | Not applicable, not intended to be used with other products.<br>The data is required only when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products.<br>SI CA comment:<br>Acceptable | |
| Chemical compatibility | BPR Guidance, Volume I, point 3.6 | | Not applicable, not intended to be used with other products.<br>The data is required only when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products.<br>SI CA comment:<br>Acceptable | |

| | | | | |
|---|---|---|---|---|
| Degree of dissolution and dilution stability | CIPAC method MT 179 | BELOX 50 (49.9 % $H_2O_2$, batch #2009983) | Test performed under normal conditions (25 °C). After dilution, rotation in a cylinder and filtration on a sieve, no residue was detected. Sample was left to stand for 18 hours and filtered again, with no resulting residue.<br><br>BELOX 50 has a total degree of dissolution, total solution stability and total dilution stability.<br>SI CA comment:<br>Acceptable | Radulović, 2018a |
| Surface tension | EU Method A.5 (Surface Tension) | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | 60.8 mN/m at 20 °C<br>SI CA comment:<br>Acceptable | Schlegl 2017 |
| Viscosity | ISO 2431 | BELOX 50 (49.9 % $H_2O_2$, batch #155885) | 0.7 $mm^2/s$ at 23 °C<br><br>$0.7*10^{-6}$ $m^2/s$<br>SI CA comment:<br>Viscosity at 40°C is missing; the measured viscosity is not at exactly 20°C.<br>Since the product contains <10% hydrocarbons, we find the study acceptable. | Schlegl 2017 |

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

The physical, chemical and technical properties of the BELOX product family are available for diluted products BELOX 35 (meta SPC 1) as well for the concentrated biocidal product BELOX 50 (meta SPC 2). The data provided are sufficient to support the BPF requested.
Shelf life stability data for BELOX 35 after 2 years of storage show 2 years stability of the product at room temperature.
Shelf life stability data for BELOX 50 after 2 years of storage show 2 years stability of the product at room temperature.

### 2.2.3 Physical hazards and respective characteristics

Meta SPC 1 and meta SPC 2

| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Reference |
|---|---|---|---|---|
| Explosives | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | Since there is no test data on the mixture itself, the available information on individual substances in mixture was used as laid down in Article 5(6) of CLP Regulation. Aqueous hydrogen peroxide without impurities has explosive limit at ≥ 86 % (w/w) (Assessment Report, Hydrogen peroxide, PT1-6, 2015). None of other ingredients are classified as explosive. Even more, all other ingredients are stabilizers that prevent or slow down decomposition of H2O2. That is why, we can conclude that products in BELOX product family (stabilized 35 -49.9 % peroxide solutions) are not explosive.<br>SI CA comment:<br>Acceptable statement. | Assessment Report, Hydrogen peroxide, PT1-6, 2015 |
| Flammable gases | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | Product is according to definition laid down in point 1.0 of the Annex I of the Regulation 1272/2008 CLP, a liquid. That is why it cannot be classified as flammable gas according to point 2.2.1. of the same Annex.<br>SI CA comment:<br>Not relevant, not a gas. Acceptable statement. | |
| Flammable aerosols | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | Product is according to definition laid down in point 2.3.1. of the Annex I of the Regulation 1272/2008 CLP not an aerosol. That is why it cannot be classified as flammable aerosol.<br>SI CA comment:<br>Not relevant, not an aerosol. Acceptable statement. | |
| Oxidising gases | BPR Guidance, Volume I, point 4 | | Product is according to definition laid down in point 1.0 of the Annex I of the Regulation 1272/2008 CLP a liquid. That is why it cannot be classified as oxidising gas according to point 2.4.1. of the same Annex. | |

| | | | | |
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| | Regulation (EC) No. 1272/2008 CLP | | SI CA comment:<br>Not relevant, not a gas. Acceptable statement. | |
| Gases under pressure | BPR Guidance, Volume I, point 4.5<br><br>Regulation (EC) No. 1272/2008 CLP | | Product is according to definition laid down in point 1.0 of the Annex I of the Regulation 1272/2008 CLP a liquid. That is why it cannot be classified as gas under pressure according to point 2.5.1.1. of the same Annex. | |
| | | | SI CA comment:<br>Not relevant, not a gas under pressure. Acceptable statement. | |
| Flammable liquids | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | There is no test data on the mixture itself so we have used available information on individual substances in mixture as laid down in Article 5(6) of Regulation 1272/2008 CLP. Since none of the substance used in products of BELOX product family is classified as flammable we can conclude that none of the products in BELOX product family is flammable liquid. | |
| | | | SI CA comment:<br>Not relevant, not a flammable liquid. Acceptable statement. | |
| Flammable solids | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | Products are according to definition laid down in point 1.0 of the Annex I of the Regulation 1272/2008 CLP a liquid. That is why it cannot be classified as flammable solids according to point 2.7.1. of the same Annex. | |
| | | | SI CA comment:<br>Not relevant, not a flammable solid. Acceptable statement. | |
| Self-reactive substances and mixtures | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | There is no test data on the mixture itself so we have used available information on individual substances in mixture as laid down in Article 5(6) of Regulation 1272/2008 CLP. Since none of the substance used in products of BELOX product family is classified as self-reactive substance we can conclude that none of the products in BELOX product family is self-reactive substance. | . |
| | | | SI CA comment:<br>Not relevant, not a self-reactive substance or mixture. Acceptable statement. | |

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| Pyrophoric liquids | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | There is no test data on the mixture itself so we have used available information on individual substances in mixture as laid down in Article 5(6) of Regulation 1272/2008 CLP. Since none of the substance used in products of BELOX product family is classified as pyrophoric liquid we can conclude that none of the products in BELOX product family is pyrophoric liquid.<br>SI CA comment:<br>Not relevant, not a pyriphoric liquid. Acceptable statement. | |
| Pyrophoric solids | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | Product is a liquid according to definition laid down in point 1.0 of the Annex I of the Regulation 1272/2008 CLP. That is why it cannot be classified as pyrophoric solids according to point 2.10.1. of the same Annex.<br>SI CA comment:<br>Not relevant, not a pyrophoric solid. Acceptable statement. | |
| Self-heating substances and mixtures | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | There is no test data on the mixture itself so we have used available information on individual substances in mixture as laid down in Article 5(6) of Regulation 1272/2008 CLP. Since none of the substance used in products of BELOX product family is classified as self-heating we can conclude that none of the products in BELOX product family is self-heating mixture.<br>SI CA comment:<br>Not relevant, not a self-heating substance or mixture. Acceptable statement. | |
| Substances and mixtures which in contact with water emit flammable gases | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP<br><br>Statement based on experience in use concerning | | According to the rule laid down in point 2.12.14 of the Annex I of the Regulation 1272/2008 CLP the classification procedure for this class need not be applied if, the substance or mixture is known to be soluble in water to form a stable mixture.<br>SI CA comment:<br>Acceptable | |

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| | the flammability in contact with water | | | |
| Oxidising liquids | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | There is no test data on the mixture itself so we have used available information on individual substances in mixture as laid down in Article 6(5) of Regulation 1272/2008 CLP. Product classification is based on the specific concentration limits for hydrogen peroxide. Studies performed by the CEFIC PEROXYGENS Sector Group have shown that aqueous solutions of Hydrogen Peroxide in the concentration range between 40,1 – 49,9% w/w are Oxidising Liquids category 3 according to the existing criteria in the CLP regulation. This new data was submitted to the authorities and is in process of being made part of the harmonised classification of hydrogen peroxide. According to these specific concentration limits, BELOX 50 is classified as an Oxidising Liquid category 3. BELOX 35 products are not oxidising liquids.<br>SI CA comment:<br>Acceptable. | |
| Oxidising solids | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP | | Product is a liquid according to definition laid down in point 1.0 of the Annex I of the Regulation 1272/2008 CLP. That is why it cannot be classified as oxidising solids according to point 2.14.1. of the same Annex.<br>SI CA comment:<br>Not relevant, not a solid. Study acceptable. | |

| | | | | |
|---|---|---|---|---|
| Organic peroxides | BPR Guidance, Volume I, point 4<br><br>Regulation (EC) No. 1272/2008 CLP<br><br>Statement based on structural formula. | | There is no test data on the mixture itself so we have used available information on individual substances in mixture as laid down in Article 5(6) of Regulation 1272/2008 CLP. According to definition of organic peroxide laid down in point 2.15.1.1. of the Annex I of the Regulation 1272/2008 CLP: Organic peroxides means liquid or solid organic substances which contain the bivalent -O-O- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures (formulations) containing at least one organic peroxide.<br>According to definition above hydrogen peroxide is not considered organic peroxide since it does not contain organic radicals. All other ingredients do not contain the bivalent -O-O- structure. Since none of the substance used in products of BELOX product family is organic peroxide we can conclude that none of the products in BELOX product family is organic peroxide.<br>SI CA comment:<br>Not relevant, hydrogen peroxide is not considered as organic peroxide. | |
| Corrosive to metals | Method 37.4 C.1 of the UN Handbook | 49.5% Hydrogen Peroxide | The performed study on 49.5% aqueous solution of hydrogen peroxide in accordance with Method 37.4 C.1. of the UN Handbook has determined no corrosive properties. Since BELOX 50 is an aqueous solution of hydrogen peroxide with added stabilisers at a similar concentration, the same conclusion is valid for BELOX 50. Since the concentration of hydrogen peroxide in the product BELOX 35 is even lower, BELOX products are not considered oxidising to metals.<br>SI CA comment:<br>Acceptable study. | Henke, 2016 |

| | | | | |
|---|---|---|---|---|
| Auto-ignition temperatures of products (liquids and gases) | method EEC A.15 Auto-ignition temperature | | No experiment was concluded, since method EEC A.15, Auto-ignition temperature (liquids and gases), does not apply to substances which are explosive.<br>Vapours of ≥ 40 % hydrogen peroxide are explosive.<br>SI CA comment:<br>Acceptable. | |
| Relative self-ignition temperature for solids | ECHA Guidance on the Application of the CLP Criteria, Section 2.11 | | Not applicable, the products are supplied as liquids.<br>According to ECHA Guidance on the Application of the CLP Criteria, Section 2.11 Self-heating substances and mixtures (ECHA) the test shall be performed on the substance or mixture in its physical form as presented.<br>SI CA comment:<br>Not relevant, not a solid. | |
| Dust explosion hazard | BPR Guidance, Volume I, point 4.17.3 | | Not applicable, the products are supplied as liquids.<br>According to the point 4.17.3 Dust explosion hazard of the Guidance on the Biocidal Products Regulation Volume I: Identity/physico-chemical properties/analytical methodology – Part A: Information Requirements (Version 1.1 November 2014) the data are required only for powders and products containing, or able to produce, dust.<br>SI CA comment:<br>Not relevant, not a dust. | |

| **Conclusion on the physical hazards and respective characteristics of the product** |
|---|
| The BELOX 50, a biocidal product within the biocidal product family BELOX which contains 49.9 %, is classified as an Oxidising Liquid category 3 according to these specific concentration limits. Other biocidal products in the family BELOX 35 have lower concentration of hydrogen peroxide (35 %) and therefore are not classified for physical hazard. |

### 2.2.4 Methods for detection and identification

The method of determining the concentration of hydrogen peroxide in all members of the biocidal product family is titration with potassium permanganate under acidic conditions and is the same as presented in the CAR.

| Analytical methods for the analysis of active substance in the product | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **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 | | |
| *Hydrogen peroxide (active substance)* | Titrimetric method | 5 replicates 35% $H_2O_2$ | 0.99998 | $Ce^{4+}$ is known to be a specific agent for peroxides in strongly acidic medium. | 90-110 | 99.3 % | 0.27 % | LOQ: 0.075 mg H2O2.<br><br>LOD: 0.021 mg $H_2O_2$. | Benetka 2018 |

### 2.2.4.1 Analytical methods for the monitoring of residues (soi, water, air, body, fluids and tissues and food)

Method for detection in soil is not applicable, because hydrogen peroxide is rapidly decomposed in soil and does not adsorb to soil matrix. Trace amounts of hydrogen peroxide in soil water may be analysed by the method for water. Analytical methods of determination of hydrogen peroxide in air and water were submitted as post-approval requirement and were evaluated by the RMS FI as acceptable and sufficient for filling the data gaps defined in the CAR and in the related BPC Opinions.

The analytical method for detection in food/feed of plant and animal origin is not relevant as not expected in food/feed of plant origin.

Hydrogen peroxide is not classified as toxic or very toxic, and therefore no analytical method for body fluids and tissues of humans or animals is required.

| **Conclusion on the methods for detection and identification of the product** |
|---|
| The formulations of hydrogen peroxide are aqueous solutions of a concentration of 49.9% (w/w) and 35% (w/w). The hydrogen peroxide content in those aqueous solutions is determined by titration with potassium permanganate under acidic conditions. The method is acceptable for all members of the biocidal product family, has been sufficiently validated and therefore is considered to be fit for the intendent purpose.<br>The monitoring methods for air and water have previously been evaluated at active substance approval.<br>The monitoring methods for soil, food/feed of plant origin and animal/human body fluids/tissue are not relevant for BELOX. |

## 2.2.5 Efficacy against target organisms

### 2.2.5.1 Function and field of use

BELOX is a broad range disinfectant (main group 1: Disinfectants) with bactericidal, fungicidal, sporicidal and virucidal activity.

It is intended to be used as:
PT 2 - Disinfectants and algaecides not intended for direct application to humans or animal;
PT 3 - Veterinary hygiene
PT 4 - Food and feed area
PT 5 - Drinking water disinfection

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

Microorganisms including bacteria and bacterial spores, fungi, and viruses are the target organisms to be controlled by BELOX. Disinfectant will be used on surfaces in private and public health area, veterinary, food and feed area, to protect humans and animals. In addition, BELOX will be used for disinfection of drinking water (for application groups 1. Disinfection at the drinking water suppliers and their water distribution systems, 4. Disinfection of water in reservoirs, and 6. Disinfection of water for animals).

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

Active substance hydrogen peroxide is cytotoxic due to its capacity to generate more reactive and cytotoxic oxygen species such as the hydroxyl radical. Hydroxyl radical is a powerful oxidant, which can initiate oxidation of biomolecules. Thus, an irreversible reduction of viability of cells is the effect on target organisms, which are microorganisms. Unacceptable suffering is therefore not relevant.

### 2.2.5.4 Mode of action, including time delay

The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species can initiate oxidation of biomolecules and cause irreversible damage to a host of cell components such as enzymes, membrane constituents, and DNA.

## 2.2.5.5 Efficacy data

| Experimental data on the efficacy of the biocidal product against target organisms | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericidal activity | PT 2, PT 4, PT 5 | Interox ST 50: 49-49.9% (w/w) $H_2O_2$ | Bacteria*: Escherichia coli, Enterococcus hirae, Staphylococcus aureus, Pseudomonas aeruginosa* | EN 1276 (1997) - Quantitative Suspension Test for the Evaluation of Bactericidal Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic, and Institutional Areas - Test Method and Requirements (Phase 2, Step 1) | Laboratory number MGS: 12319/ SO No: 1037<br><br>Dilution neutralisation method.<br><br>Product concentrations applied: 10% (v/v), 15% (v/v), 20% (v/v), 25% (v/v), 35% (v/v) and 50% (v/v).<br><br>Contact time: 5 minutes at 20°C.<br><br>Clean (0.3 g/L Bovine albumin) and dirty (3 g/L Bovine albumin) conditions. | Under clean conditions, biocidal product demonstrates bactericidal activity against all bacteria tested (log reduction > 5) when used for 5 minutes at a minimum concentration of 15% (v/v), corresponding to a concentration of 7.41% $H_2O_2$ of (w/w). Under dirty conditions, biocidal product demonstrates bactericidal activity against all bacteria tested (log reduction > 5) when used for 5 minutes at a minimum concentration of 35% (v/v), corresponding to a concentration of 17.29% $H_2O_2$ of (w/w) | Crane, 2007d IIIB 5.10-04_BS EN 12765565523 259201773881 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Fungicidal activity | PT 2, PT 4 | Interox ST 50: 49-49.9% (w/w) $H_2O_2$ | Yeast: *Candida albicans*<br><br>Mold: *Aspergillus niger* | EN 1650 (1998) - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1) | Laboratory number MGS: 12319/ SO No: 1037<br><br>Dilution neutralisation method.<br><br>Product concentrations applied: 10% (v/v), 15% (v/v), 20% (v/v), 25% (v/v), 35% (v/v), 70% (v/v) and 100% (v/v).<br><br>Contact time: 15 minutes at 20°C.<br><br>Clean (0.3 g/L Bovine albumin) and dirty (3 g/L Bovine albumin) conditions. | Under clean conditions and required contact time, biocide demonstrates fungicidal activity (log reduction more than 4) against *C. albicans* when used at a concentration of 20% (v/v) and against *A. niger* at a concentration of 35% (v/v), corresponding to a concentration of 9.88% (w/w) and 17.29% (w/w) $H_2O_2$, respectively.<br>Under dirty conditions and required contact time, biocide demonstrates fungicidal activity (log reduction more than 4) against *C. albicans* when used at a concentration of 25% (v/v) and against *A. niger* at a concentration of 35% (v/v), corresponding to a concentration of 12.35% (w/w) and 17.29% (w/w) $H_2O_2$, respectively. | Crane, 2007e IIIB 5.10-05_BS EN 16506029947 89147353963 4 |
| Sporicidal activity | PT 2, PT 4 | Interox ST 50: 49-49.9% (w/w) $H_2O_2$ | *Bacillus subtilis* spores | EN 13704 (2002) - Quantitative suspension test for the | Laboratory number MGS: 12319/ SO No: 1037 | Under clean conditions biocide demonstrates | Crane, 2007f IIIB 5.10-06_BS EN |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1) | Dilution neutralisation method.<br><br>Product concentrations applied: 10% (v/v), 15% (v/v) and 20% (v/v).<br><br>Contact time: 60 minutes at 20°C. | sporicidal activity (log reduction >4) in 60 minutes contact time and when used at the concentration of 15% (v/v) corresponding to (7.41% (w/w) $H_2O_2$.<br><br>Test was not performed under dirty conditions. | 1370468980390067282374 73 |
| Bactericidal activity, Fungicidal activity, Sporicidal activity | PT 2, PT 4 | BELOX 35: 35% (w/w) $H_2O_2$ | Bacteria*: Pseudomonas aerugiosa, Eserichia coli, Enterococcus hirae, Staphylococcus aureus*<br><br>Yeast*: Candida albicans*<br><br>Mold*: Aspergillus brasiliensis*<br><br>Spores: *Bacillus subtilis* spores | NF T 72-281 - Determination of bactericidal, fungicidal, sporicidal activity for aerial surface disinfection processes (semi-field study) | Pour plate technique and filtration.<br><br>Product applied non diluted (35% (w/w) $H_2O_2$) to reach 500 mg/$m^3$.<br><br>Contact time: 94 min including 4 minutes fogging time.<br><br>Test temperature: 21°C.<br><br>Room size: 30 $m^2$ with 78 $m^3$ in volume.<br><br>Clean conditions: 0.5% skimmed milk.<br><br>Surface: stainless steel (ø 2 cm).<br>Carriers with microorganisms were | Under clean conditions biocide demonstrates bactericidal activity (log reduction >5) against all tested bacteria within the contact time of 94 minutes when used at the concentration of 500 mg/$m^3$ corresponding to 360 ppm $H_2O_2$.<br><br>Under clean conditions biocide demonstrates fungicidal activity against *C. albicans* and *A. brasiliensis* (log reduction >4) within the contact time of 94 minutes when used at a concentration of 500 | Belinka-mikrobiologija-NF T 72-281-2011-corrected-II (1) |

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| | | | | | placed in vertical position oriented towards the opposite side of the disinfection system. The distance was 3.6 m. | $mg/m^3$ corresponding to 360 ppm $H_2O_2$.<br><br>Under clean conditions biocide demonstrates sporicidal activity (log reduction >3) within the contact time of 94 minutes when used at a concentration of 500 $mg/m^3$ corresponding to 360 ppm $H_2O_2$. | |
| Bactericidal activity | PT 3 | Interox ST 50: 49-49.9% (w/w) $H_2O_2$ | Bacteria: *Proteus vulgaris, Enterococcus hirae, Staphylococcus aureus, Pseudomonas aeruginosa* | EN 1656 (2000) - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in veterinary field. Test method and requirements (phase 2/step 1) | Dilution neutralisation method.<br><br>Product concentrations applied: 10% (v/v), 15% (v/v), 20% (v/v), 25% (v/v), 30% (v/v), 35% (v/v), 40% (v/v), 50% (v/v) and 70% (v/v).<br><br>Contact time: 30 minutes at 10°C.<br><br>Clean (3 g/L bovine albumin) and dirty (10 g/L yeast extract and 10 g/L bovine albumin) conditions. | Under clean conditions biocide demonstrates bactericidal activity (log reduction >5) within the 30 minutes contact time against all bacteria tested when used at a concentration of 20% (v/v) corresponding to a concentration of of 9.88% (w/w) $H_2O_2$.<br><br>Under dirty conditions biocide demonstrates bactericidal activity (log reduction >5) within the 30 minutes contact time against all bacteria tested when used at a concentration of 35% | Crane, 2007h, IIIB 5.10-09_BS EN 16568190573056287663850 |

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| | | | | | | (v/v) corresponding to a concentration of of 17.29% (w/w) $H_2O_2$. | |
| Bactericidal activity | PT 3 | BELOX 35 - 35% (w/w) $H_2O_2$ | Bacteria: *Proteus vulgaris, Enterococcus hirae, Staphylococcus aureus, Pseudomonas aeruginosa* | EN 1656 (2009) - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in veterinary field. Test method and requirements (phase 2/step 1) | Dilution neutralisation method.<br><br>Product concentrations applied: 4.55 % (w/w) $H_2O_2$<br><br>Contact time: 30 minutes at 10°C.<br><br>Clean (3 g/L bovine albumin) conditions. | Although applied at only one chosen concentration of 4.55% (w/w) $H_2O_2$., BELOX 35 demonstrates bactericidal activity (log reduction = 6) within the 30 minutes contact time against all bacteria tested.<br>Biocide was tested under clean conditions. | Belinka-mikrobiologija-EN 1656-corrected II |
| Fungicidal activity | PT 3 | Interox ST 50: 49-49.9% (w/w) $H_2O_2$ | Yeast: *Candida albicans*<br><br>Mold: *Aspergillus niger* | EN 1657 (2005) - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1) | Dilution neutralisation method.<br><br>Product concentrations applied: 20% (v/v), 25% (v/v), 30% (v/v), 35% (v/v), 40% (v/v), 50% (v/v), 70% (v/v) and 100% (v/v)<br><br>Contact time: 30 minutes at 10°C.<br><br>Clean (3 g/L Bovine albumin) and dirty (10 g/L Yeast extract and 10 g/L bovine albumin) conditions. | Under clean conditions biocide demonstrates fungicidal activity against *C. albicans* (log reduction >5) when used at a concentration of 20% (v/v) corresponding to a concentration 9.88% (w/w) $H_2O_2$. Effective concentration (log reduction >4) against *A. niger* is 35% (v/v) corresponding to 17.29% (w/w) $H_2O_2$. | Crane, 2007i IIIb 5.10-10_BS EN 16577188589 223369680998 |

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| | | | | | | Under dirty conditions biocide demonstrates fungicidal activity against *C. albicans* and *A. niger* when used at a concentration of 35% and 50% (v/v) corresponding to 17.29% (w/w) and 24.70% (w/w) $H_2O_2$, respectively. | |
| Fungicidal activity | PT 3 | BELOX 35 - 35% (w/w) $H_2O_2$ | Yeast: *Candida albicans*<br><br>Mold: *Aspergillus niger* | EN 1657 (2016) - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area. Test method and requirements (phase 2, step 1) | Dilution neutralisation method.<br><br>Product concentrations applied: 4.55 % (w/w) $H_2O_2$<br><br>Contact time: 30 minutes at 10°C.<br><br>Clean (3 g/L bovine albumin) conditions. | Although applied at only one chosen concentration of 4.55% (w/w) $H_2O_2$., BELOX 35 demonstrates fungicidal activity (log reduction >4) within the 30 minutes contact time against all organisms tested.<br>Biocide was tested under clean conditions. | Belinka-mikrobiologija-EN 1657-corrected-II |
| Bactericidal activity | PT 3 | Interox ST 50: 49-49.9% (w/w) H2O2 | Bacteria*:* *Enterococcus hirae*, *Proteus vulgaris, Pseudomonas aeruginosa, Staphylococcus aureus* | EN 14349 (2007) - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical | Dilution neutralisation method.<br><br>Product applied: 5% (v/v), 10% (v/v), 15% (v/v) and 20% (v/v)<br><br>Contact time: 30 minutes at 10°C. | Under clean conditions biocide demonstrates bactericidal activity (log reduction >4) on non-porous surfaces against all bacteria tested within contact time 30 minutes at a concentration of 15% | Crane, 2007j IIIB 5.10-11_BS EN 14349 clean617589066626200238 |

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| | | | | action. Test method and requirements (phase 2, step 2) | Clean conditions (3 g/L bovine albumin). | (v/v) corresponding to a concentration of 7.41% (w/w) $H_2O_2$. | |
| Bactericidal activity | PT 3 | Interox ST 50: 49-49.9% (w/w) H2O2 | Bacteria*: Enterococcus hirae*, *Proteus vulgaris, Pseudomonas aeruginosa, Staphylococcus aureus* | EN 14349 (2007) - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action. Test method and requirements (phase 2, step 2) | Dilution neutralisation method.<br><br>Product applied: 10% (v/v), 15% (v/v), 25% (v/v), 30% (v/v), 35% (v/v) and 50% (v/v).<br><br>Contact time: 30 minutes at 10°C.<br><br>Dirty conditions (10g/L yeast extract + 10g/L bovine albumin). | Under dirty conditions biocide demonstrates bactericidal activity (log reduction >4) on non-porous surfaces against all bacteria tested within contact time 30 minutes at a concentration of 25% (v/v) corresponding to a concentration of 12.35% (w/w) $H_2O_2$. | Crane, 2007k IIIB 5.10-12_BS EN 14349 dirty490541082223903364 7 |
| Bactericidal activity | PT 3 | BELOX 35 - 35% (w/w) $H_2O_2$ | Bacteria*: Enterococcus hirae*, *Proteus vulgaris, Pseudomonas aeruginosa, Staphylococcus aureus* | EN 14349 (2012) - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action. Test method and requirements (phase 2, step 2) | Dilution neutralisation method.<br><br>Product applied: 4.55% (w/w) $H_2O_2$<br><br>Contact time: 30 minutes at 10°C.<br><br>Clean conditions (3 g/L bovine albumin). | Although applied at only one chosen concentration of 4.55% (w/w) $H_2O_2$., BELOX 35 demonstrates bactericidal activity (log reduction =6) within the 30 minutes contact time against all bacteria tested on stainless steel surface.<br>Biocide was tested under clean conditions. | Belinka-mikrobiologija-EN 14349-corrected II |
| Fungicidal activity | PT 3 | BELOX 35 - 35% (w/w) $H_2O_2$ | Yeast: *Candida albicans* | EN 14348 (2012) - Quantitative surface test for the evaluation | Dilution neutralisation method. | Although applied at only one chosen | Belinka-mikrobiologij |

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| | | | Mold: *Aspergillus niger* | of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2) | Product applied: 4.55% (w/w) $H_2O_2$<br><br>Contact time: 30 minutes at 10°C.<br><br>Clean conditions (3 g/L bovine albumin). | concentration of 4.55% (w/w) $H_2O_2$., BELOX 35 demonstrates bactericidal activity (log reduction >4) within the 30 minutes contact time against all organisms tested on stainless steel surface.<br>Biocide was tested under clean conditions. | a-EN 16438-corrected-II |
| Bactericidal and fungicidal activity | PT 4 | Interox ST 50: 49-49.9% (w/w) $H_2O_2$ | Bacteria*: Escherichia coli, Enterococcus hirae, Staphylococcus aureus, Pseudomonas aeruginosa.*<br><br>Yeast: *Candida albicans.*<br><br>Mold: *Aspergillus niger*<br><br>*Spores Bacillus subtilis* | EN 13697 (2001) - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements without mechanical action (phase 2/step 2) | Laboratory number MGS: 12319/ SO No: 1037<br><br>Dilution-neutralisation method.<br><br>Tested concentrations:<br>- bacteria: 10% v/v, 15% v/v, 25% v/v<br>- yeast: 15% v/v, 25% v/v, 35% v/v<br>- mold: 25% v/v, 35% v/v, 50% v/v<br>- spores: 10% v/v, 15% v/v, 20% v/v<br><br>Contact times:<br>- bacteria: 5 minutes at 20°C<br>- fungi: 15 minutes at 20°C | Under clean conditions within the claimed contact time biocide demonstrates:<br>-bactericidal activity (log reduction >4) on non-porous surfaces against all bacteria tested when diluted and used at a concentration of 15% (v/v) corresponding to a concentration 7.41% (w/w) $H_2O_2$.<br><br>- fungicidal activity (log reduction >3) on non-porous surfaces against all fungi tested when diluted and used at a | Crane, 2007g IIIB 5.10-08_BS EN 13697 Report689019512974172042 2 |

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| | | | | | - spores: 60 minutes at 20°C.<br><br>Clean conditions (0.3 g/L Bovine albumin).<br><br>Surface: stainless steel. | concentration of 25% (v/v) corresponding to a 12.35% (w/w) $H_2O_2$.<br><br>Biocide does not possess sporicidal activity on stainless steel surface in 60 minutes at 20°C under clean conditions at any of tested concentrations.<br><br>Dirty conditions were not tested. | |
| Sporicidal activity | PT 4 | BELOX 35: 35% (w/w) $H_2O_2$ | *Geobacillus stearothermophilus* spores | Semi-field study | Dilution-neutralisation method<br><br>Material: aseptic package for milk (10x10 cm)<br>Contact time 16 sec.<br>Test temperature: 71.0±0.1°C.<br><br>Negative and blank control: demineralized water poured over the aseptic package with or without microorganism on the surface.<br>Positive control used.<br><br>No organic load. | Biocide demonstrates activity (log reduction = 7) against bacterial spores within the contact time of 16 seconds when used at a concentration of 35% (w/w) $H_2O_2$ and at high temperature (71°C). | Belinka-mikrobiologija-dezinfekcija ambalaze-Spore II |

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| | | | | | After inactivation of belox and positive control, spores were removed form aseptic package by ultrasonic bath for 30 min.<br><br>Experiments were performed in duplicates. | | |
| Virucidal activity | PT 2,<br>PT 4,<br>PT 5 | Interox ST 50: 49-49.9% (w/w) $H_2O_2$ | 2 species of viruses: Poliovirus type 1, Adenovirus type 5 | EN 14476 (2013) - Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (Phase 2/Step 1) | Laboratory number MGS: 12319/ SO No: 1037<br><br>Dilution neutralisation method.<br><br>Product concentrations applied: 35% (v/v), 70% (v/v) and 80% (v/v).<br><br>Contact time: 15 minutes at 20°C.<br><br>Clean (3 g/L bovine albumin) conditions. | Under clean conditions biocide demonstrates virucidal activity (log reduction >4) within the contact time of 15 minutes when used at a concentration of 35% (v/v) corresponding to 17.29% (w/w) $H_2O_2$.<br><br>Murine noroviruses were not included in the test. | IIIB 5.10-07_BS EN 1447684174380411044865 52 |
| Virucidal activity | PT 4,<br>PT 5 | BELOX 35: 35% (w/w) H2O2 | 2 species of viruses: Poliovirus type 1, Adenovirus type 5 | EN 14476 (2005) - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and | Dilution neutralisation method.<br><br>Product concentrations applied: 17.5% H2O2<br><br>Contact time: 15 and 60 minutes at 20°C. | Under clean conditions biocide demonstrates virucidal activity (log reduction >4) within the contact time of 15 minutes when used at | Belinka-mikrobiologija-virucidal-EN 1447636456654511992680 7 |

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| | | | | requirements (phase 2, step 1) | Clean (3 g/L bovine albumin) conditions. | a concentration of 17.5% (w/w) $H_2O_2$.<br><br>Murine noroviruses were not included in the test. | |
| Bactericidal activity, virucidal activity | PT 5 | BELOX 35: 35% (w/w) H2O2 | Bacteria: *Escherichia coli, Enterococcus faecium, Legionella rowbothamii*<br><br>Viruses: Bacteriophage MS2 - Bacteriophage PRD1 | Quantitative determination of the efficacy of drinking water disinfectants 2013/02 | Dilution neutralisation method.<br><br>Product concentrations applied: 25 mg/L $H_2O_2$ (calculated as 75.4 ppm of BELOX 35)<br><br>Contact time: After a 10 and 25 minutes at (15.0±0.1)°C<br><br>Organic load: dissolved organic C 20mg/L | Under clean conditions biocide demonstrates bactericidal and virucidal activity. Log reductions differed and are dependent upon a contact time: log reduction >5 against bacteria and > 4 against bacteriophages within the 25 minutes contact time and log reduction >3 against bacteria and > 2 against bacteriophages within the 10 minutes contact time.<br><br>BELOX 35 was tested at only one concentration. | Belinka-test efikasnosti BELOX 35-dec 2017-Voda za pice-II340504808 5319458845 |

**Conclusion on the efficacy of the product**

The BELOX is a broad range disinfectant active against microorganisms. It is intended to be used as PT2 for room disinfection by VHP. As PT3 it will be used in animal housing for non-porous surface disinfection by spraying. Within PT4 several uses are claimed: room disinfection by VHP, cork stoppers disinfection (wetted by spraying), disinfection of aseptic packaging by immersion or spraying at ≥ 70°C and disinfection of inner surfaces of drinking water piping and tanks and piping and tanks for beverages by CIP. The biocide will also be used as PT5 for drinking water disinfection including Group 1.: Disinfection at the drinking water suppliers and their water distribution systems; Group 4.: Disinfection of water in reservoirs and Group 6.: Disinfection of water for animals.

Altogether 39 studies were submitted to demonstrate the efficacy of the biocide.

Seven studies were immediately excluded from the evaluation. Namely, 3 of those were laboratory suspension tests (Phase 1) which are not accepted for product authorisation; 2 studies were done according to the ASTM standards but refer to the use in paper industry and were therefore considered not relevant; another 2 studies were performed to show efficient disinfection of instruments in a medical area, but this is the use not claimed by the applicant. Additional 15 studies were excluded because they were not performed according to the standards claimed to be used. Test conditions were either deviating from the ones described in the norms or the results were not submitted correctly. Only short reports or summary tables were received; therefore we requested the submission of the original efficacy data. The remaining 17 studies were key studies and are summarized in the table Experimental data on the efficacy of the biocidal product against target organism(s). In 9 of these, Interox ST50 was used as the tested biocide and the remaining 8 studies were done with BELOX 35. INTEROX ST50 and products from BPF BELOX are all stabilised hydrogen peroxide solutions. Since stabilisers do not affect efficacy, the efficacy results made on INTEROX ST50 can also be used to prove the efficacy of BELOX products. In original study reports of five herein used studies with Interox ST50, the batch number was missing. These studies were performed for the purpose of Hydrogen peroxide entry into Annex I with CEFIC Peroxygen Sector Group/Hydrogen peroxide subgroup as the data owner. The laboratory which did the testing provided the laboratory number MGS: 12319/ SO No: 1037. Therefore, we accepted this information instead of the bacth number of the product tested.

With these studies bactericidal, fungicidal (including yeasts and molds) and sporicidal activity of the biocide was demonstrated. Virucidal activity was not proven, as it was shown that biocide is effective only against poliovirus and adenoviruses. Obligatory target organism according to the EN14476 is murine norovirus as well, but this virus species was not included in the testing. For PT5 use however, efficacy against bacteriophages was demonstrated and thus for drinking water disinfection virucidal activity of BELOX is authorized as well.

Studies were done according to the EN norms and the Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 3.0, April 2018. When EN norms were not available, for semi-field studies in particular, testing was performed according to other national standars (French NF T 72-281, method approved by German DVGW and other). Therefore, we conclude that for all the intended uses mentioned above, BELOX products from both meta SPCs will be effective when considering following comments and when used at the authorized concentration and conditions. Disinfection of non-porous surfaces by spraying in animal housing will be efficacious against bacteria and fungi but not against spores and it will have to be performed under clean conditions

meaning that cleaning prior to the disinfection is necessary. When disinfecting aseptic packaging by immersion or spraying at ≥ 70°C, the product will not be effective against viruses and will show sporicidal activity only under low level soiling conditions. Therefore, it should be stated on the label that cleaning prior to the disinfection is necessary. Spores of heat resistant bacterium *Geobacillus stearothermophilus* were destroyed at high temperature and short contact time as shown with the semi-field study. The cork stoppers disinfection can be done with 10 – 35 % $H_2O_2$. However, at the lowest concentration 10% $H_2O_2$, disinfection should be used under clean conditions only. Disinfection of piping and tanks for drinking water was shown to be effective however, claim against *Legionella* cannot be made as the efficacy against *Legionella* was not proven with the studies and for sporicidal activity it should be stated on the label that cleaning prior to the disinfection is necessary. Disinfection of piping and tanks for beverages by CIP was proven to be effective at higher concentrations as originally claimed by the applicant and not at 45°C. Efficacy tests were performed at room temperature. Surface disinfection in enclosed spaces by VHP process has to be performed with minimum concentration of hydrogen peroxide 360 ppm in a room size up to 30 $m^2$.
The effective concentrations of the active substance $H_2O_2$ and the biocidal product BELOX 35 or 50 range from 17.29 to 35 % $H_2O_2$ and depend on the intended use of the product. The same is true for contact times.
In conclusion, the BELOX is an effective disinfectant exhibiting bactericidal, fungicidal sporicidal and limited virucidal activity only when following the instructions of use and the label claim.

#### 2.2.5.6 Occurrence of resistance and resistance management

Although differential susceptibility of species of microorganisms exists, the development of resistance is not reported in the literature. Furthermore, intensive use over more decades did not lead to the development of significant resistance levels among field populations. Therefore, resistance is not expected when used as recommended and management strategies are at this point not required.

#### 2.2.5.7 Known limitations

There are no known limitations.

#### 2.2.5.8 Evaluation of the label claims

See chapter 2.1.4 Authorised use(s).

#### 2.2.5.9 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 with other biocidal products.

### 2.2.6 Risk assessment for human health

The product is an aqueous solution of hydrogen peroxide with co-formulants in concentrations lower than 0.1 %. Therefore, the major contribution to the hazards is resulting from the hydrogen peroxide. Information on hydrogen peroxide were reproduced from the Assessment Report for hydrogen peroxide (PT1-6), where this was relevant for the assessment of the product.

#### 2.2.6.1 Assessment of effects on Human Health

***Skin corrosion and irritation***

The 35 % hydrogen peroxide caused slight to moderate reversible erythema and oedema in a skin irritation study. 49.2 % hydrogen peroxide was severely irritating to skin in a study where ulceration and necrosis of skin were noticed in the histopathology. Under CLP, the 35 % hydrogen peroxide, causing irreversible desquamation skin, triggers classification of Skin irritation 2, H315: "Causes skin irritation", and 50 % ≤ hydrogen peroxide < 70 % is currently classified with Skin corrosion 1B, H314: "Causes severe skin burns and eye damage".

| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
|---|---|
| Value/conclusion | Skin Irrit. 2 for Meta-SPC 1,<br>Skin Corr. 1 for Meta-SPC 2 |
| Justification for the value/conclusion | Product classification is based on the specific concentration limits for hydrogen peroxide laid down in Annex VI -Harmonised classification of Regulation (EC) No 1272/2008. Biocidal products of Meta SPC-1 family |

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| | contain 35 -35.2 % of hydrogen peroxide classified with Skin Irrit. 2. All other ingredients are present in concentrations that are lower than cut-off values as set out in Article 11(2) of Regulation (EC) No 1272/2008 (CLP).<br>Classification is also in line with test results described in Assessment Report for hydrogen peroxide (PT1-5), 2015. The 35 % hydrogen peroxide caused slight to moderate reversible erythema and oedema in a skin irritation study.<br>For Belox 50 pH value is 2.0 was warrants the classification of Meta SPC 2 biocide product as Skin Corrosive 1. Additionally, 49.2 % hydrogen peroxide was severely irritating to skin in a study where ulceration and necrosis of skin were noticed in the histopathology. |
| Classification of the product according to CLP | Meta SPC 1 : Skin Irrit. 2; H315 Causes skin irritation.<br>Meta SPC 2 : Skin Corr. 1, H314 Causes severe skin burns and eye damage. |

| **Data waiving** | |
|---|---|
| Information requirement | |
| Justification | Testing on the product/mixture does not need to be conducted since synergistic effects between components are not expected and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

### *Eye irritation*

Hydrogen peroxide causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. The product containing > 5 %, but less than 50 % of hydrogen peroxide is classified with Eye Dam. 1

| **Conclusion used in Risk Assessment – Eye irritation** | |
|---|---|
| Value/conclusion | Eye Dam. 1 |
| Justification for the value/conclusion | Product classification is based on the specific concentration limits for hydrogen peroxide laid down in Annex VI -Harmonised classification of Regulation (EC) No 1272/2008. The product containing > 5 % - 50 % of hydrogen peroxide is classified with Eye Dam. 1. All other ingredients are present in concentrations that are lower than cut-off values as set out in Article 11(2) of Regulation (EC) No 1272/2008 (CLP).<br>Classification is also in line with test results described in Assessment Report for hydrogen peroxide (PT1-5). Hydrogen peroxide causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated.<br>That is why all products of BELOX biocidal product family are classified with Eye Dam. 1. |
| Classification of the product according to CLP | Eye Dam. 1; H318 Causes serious eye damage. |

| Data waiving | |
|---|---|
| Information requirement | |
| Justification | Testing on the product/mixture does not need to be conducted since synergistic effects between components are not expected and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

### *Respiratory tract irritation*

Both animal data and human experience indicate that hydrogen peroxide causes respiratory irritation. In a mouse study an $RD_{50}$ value of approx. 160 mg/$m_3$ (113 ppm) and an extrapolated (by the RMS) value $RD_{10}$ value of 17.5 mg/$m^3$ (12 ppm) have been derived.

For acute, medium-term and long-term exposure the following **AEC for inhalation exposure** is proposed for hydrogen peroxide: 1.25. mg/$m^3$ based on the NOAEC in 90-day inhalation rat study with the overall assessment factor of 8. This value is reasonably well in line with human data, where a level of no symptoms at 0.5 to 0.7 mg/$m^3$ (0.36−0.5 ml/$m^3$; 8-hour mean values, no higher peak exposures) could be determined.

| Conclusion used in the Risk Assessment – Respiratory tract irritation | |
|---|---|
| Value/conclusion | STOT SE 3 |
| Justification for the conclusion | Product classification is based on the specific concentration limits for hydrogen peroxide laid down in Annex VI -Harmonised classification of Regulation (EC) No 1272/2008. Classification is also in line with test results on hydrogen peroxide.<br><br>All other ingredients are present in concentrations that are lower than cut-off values as set out in Article 11(2) of Regulation (EC) No 1272/2008 (CLP). |
| Classification of the product according to CLP | STOT SE 3; H335 May cause respiratory irritation. |

| Data waiving | |
|---|---|
| Information requirement | |
| Justification | Testing on the product/mixture does not need to be conducted since synergistic effects between components are not expected and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

### *Skin sensitization*

The available human clinical data reveals two reported cases of positive patch tests with hydrogen peroxide. Taking into account the widespread occupational and consumer use over many decades, sensitization to hydrogen peroxide seems to be rare. Hence, it is unlikely that a new skin sensitization test would give results warranting classification either. Hydrogen peroxide is not considered to be a potential skin sensitizer.

| **Conclusion used in Risk Assessment – Skin sensitisation** | |
|---|---|
| Value/conclusion | Non-sensitizer |
| Justification for the value/conclusion | Product classification is based on harmonised classification of hydrogen peroxide laid down in Annex VI of Regulation (EC) No 1272/2008. Hydrogen peroxide is not considered to be a potential skin sensitizer. Classification is also in line with test results described in Assessment Report for hydrogen peroxide (PT1-5). The available human clinical data reveals two reported cases of positive patch tests with hydrogen peroxide. Taking into account the widespread occupational and consumer use over many decades, sensitization to hydrogen peroxide seems to be rare. Hence, it is unlikely that a new skin sensitization test would give results warranting classification either. None of the other ingredients present in BELOX is classified as skin sensitizer. Therefore, classification of the products of BELOX as skin sensitizer is not considered required. |
| Classification of the product according to CLP | - |

| **Data waiving** | |
|---|---|
| Information requirement | |
| Justification | Testing on the product/mixture does not need to be conducted since synergistic effects between components are not expected and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

## *Acute toxicity*

*Acute toxicity by oral route*

The results of acute oral toxicity studies performed in rats with formulations containing hydrogen peroxide at concentrations from 35 % to 70 % demonstrated acute oral LD50 values in the range of 694-1270 mg/kg bw indicating that hydrogen peroxide, at the tested concentrations, is harmful by the oral route. When corrected to 100% hydrogen peroxide, the LD50 values were around 500 mg/kg bw.

| **Value(s) used in the Risk Assessment – Acute oral toxicity** | |
|---|---|
| Value | Acute Tox. 4 |
| Justification for the selected value(s) | The results of acute oral toxicity studies performed in rats with formulations containing hydrogen peroxide at concentrations from 35 % to 70 % demonstrated acute oral LD50 values in the range of 694-1270 mg/kg bw indicating that hydrogen peroxide, at the tested concentrations, is harmful by the oral route. When corrected to 100% |

| | |
|---|---|
| | hydrogen peroxide, the LD50 values were around 500 mg/kg bw. (Assessment Report for hydrogen peroxide (PT1-5), 2015.) For classification of the product we have calculated acute toxicity estimate (ATE) for 35 % and 49.9 % (w/w) hydrogen peroxide. ATE for 35 % H2O2 is 1428 mg/kg bw and for 49.9 % H2O2 is 1002 mg/kg bw. All other ingredients are present in concentrations that are lower than cut-off values as set out in Article 11(2) of Regulation (EC) No 1272/2008 (CLP). So, based on the criteria laid down in Table 3.1.1. of Annex I of Regulation (EC) No 1272/2008 (CLP), all product in BELOX should be classified as Acute toxic, Category 4 by oral route. |
| Classification of the product according to CLP | Acute Tox. 4; H302 Harmful if swallowed. |

| **Data waiving** | |
|---|---|
| Information requirement | |
| Justification | Testing on the product/mixture does not need to be conducted since synergistic effects between components are not expected and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

*Acute toxicity by inhalation*

The inhalation LC50 value for the test substance containing 49.3% hydrogen peroxide was > 0.17 mg/l/4 h (highest attainable vapour concentration).

| **Value(s) used in the Risk Assessment – Acute inhalation toxicity** | |
|---|---|
| Value | Acute Tox. 4 |
| Justification for the selected value(s) | In the study performed on the test substance containing 50 % hydrogen peroxide at the maximum technical attainable vapour concentration of 0.17 mg/L no deaths occurred. Based on that data we can conclude that the product that contains 49.9 % hydrogen peroxide or less is not acute toxic by inhalation. (Assessment Report for hydrogen peroxide (PT1-5), 2015.)<br>However, based on harmonised classification laid down in Annex VI of the CLP Regulation, hydrogen peroxide is classified in category 4 for acute inhalation toxicity. For this reason, it is proposed to use converted acute toxicity point estimate mentioned in Table 3.1.2 of the Regulation (EC) No 1272/2008 (CLP) as ATE values. For acute toxicity category 4 for a dust/mist the converted acute toxicity point estimate value is 1,5 mg/l.<br>Based on the formula included in section 3.1.3.6.1 of the CLP Regulation of Annex I of Regulation (EC) No 1272/2008 (CLP) and ATE 1,5 mg/l, aqueous hydrogen peroxide solutions are classified in category 4 for acute inhalation toxicity if the concentration of hydrogen peroxide is equal to or higher than 30 %. |

| | |
|---|---|
| | All other ingredients are present in concentrations that are lower than cut-off values as set out in Article 11(2) of Regulation (EC) No 1272/2008 (CLP).<br>That is why, all product in BELOX should be classified as Acute toxic, Category 4 by inhalation. |
| Classification of the product according to CLP | Acute Tox. 4; H332 Harmful if inhaled. |

| **Data waiving** | |
|---|---|
| Information requirement | |
| Justification | Testing on the product/mixture does not need to be conducted since synergistic effects between components are not expected and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

*Acute toxicity by dermal route*

The acute dermal LD50 of formulations containing 70 % hydrogen peroxide was between at 6500 and 13000 mg/kg bw in the rabbit indicating that hydrogen peroxide, at the tested concentrations, is not acutely toxic by the dermal route.

| **Value used in the Risk Assessment – Acute dermal toxicity** | |
|---|---|
| Value | not classified |
| Justification for the selected value | The acute dermal LD50 of formulations containing 70 % hydrogen peroxide was between at 6500 and 13000 mg/kg bw in the rabbit indicating that hydrogen peroxide, at the tested concentrations, is not acutely toxic by the dermal route. (Assessment Report for hydrogen peroxide (PT1-5), 2015.)<br>Besides that, hydrogen peroxide is also not classified as acutely toxic by the dermal route according to harmonised classification in Annex VI of Regulation (EC) No 1272/2008.<br>All other ingredients are present in concentrations that are lower than cut-off values as set out in Article 11(2) of Regulation (EC) No 1272/2008 (CLP).<br>Indicating that none of the products in BELOX is acutely toxic by the dermal route.<br>Indicating that the product is not acutely toxic by the dermal route. |
| Classification of the product according to CLP and DSD | - |

| **Data waiving** | |
|---|---|
| Information requirement | |
| Justification | Testing on the product/mixture does not need to be conducted since synergistic effects between components are not expected and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). |

### *Information on dermal absorption*

Hydrogen peroxide is reactive and it degrades rapidly in contact with organic material. The rapid degradation upon contact with skin explains the absence of systemic effects from exposure to hydrogen peroxide. However, application of hydrogen peroxide solutions to damaged skin, or exceptional cases with excessive amounts of exogenous hydrogen peroxide on skin, may result in some systemic dose. Hydrogen peroxide is presumed to degrade rapidly into oxygen and water in contact with blood or other body fluids. Despite the fact that hydrogen peroxide is a normal metabolite in the cell metabolism and the knowledge of the hydrogen peroxide metabolism e.g. through catalase and glutathione peroxidase enzymes, data on the effects of exogenous hydrogen peroxide exposure in humans or animals is limited and mainly consists of case reports of oxygen embolisation following the degradation of hydrogen peroxide after exposure to high amounts of the substance. No standard dermal penetration studies with hydrogen peroxide have been successfully conducted. According to point 6. How to proceed when there are no data on the formulation under consideration of the Guidance on dermal absorption (EFSA, 2017) the following default values are recommended. A default dermal absorption value of 10% may be applied for concentrated products that are water-based and value of 50% may be applied for (in use) dilutions of water-based formulations.
For biocidal products which are considered corrosive the dermal absorption value of 100 % must be taken into account, due to higher skin penetration through damaged skin. Therefore, for biocidal products containing ≥ 50 % hydrogen peroxide (Meta-SPC2) 100 % dermal absorption will be considered. The EFSA dermal absorption Guidance (2017) was endorsed in June 2018. At that stage it was agreed that 5 % of the active substance is the limit concentration to distinguish the concentrate from the dilution. Therefore, for in-use dilutions of hydrogen peroxide containing more than 5 % of the active substance 10 % dermal absorption will be taken into account (Meta-SPC1).

| **Value(s) used in the Risk Assessment – Dermal absorption** | |
|---|---|
| Substance | Hydrogen peroxide |
| Value(s)* | Meta-SPC1: 10% for concentrated products (containing ≥ 5 % active substance)<br>50% for in use dilutions of products (containing < 5 % active substance)<br>Meta-SPC2: 100% for concentrated products<br>50% for in use dilutions of products (containing < 5 % active substance) |
| Justification for the selected value(s) | According to Guidance on the Biocidal Products Regulation, Volume III: Human health, Part A: Information Requirements, 2014, point 8.6 Information on dermal absorption, default values can be used.<br>According to point 6. How to proceed when there are no data on the formulation under consideration of the Guidance on dermal absorption (EFSA, 2017) the following default values are recommended. For corrosive biocidal products 100 % dermal absoreption must be considered, while a default dermal absorption value of 10% may be applied for concentrated products (≥ 5 % active substance) that are water-based and value of 50% may be applied for (in use) dilutions (< 5 % active substance) of water-based formulations. |

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

Product does not contain any substance of concern.

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

There are no available data for mixture. However, the product is an aqueous solution of hydrogen peroxide with stabilizers in concentrations lower than 0.1 %. Therefore, the major contribution to the hazards is resulting from the hydrogen peroxide.

## 2.2.6.2 Exposure assessment

The biocidal products included in the BELOX are intended to be used in product types 2, 3, 4 and 5 by industrial/professional users only. Most of the proposed uses by the applicant to be authorised within this application are the same as uses presented in the CAR and therefore have been assessed for the active substance hydrogen peroxide for PTs 1-6, except uses in PT 4: cork stoppers disinfection and CIP of piping and tanks for beverages.

For PT 2 - Surface disinfection in enclosed spaces by VHP process the biocidal products containing 35 % or 49.9 % hydrogen peroxide are used.
All information on the use of hydrogen peroxide as surface disinfectant in enclosed spaces is derived from an exposure form prepared by a company specialised in disinfection via VHP machine (vaporised hydrogen peroxide). The products are intended for industrial/professional use of hydrogen peroxide as surface disinfectant in enclosed (sealed) spaces via machine based VHP (vaporised hydrogen peroxide). Hydrogen peroxide vapour decontaminates dry surfaces of laboratory equipment, industrial pharmaceutical isolators, biological safety cabinets, hospital rooms, emergency vehicles, laboratories and other enclosed spaces. Emission to air is controlled by the machines and catalytic decomposition of hydrogen peroxide may take place in some machines. Machines may also have sensors to detect when safe level of hydrogen peroxide is reached for re-entry into rooms/areas. If the concentration is over the Occupational Exposure Limit (OEL) or AEC, respiratory protective equipment has to be worn when re-entering the disinfected rooms/areas e.g. for collection of indicators or the machine.

For PT 3 use – Surface disinfection of animal housing by spraying the biocidal product containing 35 % or 49.9 % hydrogen peroxide is diluted to 17.29 % in-use concentration. Broilers are housed in free range with litter floor. In these housings a so-called "all in - all out" system is applied. Cleaning and disinfection of broiler housings is common practice. Disinfection of the unit is performed by farmers and cleaning contractors between two periods. Frequency of treatment is every 5-8 weeks (6-10 times/year).

For disinfection in food and feed area (PT 4) the BELOX is intended to be used for:

- aseptic packaging,
- cork stoppers disinfection,
- disinfection is enclosed spaces,
- disinfection of drinking water piping and tanks,
- CIP of piping and tanks beverages.

The biocidal products containing 35 % or 50 % of hydrogen peroxide are intended for use in aseptic packaging, disinfection of food packaging by immersion (PT4) and is identical to the representative product used for authorisation of the active substance for PT 4a, aseptic packaging.

The aseptic packing operates in closed system where exposure is limited and emission to air is negligible.
The cork stoppers disinfection is performed in specially designated machines, where after cleaning with water, disinfectant is applied automatically by spraying. After disinfection, a catalysator is added for complete decay of hydrogen peroxide and additionally corks are rinsed and dried at the end, therefore no residues are expected.
Surface disinfection by VHP in food processing facilities is identical to the surface disinfection within PT2, the only difference is the area of application.
The biocidal products are intended to be used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and container as well as piping and tanks for beverages.
The biocidal products are used for drinking water disinfection at the drinking water suppliers and their water distribution systems, water in reservoirs and water for animals. Primary exposure is expected for professionals only during loading since application is automated. Secondary exposure (oral, dermal) via drinking water is relevant and in practice residual hydrogen peroxide has to be checked to ensure that it is below the national limit.

**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 | yes | n.a. | yes | yes | no | n.a. |
| Dermal | yes | yes | n.a. | n.a. | no | no | n.a |
| Oral | no | no | n.a. | n.a. | no | no | no |

## List of scenarios

| Summary table: scenarios | | | |
|---|---|---|---|
| **Scenario number** | **Scenario** | **Primary or secondary exposure Description of scenario** | **Exposed group** |
| **Use 1: Surface disinfection by VHP (PT 2)<br>Use 5 Surface disinfection by VHP of enclosed spaces in food and feed area (PT4)** | | | |
| 1 | Loading | Primary exposure<br>Loading scenario for automated applications: the VHP machine, aseptic packaging, connecting and disconnecting VHP pipelines | Industrials<br>Professionals |
| 2 | Application - VHP process | Primary exposure<br>No exposure during application as no persons present in the room during application | Industrials<br>Professionals |
| 3 | Post application - re-entry | Primary exposure<br>Re-entry to the treated room | Industrials<br>Professionals |
| **Use 2: Disinfection of animal housing by spraying (PT 3)** | | | |
| 4 | Manual mixing and loading | Primary exposure<br>Pouring of product into a portable vessel (e.g. sprayer, canister) and dilution to in-use concentration | Professionals |
| 5 | Application - spraying | Primary exposure<br>Surface disinfection of animal housing by spraying | Professionals |
| 6 | Post application – cleaning of the spray equipment | Primary exposure<br>Cleaning of the spray equipment after application | Professionals |
| **Use 3: Aseptic packaging, disinfection of food packaging by immersion (PT 4)** | | | |
| 7 | Loading | Primary exposure<br>Loading of the machines for aseptic packaging | Industrials,<br>Professionals |
| 8 | Application -aseptic packaging | Primary exposure<br>Disinfection of food packaging by immersion into bath of hot hydrogen peroxide in aseptic filling machine | Industrials,<br>Professionals |
| 9 | Post application – maintenance | Maintenance work | Industrials,<br>Professionals |
| **Use 4: Cork stoppers disinfection PT 4** | | | |
| 10 | Loading | Primary exposure<br>Loading of the machine for cork stoppers disinfection | Industrials,<br>Professionals |
| 11 | Cork stoppers disinfection | Primary exposure:<br>Disinfection of cork stoppers in the closed machine | Industrials,<br>Professionals |
| 12 | Post application – Maintenance | Maintenance work | Industrials,<br>Professionals |
| **Use 6: Disinfection of distribution and storage systems for drinking water (PT 4)** | | | |

| | | | |
|---|---|---|---|
| 13 | Loading | Primary exposure | Industrials, Professionals |
| 14 | Application | Primary exposure<br>No exposure during automated spraying with CIP technologies | Industrials, Professionals |
| **Use 7: CIP of piping and tanks for beverages (PT 4)** | | | |
| 15 | Loading | Primary exposure<br>Manual loading scenario | Industrials, Professionals |
| 16 | Application | Primary exposure<br>No exposure during automated spraying with CIP technologies | Industrials, Professionals |
| **Use 8: Drinking water disinfection (PT 5)** | | | |
| 17 | Loading | Primary exposure | Industrials, Professionals |
| 18 | Application | Primary exposure | Industrials, Professionals |

The adverse effects of the hydrogen peroxide in humans are local at the side of contact therefore the systemic exposure is not relevant and is not taken under consideration. Only local exposures have been considered in this assessment. The corrosive/irritating effects to the skin are concentration dependent with and are almost independent from their duration. Quantitative exposure and risk assessment via the inhalation route of exposure is performed considering the AEC for inhalation 1.25 mg/m$^3$, as derived for hydrogen peroxide in the CAR (PTs 1-6, 2015). Qualitative risk characterization for potential local effects via the dermal route of exposure is performed considering both the SCLs set for hydrogen peroxide in the CLP regulations as well as appropriate risk mitigation measures (i.e. gloves, coveralls, etc.) and label instructions (i.e. P-statements associated with the H-statements). Oral exposure of professionals in these uses are considered not relevant, and therefore it is not presented in the summary tables either.

Quantitative exposure via the inhalation route of exposure is performed using the Advanced Reach Tool (ART) which takes into account both vapour and aerosols. The 90th percentile exposure values calculated with the Advanced Reach Tool are used to take into account the variability in exposure levels. It is noted that the calculated exposure may be an overestimation as the non-exposure period value was set to 0 in the ART-scenarios. Calculated liquid mole fraction is used in the ART calculations. For activity coefficient the default of 1 is used as no real representative functional groups for hydrogen peroxide was found in the XL UNIFAC or AIOMFAC which are the software tools used specifically for activity coefficient calculation.

**Industrial exposure/professional exposure**

**Use 1: Surface disinfection by VHP PT 2**

**Scenario 1**

| **Description of Scenario 1 - Loading the VHP machine** | | |
|---|---|---|
| The area to disinfect is prepared for decontamination by removing standing liquids and visible soils by wiping down and installing biological and chemical indicators to validate the cycle. The container is inserted into a compartment of the VHP machine designed to hold the container. The size of the container depends on the type and size of the machine. Once in the compartment, the cap of the container is removed by the operator and replaced with the machine's cap, which includes a plastic tube that transfers the content of the container into the machine.<br>Industrials/professionals seal the enclosed space or room and initiate the decontamination cycle. Based on information given by the Applicant the loading of one VHP machine per a room is a representative worst-case scenario.<br>In the CAR no exposure is expected for this scenario. However, there is minimal potential for exposure during loading and exchange of containers. | | |
| **Tier 1** | **Parameter** | **Value** |
| | Concentration (worst case) | 49.9 % |
| | Duration (estimated) | 30 min/day (non-exposure period 0 min) |
| | Activity class | Falling liquids |
| | Situation | Transfer of liquid product with flow of 1 - 10 l/minute |
| | Contamination level | Open process<br>Note from ART: "Handling that reduces contact between product and adjacent air" does not include processes that are fully contained by localised controls. This means that "open process" needs to be selected here if the localised control "containment – no extraction" is selected in the subsequent question on localised controls. |
| | Loading type | Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation |
| | Work area | Indoors |
| | Room size | Any size workroom |
| | Risk management measures | |
| | Primary | Medium level* containment (99.00 % reduction) |
| | Secondary | No localized controls (0.00 % reduction) |
| | Ventilation rate | Only good natural ventilation |

* Description of Containment level according to ART:

- Medium level containment: The material transfer is enclosed with the receiving vessel being docked or sealed to the source vessel. Examples include sealing heads, transfer containers and multiple o-rings. Inflatable packing head with continuous liner ensures a seal is maintained during the powder transfer and the continuous plastic liner prevents direct contact with the product. The correct type of tie off must be used.

**Calculations for Scenario 1**

| **Summary table: estimated exposure from professional uses** | | | |
|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration** | **Estimated dermal concentration** |
| Loading scenario for automated applications ART ($90^{th}$) | 1/no PPE | 0.05 mg/$m^3$ | 49.9 % |

**Scenario 2**

| **Description of Scenario 2 – Disinfection by VHP** |
|---|
| The VHP machine injects vaporised hydrogen peroxide (VHP) into the sealed area for decontamination to get the hydrogen peroxide concentration up to the effective levels of 500 - 560 mg/$m^3$ (360 - 400 ppm).<br>The succeeding sterilisation phase lasts 90 minutes during which the hydrogen peroxide vapour disinfects the surfaces inside the sealed space.<br>Access to the closed treated room/area is not allowed during the disinfection process. Therefore, there is no exposure to hydrogen peroxide as the safe level is reached before the re-entry. Sensors of the machine confirm when the safe level is reached. |

**Scenario 3**

| **Description of Scenario 3 – Re-entry to the treated room** |
|---|
| After the decontamination phase the aeration cycle starts in which the VHP machine breaks down the hydrogen peroxide in the sealed space to water and oxygen. This step is short but can also last several hours resulting in a total decontamination cycle of 3 – 8 hours.<br>When the aeration cycle is complete, sensors inform when the hydrogen peroxide level is below 1.4 mg/$m^3$ (1 ppm) and biological and chemical indicators can be collected to confirm the efficacy of the decontamination cycle. Although 1.4 mg/$m^3$ (1 ppm - the OEL-value in the current practice, according to the Applicant) is slightly above AEC (1.25 mg/$m^3$), in practice the concentration of hydrogen peroxide in air will decrease rapidly after opening the doors due to the air exchange and is expected to be below 1.25 mg/$m^3$. |

Calculations for Scenario 3

| **Summary table: estimated exposure from professional uses** | | | |
|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration** | **Estimated dermal concentration** |
| Scenario 3 | 1/no PPE | < 1.25 mg/$m^3$ | No exposure |

**Use 2: Disinfection of animal spraying PT 3**

**Scenario 4**

| **Description of Scenario 4 – Manual mixing and loading for spray application PT 3** | | |
|---|---|---|
| This scenario is described by pouring of the biocidal product into a portable sprayer and dilution to in-use concentration. The exposure to 49.9 % (w/w) hydrogen peroxide is addressed as a worst case. In the Biocides Human Health Exposure Methodology document, for PT 3 disinfection of stables the worst case considered is poultry housings with typical size of 4000 $m^2$, cleaned 3 times annually. Quantity used is suggested to be 600 litters of spray liquid, what means that 200 to 300 l of the biocidal product have to be diluted and mixed. Duration of the mixing and loading phase is estimated as 30 minutes per event. In this scenario where the diluted product is applied via spraying, the size of the receiving vessel is considered as in knapsack sprayer.<br>PPE (as rubber boots, waterproof coverall, safety goggles with side shields, long-sleeved gloves) and RPE (RPE with gas/vapour filter (APF = 10)) are worn during mixing and loading. | | |
| | **Parameters** | **Value / Description** |
| **Tier 1** | Concentration (worst case) | 49.9 % |
| | Duration (estimated) | 30 min/day (non-exposure period 0 min) |
| | Activity class | Falling liquids |
| | Situation | Transfer of liquid product with flow of 1 - 10 l/minute |
| | Contamination level | Handling that reduces contact between product and adjacent air |
| | Loading type | Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely |
| | Work area | Indoors |
| | Room size | Any size workroom |
| | Risk management measures | |
| | Primary | No localized controls (0.00 % reduction) |
| | Secondary | No localized controls (0.00 % reduction) |
| | Ventilation rate | Only good natural ventilation |
| **Tier 2** | Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)* | 10 % |

* Respiratory protective equipment at work, A practical guide (http://www.hse.gov.uk/pubns/books/hsg53.htm)

Calculations for Scenario 4

| Summary table: estimated exposure from professional uses | | | |
|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration** | **Estimated dermal concentration** |
| Manual mixing and loading (ART 90$^{th}$) | 1/no PPE (splash loading, natural ventilation) | 4.5 mg/m$^3$ | 49.9 % |
| | 2/RPE (APF =10) (splash loading, natural ventilation) | 0.45 mg/m$^3$ | 49.9 % |

**Scenario 5**

| **Description of Scenario 5 – Surface disinfection of animal housing by spraying** | | |
|---|---|---|
| Floors and walls of animal housings are disinfected by low pressure spraying with a hand-held spray. The in-use concentration is 17.29 % as shown to be effective in the submitted efficacy studies. For assessing the exposure while spraying the stable, Spraying Model 2 (’spraying with hand-held medium pressure sprayer in overhead and downward direction’) is recommended for inhalation exposure (aerosols) in HEAdhoc Recommendation 6 (No. 11). Since hydrogen peroxide is volatile, inhalation exposure was also calculated using ART which takes into account both aerosol and vapour. There is a great discrepancy in the duration and frequency of the task which might be due to different assumptions on the setting e.g. stable size, treated area, animals etc. In the Biocides Human Health Exposure Methodology document, the typical sizes for poultry houses are 4000 m2, 390 $m^2$ for pig units and 201 $m^2$ for pig breeding. Suggested duration is 40 - 400 min. A worst-case situation of 400 min is used in the exposure calculation. Duration has no effect on the inhalation exposure value as the non-exposure period is 0 min. PPE (rubber boots, waterproof coverall with hood, safety glasses with side-shields and long-sleeved gloves) and RPE (full face mask with gas/vapour filter: APF = 10) have to be worn during application activities. | | |
| | **Parameters** | **Value** |
| **Tier 1** | In-use concentration | 17.29 % |
| | Exposure duration (BHHEM) | 400 min* |
| | **Aerosol and vapour (ART)** | |
| | Emission source | Far field |
| | Activity class | Spray application of liquids<br>Surface spraying of liquids<br>Low application rate (0.03 – 0.3 L/minute) |
| | Spray direction | Spraying in any direction (including upwards) |
| | Spray technique | Spraying with no or low compressed air use *(Examples: Paint spraying using HVLP or airless techniques and Pest control operations using backpack)* |
| | Room size of the work area | 3000 $m^3$ (max. in ART) |
| | Ventilation rate | Only natural ventilation |
| **Tier 2** | Penetration through respiratory protection equipment (RPE with gas/vapour filter: APF = 10)* | 10 %<br>3 ACH |

* Duration has no effect on the inhalation exposure value as the non-exposure period is 0 min.

Calculations for Scenario 5

| Summary table: estimated exposure from professional uses | | | |
|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration** | **Estimated dermal concentration** |
| Spraying of animal housing (ART 90th) | 1/no PPE | 16 mg/m$^3$ | 17.29 % |
| | 2/RMM, RPE | 7.8 mg/m$^3$ (3 ACH)<br>0.78 mg/m$^3$ (3 ACH, RPE) | 17.29 % |

**Scenario 6**

| Description of Scenario 6 – Cleaning of the spray equipment after application |
|---|
| After use, the equipment is emptied of any residual product and rinsed with water. The sprayer is then filled with water, which is sprayed through the nozzle for complete rinsing. Professional can be exposed for a while to the maximum concentration of 17.29 % hydrogen peroxide and therefore exposure is assumed to be covered by application phase. After that due to high dilution during rinsing, exposure to hydrogen peroxide is negligible. |

## Use 3: Aseptic packaging, disinfection of food packaging by immersion (PT4)

**Scenario 7**

| Description of Scenario 7 – Loading of the machine for aseptic packaging |
|---|
| Loading of re-filling tanks with hydrogen peroxide delivered in drums or other original containers is performed using a dedicated device, the so called "peroxide re-filling station", which is capable of filling 4 tanks in about 5 minutes. The operator removes the closures of the re-filling tanks, puts in place the filling nozzles and connects the suction pipe to the original drum. The device then creates vacuum inside the re-filling tanks, thus sucking peroxide solution from the drums. When the tanks are filled, the operator disconnects all pipes and closes the re-filling tanks with their special caps with rupture disks. The instructions for use of the re-filling station specify that the loading operations must take place in a cool and ventilated place. The operator must wear rubber boots, goggles, apron and gloves.<br><br>The potential exposure is similar as in the scenario 1. For calculations, see the scenario 1. |

**Scenario 8**

| **Description of Scenario 8 – Aseptic packaging** |
|---|
| The aseptic filling machines are based on the principle of aseptically forming a tube from a sterilized sheet of package material, which is continuously filled with commercially sterile liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape. The packaging sheet material is delivered to the machine in the form of reels. The machine unwinds the reel and sterilizes it by passage through a deep bath filled with 35% (w/w) hydrogen peroxide at temperature above 70°C. After the bath and before the tube is formed, the packaging sheet material is dried from residual hydrogen peroxide by a combination of mechanical means (rubber rollers) and hot air. Therefore, no relevant residues of hydrogen peroxide remain in the packages which could contaminate food. All operations involving exposure to the packaging material to hydrogen peroxide and subsequent drying occur in a closed environment, kept under constant flow of sterile air. The sterile air itself circulates in a closed loop. It exits the closed chamber, loaded with peroxide vapours and is afterwards mixed with a stream of water. Then, separated from the water, it is sterilized by incineration at 330 °C, brought to operation temperature and fed back into the closed environment. At the end of the production forced ventilation is performed inside the aseptic area of the machine before the operator gets the consensus to open the doors of the aseptic area. Such ventilation is mandatory and automatically performed.<br>At the end of the production forced ventilation is performed inside the aseptic area of the machine before the operator gets the consensus to open the doors of the aseptic area. Such ventilation is mandatory and automatically performed. The hydrogen peroxide concentration inside the machine after ventilation should be lower than the detection limit of 0.14 mg/m$^3$ (0.1 ppm). |

Calculations for Scenario 8

| **Summary table: estimated exposure from professional uses** | | | |
|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration** | **Estimated dermal concentration** |
| Application | 1/no PPE | 0.14 mg/m$^3$ | - |

**Scenario 9**

| **Description of Scenario 9 – Maintenance work** |
|---|
| In case of trouble, the operator can only access this area when the machine has stopped in order to restore the machine condition and is exposed to hydrogen peroxide only for a very limited period of time (typically less than 1 minute) and this does not happen frequently. However, it can be assumed that the hydrogen peroxide concentration drops immediately as soon as the machine is opened. As a precautionary RMM PPE (rubber boots, waterproof coverall, safety glasses with side-shields and long-sleeved gloves) and RPE (RPE with gas/vapour filter: APF = 10) have to be worn in these cases. The equipment is designed such that it cannot be opened during use. In case of routine maintenance, the machine will be turned off and vented until all vapour is exhausted and the equipment is cooled off. |

**Further information and considerations on use in aseptic packaging**
Since the packaging sheet material is dried from residual hydrogen peroxide by a combination of mechanical means (rubber rollers) and hot air, no relevant residues of hydrogen peroxide which could contaminate food remain in the packages. Secondary exposure via food is therefore negligible.

**Use 4 Cork stoppers disinfection (PT 4)**

**Scenario 10**

| **Description of Scenario 10 – Loading in the cork stoppers disinfection** |
|---|
| Hydrogen peroxide is pumped into the machine directly form the drums or other original containers that was delivered in. The operator removes and replaces the cap with a special connection, containing the piping for transferring hydrogen peroxide to the main tank.<br>Since refilling proceeds in a closed system in a well-ventilated area, inhalation exposure is limited and can only occur when the operator connects the drum with the refilling tank. Hence evaporation of hydrogen peroxide is expected only incidentally.<br>The dermal exposure to 35 % or 49.9 % hydrogen peroxide can occur during change of the cap on the drum. That is why; the operator is obliged to wear long sleeved gloves, safety goggles with side shields, apron and rubber boots.<br>The potential exposure is similar as in the scenario 1. For calculations see the scenario 1. |

**Scenario 11**

| **Description of Scenario 11 – Cork stoppers disinfection by spraying** |
|---|
| Cork stoppers are loaded in dry machine drum which is then hermetically closed. Cork stoppers are cleaned with water that is pumped out of the machine after cleaning faze. Disinfectant is then automatically mixed with water to achieve desired concentration (10 - 35 % $H_2O_2$) and sprayed over the cork stoppers. Cork stoppers are rolled in the drum for at least 15 min to achieve equal wetting of all cork stoppers. After disinfection, catalysator is added to break down hydrogen peroxide to oxygen and water and temperature is risen to at least 40 ˚C. After decomposition of hydrogen peroxide, cork stoppers are rinsed again with water and dried. At the end of the process maximum permitted residue of the hydrogen peroxide is < 0.2 mg /cork (ISO 21128 Cork stoppers – Determination of oxidizing residues – Iodometric titration method). All operations involving exposure to the cork stoppers to hydrogen peroxide occur in a closed environment. Because of complete decomposition of the hydrogen peroxide at the end of the process, no exposure is expected. |

**Scenario 12**

| **Description of Scenario 12 – Exposure during maintenance work** |
|---|
| Typically, when maintenance takes place, the machine has to be stopped and the hydrogen peroxide solution is pumped out into a separate container and the area is washed with water in an automated process. Only then the area is opened for any maintenance work that has to take place. Maintenance work does not happen very frequently.<br><br>Nevertheless, an operator may be exposed to residues of hydrogen peroxide only for a very limited period of time (typically less than 1 minute) in worst-case and this exposure happens rarely. PPE |

| |
|---|
| (as rubber boots, waterproof coverall, safety goggles with side shields, long-sleeved gloves) and RPE (RPE with gas/vapour filter (APF = 10)) should be worn during the maintenance. |

**Further information and considerations on use for cork stoppers disinfection**

Since the hydrogen peroxide is broken down after disinfection is finished and cork stoppers are again rinsed with water and dried no relevant residues of hydrogen peroxide which could contaminate food remain on the cork stoppers. According to ISO 21128 Cork stoppers – Determination of oxidizing residues – Iodometric titration method at the end of the process maximum permitted residue of the hydrogen peroxide is < 0.2 mg /cork. Secondary exposure via food is therefore negligible.

Considering that hydrogen peroxide is rapidly broken down to oxygen and water in the environment, no residues appear and secondary exposure via the environment is not expected.

**Use 5: Surface disinfection of enclosed spaces in food and feed area (PT4)**

All information on the use of hydrogen peroxide as surface disinfectant in enclosed spaces is derived from an exposure form prepared by a company specialised in disinfection via VHP machine (vaporised hydrogen peroxide). Hydrogen peroxide vapour decontaminates dry surfaces of food and feed areas and other enclosed spaces.
Process is same as PT 2 Surface disinfection in enclosed spaces by VHP process, so all scenarios and calculations can be applied also for PT4.

**Use 6: Disinfection of distribution and storage systems for drinking water**

**Scenario 13**

| **Description of Scenario 13 – Loading** |
|---|
| The product is supplied in drums, IBC or tanks of different capacities in a concentration of 35 and 49.9 % (w/w) of hydrogen peroxide. The product in drums and IBC are directly stored for use in well ventilated areas. The product delivered in tanks is transferred to high density polyethylene deposits using passivated hoses. Personal protection equipment as rubber boots, waterproof coverall, long sleeved gloves and safety goggles with side shield are worn during loading.<br>The product is used for cleaning and disinfection of distributing and storing installations for drinking water as pipes and container. Since the usage dose is 9.88 % (w/w) hydrogen peroxide the product should be diluted.<br>Smaller quantities (up to 200 L) of 9.88 % (w/w) hydrogen peroxide solution is prepared manually by pouring the product into receiving vessel. Water is then pumped into the vessel for dilution. Whole process takes up to 20 min. The process takes place in good natural ventilated (open windows and/or doors) room. PPE (as rubber boots, waterproof coverall, safety goggles with side shields, long-sleeved gloves) and RPE (RPE with gas/vapour filter (APF = 10)) are worn during manual mixing and loading.<br>Higher quantities of 9.88 % (w/w) hydrogen peroxide solution is prepared by pumping the product to receiving vessel using passivated hoses. Water is then pumped in for dilution.<br><br>Covered by scenario 4 manual mixing and loading as worst case. |

**Scenario 14**

| **Description of Scenario 14 – Disinfection of distribution and storage systems for drinking water** |
|---|
| The piping system is emptied and cleaned mechanically; deposits are removed before disinfection. A CIP machine that pumps hydrogen peroxide solution through the piping system is attached. A detector that indicates when the disinfection process is complete is set up at the outlet. CIP machine mixes the biocidal product with water to concentration 9.88% of hydrogen peroxide. The distribution and storing systems get disinfected by either automatic spraying or injecting 9.88 % (w/w) hydrogen peroxide in container or in pipes. After 60 min contact time for tanks and 3h for pipes, tanks and pipes have to be rinsed with clean drinking water. |

**Further information and considerations on disinfection of distribution and storage systems for drinking water**

The water treatment plant is signalled and closed and can only be assessed by authorised personnel. Thus, the exposure of the general public is not expected.

Secondary exposure (oral and dermal) to hydrogen peroxide residues in drinking water pipes and container is regarded unlikely since the equipment is flushed after the disinfection process is the outlet of the drinking water treatment plant and at the final-end-tap to assure that national limit values for hydrogen peroxide are not exceeded. In the European Union different limit values for hydrogen peroxide in drinking water are derived to protect human health and underlie national legislation.

Considering that hydrogen peroxide is rapidly broken down to oxygen and water in the environment no residues appear and secondary exposure via the environment is not expected.

**Use 7: CIP of piping and tanks for beverages**

**Scenario 15**

| **Description of Scenario 15 – Loading for CIP** |
|---|
| The product is supplied in 1 l bottles or larger volume drums and IBCs in a concentration of 35 or 49.9 % (w/w) of hydrogen peroxide and is used for disinfection of pipes and container for beverages. The product BELOX 35 or BELOX 50 is diluted with water heated up to 45 ˚C to make a 9.88 % solution of hydrogen peroxide. PPE (as rubber boots, waterproof coverall, safety goggles with side shields, long-sleeved gloves) and RPE (RPE with gas/vapour filter (APF = 10)) are worn during mixing and loading.<br><br>Covered by scenario 4. |

**Scenario 16**

| Description of Scenario 16 – CIP of piping and tanks for beverages |
|---|
| Clean tap head and connect it with cleaning container with 9.88 % hydrogen peroxide solution. Open tap and fill lines completely with the disinfection solution. Leave disinfection solution to act at least for 15 min. After 15 min tap the remaining disinfection solution. Then flush out the container with fresh tap water, fill 1/3 of the container with water and rinse the tap with fresh water.<br><br>The frequency of the process depends on use. Typically, the piping system for beverages is cleaned and disinfected every time the beverage that is being delivered through the system is changed – the highest frequency for this would be once daily. For large-scale operations that rarely or never change the beverage that is being delivered through the piping system, the frequency of cleaning depends on the properties of the beverage itself (solids content, temperature at which it is being delivered, etc.) and is determined by the user.<br><br>The exposure occurs when connecting the CIP machine to the piping, where the operator can be exposed to peroxide residues at the connector and is covered by scenario for manual loading. |

**Further information and considerations on scenario 16**
Secondary exposure (oral and dermal) to hydrogen peroxide residues in piping and tanks for beverages is regarded unlikely since the equipment is flushed with clean water after the disinfection process is completed. Even more, any residues of hydrogen peroxide would break down immediately after contact with organic material (beverages).

Considering that hydrogen peroxide is rapidly broken down to oxygen and water in the environment no residues appear and secondary exposure via the environment is not expected.

**Use 8: Drinking water disinfection**

**Scenario 17**

| Description of Scenario 17 – Loading |
|---|
| The product is supplied in drums of 5 – 220 L, in 1000 L IBC or tanks of different capacities in a concentration of 35 and 49% (w/w).<br>Smaller quantities (up to 200 L) of the product are transferred manually by pouring the product into receiving vessel. Whole process takes up to 20 min. The product delivered in IBC or tanks is transferred to high density polyethylene deposits using passivated hoses.<br>Process takes place in good natural ventilated room (open windows and/or doors).<br>PPE (as rubber boots, waterproof coverall, safety goggles with side shields, long-sleeved gloves) and RPE (RPE with gas/vapour filter (APF = 10)) are worn during mixing and loading. The scenario is covered by scenario 4. |

**Scenario 18**

| Description of Scenario 18 – Drinking water disinfection |
|---|
| After transfer to a holding tank, an automated dosing system continuously applies hydrogen peroxide to the water that is being treated. The process is set up so that an initial concentration |

of 25 mg/L is maintained. After the disinfection process, the water is released into the water delivery system with a maximum residual concertation of 5 mg/L.
During the drinking water disinfection, no exposure to industrial/professional is expected.

**Further information and considerations on use in drinking water**

Secondary exposure (oral and dermal) via drinking water has to be expected. Drinking water is checked daily for hydrogen peroxide concentration at the outlet of the drinking water treatment plant and at the final-end-tap to assure that national limit values for hydrogen peroxide are not exceeded.

Considering that hydrogen peroxide is rapidly broken down to oxygen and water in the environment, no residues appear and secondary exposure via the environment is not expected.

## Non-professional exposure

All products in the biocidal product family BELOX are only for industrial and professional use and therefore no non-professional exposure exist.

## Exposure of the general public

Exposure of general public or secondary exposure in general is not considered as there is no residual hydrogen peroxide on treated surfaces or equipment. Volatile residues do not occur due to a rinsing step and high reactivity of the active substance. Inhalation exposure of general public is eliminated as re-entry is not possible before reaching the safe levels.

## Monitoring data

No monitoring data has been submitted.

## Dietary exposure

Since the instructions for use clearly state that disinfection of animal housing should take place in an empty stable and due to the inherent characteristic of hydrogen peroxide to break down to oxygen and water as a reaction with organic material and in presence of light, livestock exposure and dietary exposure via food is non-existent.

Exposure to hydrogen peroxide is expected in drinking water for PT5 drinking water disinfectants.

| **Summary table of main representative dietary exposure scenarios** | | | |
|---|---|---|---|
| **Scenario number** | **Type of use[1]** | **Description of scenario** | **Subject of exposure[2]** |
| 1. | Residential use | Exposure via drinking water disinfected with the disinfectant | Drinking water |

*Scenario 1*
Drinking water is checked daily for hydrogen peroxide concentration at the outlet of the drinking water treatment plant and at the final-end-tap to assure that national limit values for hydrogen peroxide are not exceeded.

**Scenario 1**

When used as a drinking water disinfectant, residues of hydrogen peroxide may remain in the system long enough to be present at a water outlet. Monitoring of concentrations of hydrogen peroxide is expected whenever it is used as a drinking water disinfectant.

Before it is released in the system, the drinking water from the treatment plant must have the concentration of 5 mg/L or below of hydrogen peroxide. Due to the rapid breakdown of hydrogen peroxide, the final concentration of hydrogen peroxide in drinking water intended for human use is anticipated to be below 0.1 mg/L.

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

Exposure during the production and formulation of the active substance should be addressed under other EU legislation (e.g. REACH) and not repeated under Regulation (EC) No. 528/2012. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for hydrogen peroxide which is an existing biocidal active substance within the EU.

However, the exposure associated with production, formulation and disposal of the biocidal product was assessed by the applicant and is presented below, but it was not further evaluated by the eCA.

The production of hydrogen peroxide is well evaluated in the EU Risk Assessment Report Hydrogen Peroxide (2003), pg. 62-63:

The predominant industrial method for the production of hydrogen peroxide (Goor et al., 1989) is the anthraquinone autoxidation process. The crude aqueous hydrogen peroxide from the extraction stage (H2O2 15 - 40%, w/w) is concentrated by distillation, diluted further to commercial products of 30 - 70 % (w/w) and collected in storage tanks. The product is stabilised.

Hydrogen peroxide is an automated, closed and continuous process. Some exposure to the compound may incidentally occur during distillation, stabilisation, dilution and sampling/laboratory works. Small leaks may also occur.

CEFIC (1997e,(…)3) reports on occupational exposure measurements during 1985-1995. When summarising the exposure at different assignments, the personal 8-hour TWA exposures ranged from 0.24 to 0.79 mg/m$^3$, the overall mean being 0.37 ± 0.05 (sem) concerning four different jobs. Area concentrations (8-hour TWA) were measured only at stabilization with a mean concentration of 0.24 ± 0.14 (sd), n=2. The short-term exposures (15 min) ranged from <0.01 to 1.85 mg/m$^3$ with the overall mean of 0.55 ± 0.26 (sem) concerning two different assignments, laboratory work and diverse tasks. The highest short-term mean, 0.92±0.66 mg/m$^3$ (sd), n=6, was measured in the laboratory where the highest measured peak value was 3.6 mg/m$^3$. At stabilisation and dilution, peak concentrations of 5.66 and 6.34 mg/m$^3$, respectively, were found indicating probably occasional incidents, and one measurement gave 10.2 mg/m$^3$ which were caused by a leaking valve. The results show that the measured 8-hour TWA airborne mean

3 ECETOX Updated report on OEL (1997)

concentrations were well below the OEL (1.4 mg/m$^3$ 8-hour TWA), but incidental short-term exposures at stabilisation, dilution and laboratory jobs could sometimes be higher than the 15-min STEL (3 mg/m$^3$).

The highest personal exposure in production (reasonable worst case), 0.8 mg/m$^3$, was at stabilisation.

Occupational exposure at production of $H_2O_2$ (according to data from CEFIC, 1997)

| **Chemical manufacture/job**<br><br>**Production of hydrogen peroxide** | **Personal exposure**<br><br>**Mean ± sd, (n), range, mg/m$^3$** | **Area concentration**<br><br>**Mean ± sd, (n), range, mg/m3** | **Short-term exposure**<br><br>**Mean ± sd, (n), range, mg/m$^3$** | **Highest value measured mg/m$^3$** | **Method**<br><br>**(m)** |
|---|---|---|---|---|---|
| - Synthesis | 0.24 ± - | - | - | | Dr |
| - Distillation | 0.4 ± - | - | - | | Dr |
| - Stabilisation | 0.52 ± 0.22<br>0.26 – 0.79 | 0.24 ± 0.14<br>0.10 – 0.37 | | a) 5.66 | Dr, ns), lq |
| - Dilution | - | - | - | b) 6.34 (area) | lq |
| - Laboratory | 0.32 ± 0.22<br>0.02 – 0.5 | - | 0.92 ± 0.6)<br>0.11 – 1.85 | 3.6 | Dr, ns |
| - Other jobs<br>- Storage, packaging | | - | 0.18 V 0.26<br><0.01 – 0.85 | c) 10.2 (leak) | Ns23, lq, Dr, qm |

x = arithmetic mean, n = number of measured events, M = number of the various jobs, sd = standard deviation,
sem = standard error of the mean, ns = not stated, lq = liquid absorption, Dr = Dräger instrument, pm = portable monitor, m = use frequency for the method, a) over open vessel, b) not stated what happened, c) unmanned pump house, leakage

Considering the described peak concentrations in the EU-RAR especially at stabilisation, dilution and at laboratory work, in addition to the usual personal protection equipment (coverall, boots, gloves) forced ventilation and inhalation mask is required during these procedures and when handling hydrogen peroxide in the laboratory in order to be within the STEL or to be protected when STEL is exceeded.

### *Aggregated exposure*

Currently no methodology has been developed how an aggregated exposure assessment shall be performed. However, hydrogen peroxide has only local effects at the site of first contact, aggregated exposure is not considered to be relevant.

### *Summary of exposure assessment*

| Summary table: estimated exposure from professional uses | | | |
|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation concentration** | **Estimated dermal concentration** |
| **Use 1: Surface disinfection by VHP (PT 2)**<br>**Use 5 Surface disinfection by VHP of enclosed spaces in food and feed area (PT4)** | | | |
| **Scenario 1- Loading of VHP, spraying and fogging machines ART (90th)** | 1/no PPE | 0.05 mg/m$^3$ | 49.9 % |
| **Scenario 2 - Disinfection by VHP** | - | - | - |
| **Scenario 3 - Re-entry to the treated room** | 1/no PPE | < 1.25 mg/m$^3$ | No exposure |
| **Use 2: Disinfection of animal housing by spraying (PT 3)** | | | |
| **Scenario 4 - Manual mixing and loading** | 1/no PPE (splash loading, natural ventilation) | 4.5 mg/m$^3$ | 49.9 % |
| | 2/RPE (splash loading, natural ventilation) | 0.45 mg/m$^3$ | 49.9 % |
| **Scenario 5 – Surface disinfection of animal housing by spraying** | 1/no PPE | 16 mg/m$^3$ | 17.29 % |
| | 2/RPE, 3 ACH | 7.8 mg/m$^3$ (RPE)<br>0.78 mg/m$^3$ (3 ACH, RPE) | 17.29 % |
| **Scenario 6 – Cleaning of the spray equipment after application (covered by application phase)** | - | - | - |
| **Use 3: Disinfection of food packages in closed aseptic packaging machines PT4** | | | |
| **Scenario 7 – Loading the aseptic machine (= scenario 1)** | 1/no PPE | 0.05 mg/m$^3$ | 49.9 % |
| **Scenario 8 – Aseptic packaging** | 1/no PPE | 0.14 mg/m$^3$ | - |
| **Scenario 9 – Maintenance work** | PPE, RPE | | |
| **Use 4 PT 4 Food and feed area disinfectants – Cork stoppers disinfection** | | | |

| | | | |
|---|---|---|---|
| **Scenario 10 – Loading in the cork stoppers disinfection (= scenario 1)** | 1/no PPE | 0.05 mg/m$^3$ | 49.9 % |
| **Scenario 11 – Cork stoppers disinfection by spraying** | - | - | - |
| **Scenario 12 – Maintenance work** | PPE, RPE | | |
| **Use 6: Disinfection of distribution and storage systems for drinking water** | | | |
| **Scenario 13 – Loading (= scenario 4)** | 1/no PPE (splash loading, natural ventilation) | 4.5 mg/m$^3$ | 49.9 % |
| | 2/RPE (splash loading, natural ventilation) | 0.45 mg/m$^3$ | 49.9 % |
| **Scenario 14 – Disinfection of distribution and storage systems for drinking water** | - | - | - |
| **Use 7: CIP of piping and tanks for beverages** | | | |
| **Scenario 15 – Loading for CIP (= scenario 4)** | 1/no PPE (splash loading, natural ventilation) | 4.5 mg/m$^3$ | 49.9 % |
| | 2/RPE (splash loading, natural ventilation) | 0.45 mg/m$^3$ | 49.9 % |
| **Scenario 16 - CIP of piping and tanks for beverages** | - | - | - |
| **Use 8: Drinking water disinfection** | | | |
| **Scenario 17 – Loading (= scenario 4)** | 1/no PPE (splash loading, natural ventilation) | 4.5 mg/m$^3$ | 49.9 % |
| | 2/RPE (splash loading, natural ventilation) | 0.45 mg/m$^3$ | 49.9 % |
| **Scenario 18 – Drinking water disinfection** | - | - | - |

### 2.2.6.3 Risk characterisation for human health

The product is an aqueous solution of hydrogen peroxide with co-formulants in concentrations lower than 0.1 %. The major contribution to the hazards is resulting from the hydrogen peroxide. Therefore, risk characterization is focused on hydrogen peroxide.

The adverse effects of hydrogen peroxide in humans are limited to local effects at the site of first contact with the body and to embolism in some cases. No clear systemic effects were observed which is plausible in the light of the mode of action, i.e. direct chemical reactivity leading to rapid degradation. Corrosion and/or irritation of the skin and mucous membranes are the most prominent observations in the variety of animal studies. These effects are concentration dependent with no or only minor dependence from exposure duration.

**Indicative dermal reference value**

No dermal irritation was noted after application of 10% hydrogen peroxide. The 35 % hydrogen peroxide caused slight to moderate reversible erythema and edema in a skin irritation study. However, irreversible desquamation of skin triggers classification of Skin irritation 2, H315: "Causes skin irritation". In view of the absence of systemic effects after exposure to hydrogen peroxide, only external exposure limits are relevant to account for the potential local effects of hydrogen peroxide. Since in the intended use(s) the in-use concentration of hydrogen peroxide is below a skin irritating threshold (**concentration limit for classification as skin irritating is 35%**), only the inhalation route of exposure has been identified to be relevant in the quantitative exposure and risk assessment. In the absence of more accurate data, potential exposure in the different use scenarios should be compared to the thresholds set for classification. In mixing and loading exposure to undiluted products may occur. For undiluted products being loaded and mixed for the later use, the qualitative risk assessment for dermal and eye adverse effects was also addressed.
Serious eye damage/eye irritation: Hydrogen peroxide causes concentration dependent eye lesions. At higher concentrations, severe and irreversible damage to the rabbit eye has been demonstrated. The results support the current classification with Eye irritation 2, H319: "**Causes serious eye irritation" for 5 % ≤ hydrogen peroxide < 8 %**, and for **8% ≤ hydrogen peroxide < 50% classification with Eye damage 1, H318.**

**Inhalation reference values**
The following **AEC for inhalation exposure** is proposed for hydrogen peroxide: For acute, medium-term and long-term exposure: **1.25 mg/m³** based on the NOAEC in 90-day inhalation rat study with the overall assessment factor of 8 (interspecies 2.5 and an intraspecies assessment factor of 3.2). This value is reasonably well in line with human data, where a level of no symptoms at 0.5 to 0.7 mg/m³ (0.36−0.5 ml/ m³; 8-hour mean values, no higher peak exposures) could be determined.
Qualitative risk assessment was performed for local dermal and eye effects, taking into account the specific concentration limits for skin and eye irritation.

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

| Reference | Study | NOAEC | AF[1] | Correction for oral absorption | Value |
|---|---|---|---|---|---|
| $AEC_{short-term}$ | 90-day inhalation rat study | 10 mg/m³ $H_2O_2$ | 8 | - | 1.25 mg/m³ $H_2O_2$ |

| | | | | | |
|---|---|---|---|---|---|
| $AEC_{medium-term}$ | 90-day inhalation rat study | 10 mg/m³ $H_2O_2$ | 8 | - | 1.25 mg/m³ $H_2O_2$ |
| $AEC_{long-term}$ | 90-day inhalation rat study | 10 mg/m³ $H_2O_2$ | 8 | - | 1.25 mg/m³ $H_2O_2$ |
| Local effect - Skin irritation | | Specific concentration limit ≥ 35 % | - | - | 35 - <50 % $H_2O_2$ |
| Local effect – Eye damage | | Specific concentration limit ≥ 8 % | | | 8 - ≤ 50 % $H_2O_2$ |
| Local effect - Eye irritation | | Specific concentration limit ≥ 5 % | - | - | 5 - ≤ 8 % $H_2O_2$ |

[1] Hydrogen peroxide reacts directly with cells in contact. Therefore, to extrapolate the animal data to humans an assessment factor of 2.5 and an intraspecies assessment factor of 3.2 for the remaining uncertainty is considered sufficient to derive an AEC value.

**Maximum residue limits or equivalent**

Considering that hydrogen peroxide is rapidly broken down to oxygen and water in the environment no residues appear.

## *Risk for industrial/professional users*

**Systemic effects**

The adverse effects of hydrogen peroxide in humans are limited to local effects at the site of first contact with the body and to embolism in some cases. No clear systemic effects were observed.

**Local effects**

***PT 2 Surface disinfection in enclosed spaces by VHP process***

***Inhalation exposure: quantitative risk assessment for local respiratory effects***

| **Task/ Scenario** | **Tier** | **AEC mg/m³ $H_2O_2$** | **Estimated exposure mg/m³ $H_2O_2$** | **Estimated exposure / AEC (%)** | **Acceptable (yes/no)** | **RPE** |
|---|---|---|---|---|---|---|
| Loading/ Scenario 1 | Tier 1 | 1.25 | 0.05 | 4 | yes | - |
| Post-application/ Scenario 3 | Tier 1 | 1.25 | <1.25 | < 100 | yes | - |

Following the completed aeration cycle, sensors inform when the hydrogen peroxide level is below 1.4 mg/$m^3$ and the doors can be opened. Even though the concentration of hydrogen peroxide at that moment will be slightly above the AEC (1.25 mg/$m^3$) it is expected to decrease rapidly after opening the doors due air exchange and the professional is not expected to be exposed to hydrogen peroxide levels above the reference value. If the concentrations are above 1.25 mg/$m^3$, RPE (half mask/full face mask with gas/vapour filter) must be worn when re-entry in space after treatment.

***Qualitative risk assessment for local effects***

| 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 | Rough degree of exposure | Relevant RMM&PPE | Conclusion on risk |
| High | Eye Dam. 1, H318<br><br>Skin Irrit 2, H315<br>STOT SE 3, H335 | Concentration 35 -49.9 %<br><br>classification limit:<br>8 ≤ C< 50 % (Eye damage)<br>35 % ≤ C < 50 % (Skin irritation)<br>35 % ≤ C (respiratory irritation) | 2 | Industrial, professional | Loading: placement of re-filling tank into machine, connecting re-filling tank with machine (Scenario 1) | Skin<br><br>Eye<br><br>RT | 30 min/day, 200 days/year | 35-49.9 % a.s. | ***RMM***<br>*- Labelling according to CLP*<br>*- Organisational RMM such as training for staff on good practice, good standard of personal hygiene.*<br>*- Regular cleaning of equipment and work area*<br>*- Avoidance of contact with contaminated tools and objects*<br>***PPE***<br>*- use of appropriate PPE: safety goggles with side shields, apron, long sleeved gloves and rubber boots* | **Acceptable:**<br>+ low likelihood of exposure<br>+ short actual exposure<br>+ high degree of operational and organisational RMM in use<br>+ Industrials/ professionals using appropriate PPE<br>*Good standard of personal hygiene.* |

The risk for dermal and eye local effects due to exposure to hydrogen peroxide during proposed use of BELOX for surface disinfection in enclosed spaces by VHP process does not present risk for local dermal and eye effects. RPE (full face mask with gas/vapour filter) must be worn when re-

entry in space after treatment, if the concentrations are above 1.25 mg/$m^3$. The application of the product for surface disinfection in enclosed spaces by VHP process is considered not to represent a health risk.

***PT 3 Disinfection of animal housing***

***Inhalation exposure: quantitative risk assessment for local respiratory effects***

| **Task/ Scenario** | **Tier** | **AEC mg/m³ $H_2O_2$** | **Estimated exposure mg/m³ $H_2O_2$** | **Estimated exposure / AEC (%)** | **Acceptable (yes/no)** | **RPE** |
|---|---|---|---|---|---|---|
| Mixing and loading/ Scenario 4 | Tier 1 | 1.25 | 4.5 | 360 | No | - |
| Mixing and loading/ Scenario 4 | Tier 2/ RPE (APF = 10) | 1.25 | 0.45 | 36 | Yes | Yes |
| Application/ Scenario 5 | Tier 1 | 1.25 | 16 | 1280 | No | - |
| Application/ Scenario 5 | Tier 2/ RPE (APF = 10), ACH 3 | 1.25 | 7.8 (RPE)<br>0.78 (RPE, ACH 3) | 624<br>62.4 | No<br>Yes | Yes<br>Yes + RMM (ACH 3) |

Inhalation exposure to hydrogen peroxide during manual mixing and loading is acceptable only if professional wears respiratory protection equipment (full face mask with gas/vapour filter) with Assigned Protection Factors minimum 10. If air is changed 3 times per hour and professional is wearing RPE (full face mask with gas/vapour filter, APF 10), risk is manageable for operator performing spraying of animal housing.

***Qualitative risk assessment for local effects***

| **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 | Rough degree of exposure | Relevant RMM&PPE | Conclusion on risk |
| High | Eye Dam. 1, H318<br><br>Skin Irrit 2, H315<br><br>STOT SE 3, H335 | Concentration 35 -49.9 % classification limit:<br>8 ≤ C< 50 % (Eye damage)<br>35 % ≤ C < 50 % (Skin irritation)<br>35 % ≤ C (respiratory irritation) | 3 | Professional | Manual loading (Scenario 4) | Skin<br><br>Eye<br><br>RT | 3 × per day, 30 minutes, 200 days/year | 35-49.9 % a.s. | ***RMM***<br>*- Labelling according to CLP*<br>*- Organisational RMM such as training for staff on good practice, good standard of personal hygiene*<br>*- Minimisation of manual phases*<br>*- Operational RMM such as mechanical ventilation*<br>*- Avoidance of contact with contaminated tools and objects*<br>***PPE, RPE:***<br>*- use of appropriate PPE waterproof coverall, long sleeved gloves, rubber boots, full face mask with gas/vapour filter* | ***Acceptable***<br>+ *Engineering controls;*<br>+ *Low frequency;*<br>+ *Short duration;*<br>+ *Professionals, using PPE (coverall, gloves, goggles, boots), RPE;*<br>+ *Professionals, following instructions for use;*<br>*Good standard of personal hygiene.* |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| High | Eye Dam. 1, H318 | Concentration 17.3 %<br><br>Classification limit:<br>8 ≤ C< 50 %<br>(Eye damage) | 3 | Professional | Spray application (Scenario 5) | Eye | 1×/day, 400 min, 200 days/year | 17.3 % a.s. | ***RMM***<br>*-Organisational RMM such as training for staff on good practice, good standard of personal hygiene.*<br>*- Containment as appropriate*<br>*- Avoidance of contact with contaminated tools and objects*<br>*- Good standard of general/mechanical ventilation (minimum 3 ACH required)*<br>***PPE, RPE:***<br>*-use of appropriate PPE waterproof coverall with hood, full face mask (APF 10), long sleeved gloves, rubber boots* | ***Acceptable***<br>+ *Low frequency;*<br>+ *Low likelihood of eye exposure*<br>+ *professionals using appropriate PPE, RPE*<br>*Good standard of personal hygiene.* |

During manual spraying the critical effect is local eye damage. The local risk assessment was performed for mixing and loading where the professional exposure to hydrogen peroxide is acceptable if RMM to control and minimize exposure, e.g. no splashes, no hand to face transfer, are ensured and PPE and RPE (full face mask (APF 10)) are worn. Considering the degree and actual exposure under best practice conditions during manual spraying, the risk for local effect is manageable if all RMM, PPE and RPE are implemented. The duration of exposure depends on the size of the animal housing and is expected to be much shorter than 400 min. Natural/mechanical ventilation is required for managing the concentration in air. As professional is instructed to wear full face mask, the likelihood of exposure of eyes is low.

***PT 4 Food and feed area disinfectants - Aseptic packaging***

***Inhalation exposure: quantitative risk assessment for local respiratory effects***

| ***Task/ Scenario*** | ***Tier*** | ***AEC mg/m³ $H_2O_2$*** | ***Estimated exposure mg/m³ $H_2O_2$*** | ***Estimated exposure / AEC (%)*** | ***Acceptable (yes/no)*** | ***RPE*** |
|---|---|---|---|---|---|---|
| Loading/ Scenario 7 | Tier 1 | 1.25 | 0.05 | 4 | yes | - |
| Application/ Scenario 8 | Tier 1 | 1.25 | 0.14 | 11.2 | yes | - |

Inhalation exposure to hydrogen peroxide during automated loading of aseptic machine does not exceed the reference value. During the application the professional is exposed to hydrogen peroxide only at the end of process when the machine is opened. During maintenance work PPE and RPE are required.

***Qualitative risk assessment for local effects***

| 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 | Rough degree of exposure | Relevant RMM&PPE | Conclusion on risk |
| High | Eye Dam. 1, H318<br>Skin Irrit 2, H315<br>STOT SE 3, H335 | Concentration 35 -49.9 % classification limit:<br>8 ≤ C< 50 % (Eye damage)<br>35 % ≤ C < 50 % (Skin irritation)<br>35 % ≤ C (respiratory irritation) | 4 | Professional | Loading: placement of re-filling tank into machine, connecting re-filling tank with machine (Scenario 7) | Skin<br>Eye<br>RT | Re-filling 4 tanks in 5 minutes, 200 days/year | 35 %, High level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation | ***RMM***<br>*- Labelling according to CLP*<br>*- Organisational RMM such as training for staff on good practice, good standard of personal hygiene.*<br>*-Regular cleaning of equipment and work area*<br>*- Avoidance of contact with contaminated tools and objects*<br>***PPE***<br>*-use of appropriate PPE: rubber boots, long sleeved gloves, safety goggles with side shields, apron* | **Acceptable:**<br>+ low likelihood of exposure<br>+ high degree of operational and organisational RMM in use<br>+ professionals using appropriate PPE |

Loading of the re-filling tank, placement of re-filling tank into machine and connecting re-filling tank with machine for aseptic packaging is considered not to represent a health risk regarding respiratory, dermal or eye local effects assumed personal protection equipment as rubber boots, safety goggles with side-shields, long-sleeved gloves and waterproof coverall are worn.
During the application of the product the values of hydrogen peroxide concentration inside the machine after ventilation are measured to be lower than the detection limit of 0.1 ppm and risk of inhalation exposure is therefore negligible. The risk for local dermal and ocular effects during application was not assessed since no exposure is expected during that task.
In case of maintenance work, the operator should wear general personal protection equipment (waterproof coverall, long sleeved gloves and rubber boots) and full-face mask with gas/vapour filter (APF 10) to minimize inhalation exposure.

### *PT 4 Food and feed area disinfectants - Cork stoppers disinfection*

Disinfection of cork stoppers includes loading of cork stopper (scenario 10) for which the risk assessment is covered by scenario 1, disinfection of cork stoppers by spraying which takes place in hermetically closed drum and therefore no human exposure is expected at that task.

***Inhalation exposure: quantitative risk assessment for local respiratory effects***

| **Task/ Scenario** | **Tier** | **AEC mg/m³ $H_2O_2$** | **Estimated exposure mg/m³ $H_2O_2$** | **Estimated exposure / AEC (%)** | **Acceptable (yes/no)** | **RPE** |
|---|---|---|---|---|---|---|
| Loading/ Scenario 10 | Tier 1 | 1.25 | 0.05 | 4 | yes | / |

***Qualitative risk assessment for local effects***

| **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 | Rough degree of exposure | Relevant RMM&PPE | Conclusion on risk |
| High | Eye Dam. 1, H318<br><br>Skin Irrit 2, H315<br>STOT SE 3, H335 | Concentration 35 -49.9 % classification limit: 8 ≤ C< 50 % (Eye damage) 35 % ≤ C < 50 % (Skin irritation) 35 % ≤ C (respiratory irritation) | 4 | Professional user | Loading: placement of re-filling tank into machine, connecting re-filling tank with machine (Scenario 10) | Skin<br><br>Eye<br><br>RT | Re-filling 4 tanks in 5 minutes, 200 days/year | 35 %, High level of containment, practically no exposure; no splashes, no hand to eye transfer, no (liquid or solid) aerosol formation | ***RMM***<br>*- Labelling according to CLP*<br>*- Organisational RMM such as training for staff on good practice, good standard of personal hygiene.*<br>*- Regular cleaning of equipment and work area*<br>*- Avoidance of contact with contaminated tools and objects*<br>***PPE***<br>*-use of appropriate PPE: rubber boots, long sleeved gloves, safety goggles with side shields, apron* | **Acceptable:**<br>+ low likelihood of exposure<br>+ high degree of operational and organisational RMM in use<br>+ professionals using appropriate PPE |

The exposure to the product during mixing and loading is not considered to represent a health risk for the worker assuming that the general personal protection equipment (safety goggles with side shields, long sleeved gloves, rubber boots and apron) is worn.
The exposure to the product during application is not considered to represent a health risk for the worker since it is closed process.
In case of opening machine order to resume the production, the operator should wear the following personal protection equipment (rubber boots, safety glasses with side-shields and long-sleeved gloves) and respiratory protection – full face mask with gas/vapour filter, APF=40 to minimize inhalation exposure.

***PT 4 Food and feed area disinfectants - Surface disinfection in enclosed spaces***

The use of the product for surface disinfection in enclosed spaces by VHP process is the same as disinfection via VHP machine, that means the same as evaluated for PT 2 use. The proposed PT 4 use of food and feed area disinfectants is thereafter acceptable.

***PT 4 Food and feed area disinfectants - Disinfection of container and pipework associated with drinking water***

| **Task/ Scenario** | **Tier** | **AEC mg/m³ $H_2O_2$** | **Estimated exposure mg/m³ $H_2O_2$** | **Estimated exposure / AEC (%)** | **Acceptable (yes/no)** | **RPE** |
|---|---|---|---|---|---|---|
| Mixing and loading/ Scenario 13 | Tier 1 | 1.25 | 4.5 | 360 | No | |
| Mixing and loading/ Scenario 13 | Tier 2/ RPE (APF = 10) | 1.25 | 0.45 | 36 | Yes | Yes |

| **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 | Rough degree of exposure | Relevant RMM&PPE | Conclusion on risk |
| High | Eye Dam. 1, H318<br><br>Skin Irrit 2, H315<br><br>STOT SE 3, H335 | Concentration 35 -49.9 % classification limit:<br>8 ≤ C< 50 % (Eye damage)<br>35 % ≤ C < 50 % (Skin irritation)<br>35 % ≤ C (respiratory irritation) | 4 | Professional | Manual loading (Scenario 13) | Skin<br><br>Eye<br><br>RT | 20 minutes, 200 days/year | 35-49.9 % a.s. | ***RMM***<br>*- Labelling according to CLP*<br>*- Organisational RMM such as training for staff on good practice, good standard of personal hygiene*<br>*- Minimisation of manual phases*<br>*- Operational RMM such as mechanical ventilation*<br>*- Avoidance of contact with contaminated tools and objects*<br>***PPE, RPE:***<br>*- use of appropriate PPE waterproof coverall, long sleeved gloves, rubber boots, full face mask with gas/vapour filter* | ***Acceptable***<br>+ *Engineering controls;*<br>+ *Low frequency;*<br>+ *Short duration;*<br>+ *Professionals, using PPE (coverall, gloves, goggles, boots), RPE;*<br>+ *Professionals, following instructions for use;*<br>*Good standard of personal hygiene.* |

Disinfection of distribution and storage systems for drinking water doesn't represent risk to human health if industrial/professional wears PPE and RPE (full face mask with gas/vapour filter, APF = 10) in case of manual loading. Since the application phase of disinfectant takes place in closed system, no exposure is expected.

***PT 4 Food and feed area disinfectants - CIP of piping and tanks for beverages***

| Task/ Scenario | Tier | AEC mg/m³ $H_2O_2$ | Estimated exposure mg/m³ $H_2O_2$ | Estimated exposure / AEC (%) | Acceptable (yes/no) | RPE |
|---|---|---|---|---|---|---|
| Mixing and loading/ Scenario 15 | Tier 1 | 1.25 | 4.5 | 360 | No | |
| Mixing and loading/ Scenario 15 | Tier 2/ RPE (APF = 10) | 1.25 | 0.45 | 36 | Yes | Yes |

**Conclusion**

The proposed use of hydrogen peroxide for CIP of piping and tanks for beverages does not present health risk due to inhalation exposure of hydrogen peroxide. On the other side, dermal exposure to 49.9 % (w/w) hydrogen peroxide presents a risk if not personal protective equipment is used during loading of biocidal product. That is why, personal protection equipment (impermeable gloves and coverall, rubber boots, face shield/safety goggles with side shields) has to be worn during mixing and loading.

| **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 | Rough degree of exposure | Relevant RMM&PPE | Conclusion on risk |
| high | Eye Dam. 1, H318<br><br>Skin Irrit 2, H315<br><br>STOT SE3, H335 | Concentration 35-49.9 %<br><br>classification limit:<br>8 ≤ C< 50 % (eye dam.)<br>C ≤ 35 % (skin irritation) | 4 | Professional | Manual loading into receiving vessel (Scenario 15) | Skin<br><br>Eye<br><br>RT | 20 minutes, 200 days/year | 35 -49.9 % a.s. | ***RMM***<br>*- Labelling according to CLP*<br>*- Organisational RMM such as training for staff on good practice, good standard of personal hygiene*<br>*- Minimisation of manual phases*<br>*- Operational RMM such as mechanical ventilation*<br>*- Avoidance of contact with contaminated tools and objects*<br>***PPE, RPE:***<br>*- use of appropriate PPE waterproof coverall, long sleeved gloves, rubber boots, full face mask with gas/vapour filter* | ***Acceptable***<br>+ *Engineering controls;*<br>+ *Low frequency;*<br>+ *Short duration;*<br>+ *Professionals, using PPE (coverall, gloves, goggles, boots), RPE;*<br>+ *Professionals, following instructions for use;*<br>*Good standard of personal hygiene.* |

### *PT 5 Drinking water disinfectants*

| Task/ Scenario | Tier | AEC mg/m³ $H_2O_2$ | Estimated exposure mg/m³ $H_2O_2$ | Estimated exposure / AEC (%) | Acceptable (yes/no) | RPE |
|---|---|---|---|---|---|---|
| Mixing and loading/ Scenario 17 | Tier 1 | 1.25 | 4.5 | 360 | No | |
| Mixing and loading/ Scenario 17 | Tier 2/ RPE (APF = 10) | 1.25 | 0.45 | 36 | Yes | Yes |

| **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 | Rough degree of exposure | Relevant RMM&PPE | Conclusion on risk |
| high | Eye Dam. 1, H318<br><br>Skin Irrit 2, H315<br><br>STOT SE3, H335 | Concentration 35-49.9 %<br><br>classification limit:<br>8 ≤ C< 50 % (eye dam.)<br>C ≤ 35 % (skin irritation) | 4 | Professional user | Manual loading into receiving vessel (Scenario 17) | Skin<br><br>Eye<br><br>RT | 20 minutes, 200 days/year | 35 -49.9 % a.s. | ***RMM***<br>*- Labelling according to CLP*<br>*- Organisational RMM such as training for staff on good practice, good standard of personal hygiene*<br>*- Minimisation of manual phases*<br>*- Operational RMM such as mechanical ventilation*<br>*- Avoidance of contact with contaminated tools and objects*<br>***PPE, RPE:***<br>*- use of appropriate PPE waterproof coverall, long sleeved gloves, rubber boots, full face mask with gas/vapour filter* | ***Acceptable***<br>+ *Engineering controls;*<br>+ *Low frequency;*<br>+ *Short duration;*<br>+ *Professionals, using PPE (coverall, gloves, goggles, boots), RPE;*<br>+ *Professionals, following instructions for use;*<br>*Good standard of personal hygiene.* |

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***Summary table of quantitative risk assessment for inhalation exposure and qualitative risk assessment for local effects***

| Summary table: estimated exposure from professional uses | | | |
|---|---|---|---|
| **Exposure scenario** | **Tier/PPE** | **Risk assessment for inhalation exposure** | **Risk assessment for local dermal and eye effects** |
| **Use 1: Surface disinfection by VHP (PT 2)**<br>**Use 5 Surface disinfection by VHP of enclosed spaces in food and feed area (PT4)** | | | |
| **Scenario 1- Loading of VHP, spraying and fogging machines ART (90th)** | 1/no PPE | Acceptable | Not acceptable |
| | 2/long-sleeved gloves, rubber boots, goggles with side shields, apron | Acceptable | Acceptable |
| **Scenario 2 - Disinfection by VHP** | - | - | - |
| **Scenario 3 - Re-entry to the treated room** | 1/no PPE | Acceptable | Acceptable |
| **Use 2: Disinfection of animal housing by spraying (PT 3)** | | | |
| **Scenario 4 - Manual mixing and loading for spray application PT 3** | 1/no PPE (splash loading, natural ventilation) | Not acceptable | Not acceptable |
| | 2/impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields, RPE 10 | Acceptable | Acceptable |
| **Scenario 5 – Surface disinfection of animal housing by spraying** | 1/no PPE | Not acceptable | Not acceptable |
| | 2/ impermeable coverall with hood, long-sleeved gloves, rubber boots, goggles with side shields, RPE 10, RMM (3 ACH) | Acceptable | Acceptable |
| **Scenario 6 – Cleaning of the spray equipment after application** | | | |

| | | | |
|---|---|---|---|
| **Use 3: Disinfection of food packages in closed aseptic packaging machines PT4** | | | |
| **Scenario 7 – Loading the aseptic machine** | 1/no PPE | Acceptable | Not acceptable |
| | 2/long-sleeved gloves, rubber boots, goggles with side shields, apron | Acceptable | Acceptable |
| **Scenario 8 – Aseptic packaging** | 1/no PPE | Acceptable | Acceptable |
| **Scenario 9 – Maintenance work** | PPE, RPE | | |
| **Use 4 PT 4 Food and feed area disinfectants – Cork stoppers disinfection** | | | |
| **Scenario 10 – Loading in the cork stoppers disinfection** | 1/no PPE | Acceptable | Not acceptable |
| | 2/long-sleeved gloves, rubber boots, goggles with side shields, apron | Acceptable | Acceptable |
| **Scenario 11 – Cork stoppers disinfection by spraying** | - | - | - |
| **Scenario 12 – Exposure during maintenance work** | PPE, RPE | | |
| **Use 6: Disinfection of distribution and storage systems for drinking water** | | | |
| **Description of Scenario 13 – Loading** | 1/no PPE (splash loading, natural ventilation) | Not acceptable | Not acceptable |
| | 2/impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields, RPE 10 | Acceptable | Acceptable |

| | | | |
|---|---|---|---|
| **Scenario 14 – Disinfection of distribution and storage systems for drinking water** | - | - | - |
| **Use 7: CIP of piping and tanks for beverages** | | | |
| **Description of Scenario 15 – Loading for CIP** | 1/no PPE | Acceptable | Not acceptable |
| | 2/RPE 10, impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields | Acceptable | Acceptable |
| **Scenario 15 - Disinfection of piping and tanks for beverages** | - | -- | - |
| **Use 8: Drinking water disinfection** | | | |
| **Scenario 17 – Loading** | 1/no PPE | Not acceptable | Not acceptable |
| | 2/RPE 10, impermeable coverall, long-sleeved gloves, rubber boots, goggles with side shields | Acceptable | Acceptable |
| **Scenario 18 – Drinking water disinfection** | - | - | - |

### *Risk for non-professional users*

The product is registered only for professional use so no exposure is expected.

### *Risk for the general public*

The product is registered only for professional use so no primary exposure is expected.

Secondary exposure

**Product type 4**.

Since the hydrogen peroxide is broken down after disinfection is finished and cork stoppers are again risen with water and dried no relevant residues of hydrogen peroxide which could

contaminate food remain on the cork stoppers. According to ISO 21128 Cork stoppers – Determination of oxidizing residues – Iodometric titration method at the end of the process maximum permitted residue of the hydrogen peroxide is < 0.2 mg /cork. Secondary exposure via food is therefore negligible.

Pipes and containers disinfected with hydrogen peroxide are flushed before refilled with drinking water and relevant residual hydrogen peroxide is regarded as negligible under disinfection of distribution systems for drinking water (PT 4).

Hydrogen peroxide used under PT 4 (aseptic packaging) evaporates while the wrapping material is heated before filling with food and no residues in food are expected.

Secondary exposure (oral and dermal) to hydrogen peroxide residues in piping and tanks for beverages is regarded unlikely since the equipment is flushed with clean water after the disinfection process is completed. Even more, any residues of hydrogen peroxide would break down immediately after contact with organic material (beverages).

**Product type 5**. Secondary oral or dermal human exposure to residual hydrogen peroxide in food and drinking water is possible as a result of disinfection of drinking water intended for human use. As far as there is no data on the effects of chronic oral exposure, it is not possible to determine a normal reference value (Acceptable Daily Intake, ADI) for a safe level of hydrogen peroxide in drinking water. The final concentration of hydrogen peroxide in drinking water intended for human use is anticipated to be below 0.1 mg/L at the consumer tap. Since the margin of safety is at least 1000 when the concentration in drinking water is compared to the NOAEC (NOAEL) of 100 mg/L observed in the 90-day drinking water study in a sensitive, catalase-deficient strain of mice, suggesting that potential human health risks in the general public are adequately controlled under the conditions of hydrogen peroxide use in disinfection of human drinking water.

Secondary dermal and inhalation exposure of humans to hydrogen peroxide in water via shower and washing is considered negligible.

Risks from different sources, including water and dental care products.

Due to the lack of guidance, the combined exposure has not been assessed. However, a daily oral consumer exposure level from various non-biocidal sources is estimated to be up to milligram(s). This amount includes exposure via drinking water, tooth and mouth care products as well as dietary intake by natural hydrogen peroxide in food sources. Regulation 1223/2009/EC allows the use of hydrogen peroxide, present or released, in oral products sold to consumers up to a maximum concentration of 0.1%, i.e. 1 mg/ mL (i.e. 1 g/L). For human drinking water, additional sources of hydrogen peroxide in drinking water include hydrogen peroxide used in other types of chemical water treatments, as well as generation of hydrogen peroxide from other chemicals and UV radiation used in disinfection of water. Relevant exposure of professionals occurs through inhalation and/or dermal route. Exposure via these routes in acceptable PTs does not substantially increase the level of exposure via drinking water, tooth and mouth care products and food.

## 2.2.7 Risk assessment for animal health

The product is an aqueous solution of hydrogen peroxide with stabilizers in concentrations lower than 0.1 %. The major contribution to the hazards is resulting from the hydrogen peroxide. Therefore, risk assessment for animal health is focused on hydrogen peroxide. Information on hydrogen peroxide were reproduced from the Assessment Report for hydrogen peroxide (PT1-6), where this was relevant for the assessment of the product.

PT4 There are no relevant residues of hydrogen peroxide expected in food and feeding stuff due to the rapid degradation of hydrogen peroxide to water and oxygen in the environment.

PT5 Drinking water for animals is consumed especially by chicken, broilers, which have a short lifespan, typically about one month. Due to a relatively short life-span, long term assessment is not necessary. A comparison of the final concentration of hydrogen peroxide in drinking water, 5 mg/L, to the NOAEC of 100 mg/L from the 90-day drinking water study gives a ratio of 1:20. The ratio is a sufficient margin of safety for a substance with local effects at the site of contact.

## 2.2.8 Risk assessment for the environment

The BELOX product family includes four products, i.e. BELOX 35 SB, BELOX 35 FP, BELOX 35 E with hydrogen peroxide purity of 35 % (w/w) and BELOX 50 with hydrogen peroxide purity of 49.9 % (w/w). Uses evaluated include surface disinfection in enclosed spaces by vaporised hydrogen peroxide (VHP) process for private and public health area (PT2) or food and feed area (PT4), disinfection of animal housing (PT3), aseptic packaging (PT4), cork stoppers disinfection (PT4), disinfection of inner surfaces of drinking water piping and tanks (PT4), CIP of piping and tanks for beverages (PT4) and drinking water disinfection (PT5).

Hydrogen peroxide decomposes rapidly into water and oxygen in different environmental compartments, having half-lives of 2 minutes in sewage sludge, 5 days in surface water, 12 hours in soil and 24 hours in air. Therefore, hydrogen peroxide decomposes already in sewage before reaching the STP. The low measured value of Henry's law constant ($7.5 \cdot 10^{-4}$ Pa $m^3$/mol) indicates very low volatilisation of hydrogen peroxide from water. As hydrogen peroxide is miscible with water in all proportions and taking into account that the calculated log $K_{OC}$ is 0.2036 mL/g, it is expected that hydrogen peroxide has a low potential for adsorption to soil and for partitioning to suspended matter or sediment. The estimated log $K_{ow}$ of –1.57 indicates negligible potential of bioconcentration of hydrogen peroxide in biota. The BCFs calculated according to the ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) for fish and earthworm are 1.4 and 0.84, respectively. Therefore, no accumulation of hydrogen peroxide in the food chain is expected either.

### 2.2.8.1 Effects assessment on the environment

The product family contains one active substance that needs to be considered for environmental risk assessment, i.e. hydrogen peroxide and no substances of concern. The

PNECs for hydrogen peroxide obtained from the Assessment Report (2015) are summarized below:

$PNEC_{aquatic}$ = 0.0126 mg/L
$PNEC_{STP}$ = 4.66 mg/L
$PNEC_{soil}$ = 0.0018 mg/kg

Considering the low n-octanol/water partition coefficient of hydrogen peroxide (log $K_{ow}$ = –1.57), the expected low adsorption to organic matter (QSAR based log $K_{OC}$ is 0.2036 mL/g) and its generally rapid abiotic degradation in surface waters, hydrogen peroxide is not expected to partition into the sediment. Because of the lack of exposure, a proposal for a PNEC for sediment-dwelling organisms is not considered necessary. Furthermore, any potential risk to sediment dwelling organisms is considered to be adequately covered by using the PNEC for the water phase.

The log $K_{ow}$ of -1.57 is indicating no potential for bioaccumulation. Therefore, hydrogen peroxide has only low potential to accumulate in living organisms and effect assessment through primary/secondary poisoning has not been carried out.

### *Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required*

Since there are valid data available on each of the components in the mixture and synergistic effects between any of the components are not expected, classification of the mixture is made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Classification of the product is therefore concluded when the active substance data are considered. The BELOX biocidal product family includes products with hydrogen peroxide purity of 35 - 49.9 % (w/w). As aquatic Chronic 3 classification is applied according to the 2 ATP to CLP Regulation (Regulation (EC) No 286/2011), products within the BELOX biocidal product family are classified as Aquatic Chronic 3.

### *Further Ecotoxicological studies*

No further ecotoxicological studies have been conducted for the hydrogen peroxide or for any product within the BELOX.

| **Data waiving** | |
|---|---|
| Information requirement | Not relevant |
| Justification | The products of the BELOX are aquatic dilution of hydrogen peroxide (active substance), with low concentrations (≤ 0.02 % (w/w)) of stabilizers. There are valid data available for the active substance in the Assessment Report (2015), while none of the stabilizers is classified as toxic to aquatic organisms. Therefore, no further ecotoxicological studies are required. |

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

No new data is available for the hydrogen peroxide or for any product within the BELOX.

| **Data waiving** | |
|---|---|
| Information requirement | Not relevant |
| Justification | No additional test on other specific, non-target organisms (flora and fauna) is needed on the basis of intended uses, data available on the active substance or risk assessment. |

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

No new data is available for the hydrogen peroxide or for any product within the BELOX.

| **Data waiving** | |
|---|---|
| Information requirement | Not relevant |
| Justification | The products of the BELOX are not in the form of bait or granules. |

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

No new data is available for the hydrogen peroxide or for any product within the BELOX.

| **Data waiving** | |
|---|---|
| Information requirement | Not relevant |
| Justification | The products of the BELOX are not in the form of bait or granules. |

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

Secondary ecological effect studies may be required when a habitat such as a water body, wetland, forest or field is treated. No testing on secondary ecological effect is needed, as the products of the BELOX will not be applied to large proportions of a specific habitat.

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

**PT2, PT4:** ***Surface disinfection in enclosed spaces by VHP process for private and public health area (PT2) or food and feed area (PT4)***

The product is used for disinfection of rooms using VHP process. Following the VHP machine manufacturer's instructions, concentration of hydrogen peroxide should reach 360 - 400 ppm, while the sterilization phase should be at least 90 minutes long. Emissions from this process are low since the whole disinfection cycle is carried out in closed rooms and also because treated surfaces are not needed to be rinsed after the application. Nevertheless, there may be cases (i) where treated surfaces are swept after disinfection, although cleaning is necessary already before disinfection or (ii) that some of the remaining hydrogen peroxide will be removed at the next cleaning and therefore released into the sewer. Moreover, residual hydrogen peroxide solution in the cartridge may be discharged into the sewer too. However, in a realistic worst case, no relevant amount of hydrogen peroxide would be expected to reach sewage due to its rapid degradation.

Air emissions are minor, since vaporised hydrogen peroxide should be decomposed by the VHP machine after disinfection. However, residual hydrogen peroxide in the room air after the decomposition step may reach the environment by ventilation.

**PT3:** ***Disinfection of animal housing***

Disinfection of animal housing is applied by spraying the surfaces using aqueous solution of hydrogen peroxide (17.29 % (w/w)) with usual application rate of 0.15 L/$m^2$ and sterilization phase of at least 30 minutes. No direct emissions of hydrogen peroxide to water or soil will occur, since stables and barns are closed during application and any wastewater is directed into the manure storage pit. Therefore, only indirect emissions of hydrogen peroxide may take place when manure is spread to grassland or arable land.

Due to rapid degradation of hydrogen peroxide, only traces of hydrogen peroxide remain on treated surfaces when the housing is re-stocked with animals. These traces are then mixed with litter and with the manure produced by animals. Emissions into the manure storage pit occur also in case rinsing after the application is carried out. Since manure is rich in organic matter and microorganisms, hydrogen peroxide will be decomposed by the time manure is spread to soil.

Emissions to air are negligible, since hydrogen peroxide does not evaporate from the aqueous spray solutions and application is carried out in closed housing.

Preparation of spray solutions comprises only simple dilution of hydrogen peroxide biocidal products (35 or 49.9 % (w/w)) to the in-use concentration. Any wastewaters from preparation or from cleaning of application equipment are directed into the manure storage pit. Amounts of wastewaters from preparation or cleaning are minor as compared to the spray volume.

**PT4:** ***Aseptic packaging***

Disinfection of packaging material for food products involves immersion in a bath or spraying with aqueous solution of hydrogen peroxide (≥ 35 % (w/w)) at ≥ 70 °C for at least 15 seconds. The only relevant emission of hydrogen peroxide is into sewage, where its degradation is expected to be rapid. In the sewer, hydrogen peroxide is degraded either by oxidation of organics or in reactions with microorganisms. Emissions to air remain negligible due to the internal circulation and scrubbing of ventilated air.

**PT4:** ***Cork stoppers disinfection***
Disinfection of cork stoppers takes place in specially designed machines. The cork stoppers should be wetted by spraying in a bath with aqueous solution of hydrogen peroxide (10 - 35 % (w/w)) at ≥ 20 °C for at least 15 minutes. After disinfection phase, catalyst is added to break down hydrogen peroxide into oxygen and water at temperature ≥ 40 °C. Finally, cork stoppers are rinsed with water and dried. Emissions into air are minor, since hydrogen peroxide is broken down after disinfection process and remaining hydrogen peroxide does not tend to evaporate. Likewise, only minor amounts of hydrogen peroxide might be discharged to sewage, where degradation of hydrogen peroxide is expected to be rapid.

**PT4:** ***Disinfection of inner surfaces of drinking water piping and tanks***
Disinfection of inner surfaces of drinking water piping and tanks is performed either by spraying or injecting 9.88 % (w/w) hydrogen peroxide into pipes or tank. Hydrogen peroxide is decomposed during the disinfection process by oxidation reactions with organic or inorganic compounds, as well as by biotic and abiotic catalysis. Residual hydrogen peroxide from the disinfection of distribution systems for drinking water is discharged only in sewage, with no other relevant emission pathways as residual concentration of disinfectants should not exceed national level limits before discharged.

**PT4:** ***CIP of piping and tanks for beverages***
Disinfection of piping and tanks is performed by using aqueous solution of hydrogen peroxide (9.88 % (w/w)) for 15 minutes. In order to ensure that beverages are not contaminated by hydrogen peroxide, all disinfected equipment is rinsed with water after application. The main route of exposure to the environment is therefore via sewage.

**PT5:** ***Drinking water disinfection***
The product is added continuously to the drinking water by a dosing system. Hydrogen peroxide in drinking water for disinfection has an initial concentration of 25 mg/L to maintain residual concentration of 5 mg/L at the final point. The treatment should be carried out in the deposit to assure that the product has enough contact time (15 hours) with water. Residual hydrogen peroxide in tap water is discharged to sewage along with used water. During water use, hydrogen peroxide is decomposed by oxidation reactions with organic or inorganic compounds, as well as by biotic and abiotic catalysis. Thus, residual hydrogen peroxide from the disinfection of drinking water is discharged to sewage, with no other relevant emission pathways.

In the sewage, residual hydrogen peroxide is decomposed further, by the same mechanisms as discussed above. However, reaction partners or catalytically active components are much more abundant in sewage than during the use of drinking water.

Relevant receiving compartments for all PTs described above are summarized in section Fate and distribution in exposed environmental compartments (Chapter 2.2.8.2 Exposure assessment).

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

No new data is available for the active substance or for any biocidal product of the biocidal family.

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

### *Leaching behaviour (ADS)*

No new data is available for the hydrogen peroxide or for any product within the BELOX.

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

No new data is available for the hydrogen peroxide or for any product within the BELOX.

| **Data waiving** | |
|---|---|
| Information requirement | Not relevant |
| Justification | No further testing is considered necessary to determine the distribution and dissipation of the products in soil. |

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

No new data is available for the hydrogen peroxide or for any product within the BELOX.

| **Data waiving** | |
|---|---|
| Information requirement | Not relevant |
| Justification | No further testing is considered necessary to determine the distribution and dissipation of the products in water and sediment. |

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

No new data is available for the hydrogen peroxide or for any product within the BELOX.

| **Data waiving** |
|---|

| | |
|---|---|
| Information requirement | Not relevant |
| Justification | No further testing is considered necessary to determine the distribution and dissipation of the products in air. |

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

No new data is available for the hydrogen peroxide or for any product within the BELOX.

The products of the BELOX are not intended to be sprayed near to surface water. Therefore no overspray study is needed to assess risks to aquatic organisms or plants under field conditions.

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

The products of the BELOX can be sprayed, but only indoor and on a small scale. Therefore, no overspray behaviour is needed to assess risks to bees and non-target arthropods under field conditions.

#### 2.2.8.2 Exposure assessment

The BELOX product family consists of four products: BELOX 35 SB, BELOX 35 FP, BELOX 35 E and BELOX 50. The BELOX products are intended to be used in PT2, 3, 4 and 5. Most of the proposed uses by the applicant to be authorised within this application are the same as uses presented in the CAR (2015) and have been assessed for the active substance hydrogen peroxide for PTs 1-6, except cork stoppers disinfection and CIP of piping and tanks for beverages. In-use concentration used in the exposure and risk assessment is for disinfection of animal housing and disinfection of inner surfaces of drinking water piping and tanks higher than in the CAR (2015) and has been changed by the eCA, because the in-use concentration given by the applicant is not effective according to the submitted efficacy studies.

**Use 1, 5: Surface disinfection in enclosed spaces by VHP process for private and public health area (PT2) or food and feed area (PT4)**
The products intended for surface disinfection by VHP process contains up to 49.9 % (w/w) hydrogen peroxide. Proposed use is similar to the representative use described in CAR (2015), except that within this application concentrations of 360 - 400 ppm and in CAR (2015) 250 - 400 ppm are claimed. The products are intended for professional use of hydrogen peroxide as surface disinfectant in enclosed (sealed) spaces via machine based VHP process. Emission to air is controlled by the VHP machine and catalytic decomposition of hydrogen peroxide may take place in some machines.

**Use 2: Disinfection animal housing (PT3)**
Disinfection of animal housing was assessed in CAR (2015). With an in-use concentration of 17.29 % (w/w) which is higher concentration used for the representative product (i.e. 7.4 % (w/w)) in CAR (2015), the fraction remaining in the manure after 12 hours is considered low ($F_{deg}$ = 7.5 · $10^{-37}$) and therefore negligible amounts of hydrogen peroxide may be present in manure when it is spread to grassland or arable land.

**Use 3: Aseptic packaging (PT4)**
The products intended for use in aseptic packaging using immersion or wetting system contains up to 35 % (w/w) hydrogen peroxide. The products are similar to the representative product used for authorisation of the active substance in aseptic packaging. The risk assessment for the representative product has been performed for disinfection via immersion bath. Emissions to air are negligible, while emissions from scrubbers that catch hydrogen peroxide evaporated from the immersion bath and the drying process are discharged into sewage.

**Use 4: Cork stoppers disinfection (PT4)**
The products intended for cork stoppers disinfection contains up to 49.9 % (w/w) hydrogen peroxide. The disinfection process is performed in specially designed machines where the cork stoppers should be wetted by spraying in a bath. All operations involving exposure to the cork stoppers to hydrogen peroxide occur in a closed system and therefore only relevant emission of hydrogen peroxide from this use is into sewage.

**Use 6: Disinfection of inner surfaces of drinking water piping and tanks (PT4)**
When pipes or water storage tanks are newly installed, repaired or cleaned, a disinfection step is necessary before commissioning. The products intended for disinfection of inner surfaces of drinking water piping and tanks contains up to 49.9 % (w/w) hydrogen peroxide. Proposed use is similar to the representative use described in CAR (2015), except that within this application hydrogen peroxide concentrations of 9.88 % (w/w) and in CAR (2015) 2 % (w/w) are claimed.

**Use 7: CIP of piping and tanks for beverages (PT4)**
The products intended for CIP of piping and tanks for beverages contains up to 49.9 % (w/w) hydrogen peroxide. The in-use concentration is 9.88 % (w/w) of hydrogen peroxide, which is filled into the pipes for a contact time of typically 15 minutes. Hydrogen peroxide is partly decomposed already during disinfection of installations by oxidation reactions with organic or inorganic compounds, as well as through abiotic degradation. Furthermore, as all disinfected equipment is rinsed with water after application, the main route of exposure to the environment is via sewage.

**Use 8: Drinking water disinfection (PT5)**
The products intended for use in drinking water disinfection, where the product is added continuously to the drinking water by a dosing system contains up to 49.9 % (w/w) hydrogen peroxide. Hydrogen peroxide in drinking water for disinfection has an initial concentration of 25 mg/L to maintain ≤ 5 mg/L residual at the final point. The main emission pathway will be therefore to sewage, as residual hydrogen peroxide in tap water is discharged to sewage along with the used water.

**General information**

| | |
|---|---|
| Assessed PT | PT2 |
| Assessed scenarios | Scenario 1: Surface disinfection in enclosed spaces by VHP process |
| ESD(s) used | No harmonized scenario or TAB entry was available at the time of the assessment. Modified scenario used for approval of active substance was applied (CAR, 2015). |
| Approach | Scenario 1: Maximum target concentration |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No<br>Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied.<br><br>The degradation of hydrogen peroxide in the sewer ($F_{sewage}$) was considered same as it is detailed in CAR (2015), except the applicant assumed half-life of 6 minutes in raw sewage (instead of temperature corrected value of 11.2 minutes as in CAR) and a residence time in sewage of 30 minutes (instead of 60 minutes as in CAR). As obtained $F_{sewage}$ of 0.0313 is worst-case compared to 0.024 used in CAR, 0.0313 was accepted for the risk assessment:<br>$F_{sewage} = \exp(- \ln(2)/6 \text{ min} \cdot 30 \text{ min}) = 0.0313$<br><br>The residual hydrogen peroxide in the room air after the decomposition step ($F_{air}$) was estimated as the quotient of the maximum residual concentration in air after the decomposition step and the minimum target concentration in air, i.e. 1 ppm/360 ppm = 0.0028. |

## *Emission estimation*

### Scenario 1: Surface disinfection in enclosed spaces by VHP process

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Surface disinfection in enclosed spaces by VHP process (use 1) | | | |
| Room size | 566 | $m^3$ | provided by the applicant |
| Target concentration of hydrogen peroxide, maximum | 400 | ppm | provided by the applicant |
| Application rate of hydrogen peroxide | 556 | $mg/m^3$ | |
| Amount of hydrogen peroxide used to disinfect a large room, realistic worst case ($M_{appl}$) | 0.315 | kg/appl | |
| Number of applications with one machine during one day, maximum ($N_{appl}$) | 3 | $day^{-1}$ | CAR, 2015 |
| Number of machines operating daily at the same local scale, realistic worst case ($N_{machines}$) | 3 | - | CAR, 2015 |
| Fraction of hydrogen peroxide emitted to sewage, worst case ($F_{water}$) | 0.05 | - | CAR, 2015 |
| Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst case ($F_{sewage}$) | 0.0313 | - | based on approach detailed in CAR, 2015 |
| Fraction of hydrogen peroxide used that is emitted to air, worst case ($F_{air}$) | 0.0028 | - | based on approach detailed in CAR, 2015 |

Calculations for Scenario 1

$Elocal_{water} = M_{appl} \cdot N_{appl} \cdot N_{machines} \cdot F_{water} \cdot F_{sewage}$
$Elocal_{air} = M_{appl} \cdot N_{appl} \cdot N_{machines} \cdot F_{air}$

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | 4.43E-03 | |
| Air | 7.87E-03 | |

**General information**

| | |
|---|---|
| Assessed PT | PT3 |
| Assessed scenarios | Scenario 2: Disinfection of animal housing |
| ESD(s) used | No harmonized scenario or TAB entry was available at the time of the assessment. The agreed approach used for approval of active substance was applied (CAR, 2015). |
| Approach | Scenario 2: Semi-quantitative approach |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No<br>Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied.<br><br>The degradation of hydrogen peroxide in the manure before spreading to soil was considered according to the CAR (2015). As no degradation rate in manure is available, the decomposition of hydrogen peroxide is calculated using the half-life of 6 minutes obtained in similar media regarding microbial density (Document IIA, 2015). Assuming that the last application of the product containing hydrogen peroxide take place 12 hours before the manure is applied to agricultural land and using single first-order kinetics, fraction remaining in the manure after degradation can be calculated as follows:<br><br>$F_{deg}$ = exp(- ln(2)/0.1 hours · 12 hours) = 7.5E-37<br><br>The fraction of hydrogen peroxide remaining after 12 hours ($F_{deg}$) is so low that in practice hydrogen peroxide is completely degraded. Moreover, since hydrogen peroxide acts as oxygen source for microorganisms, all hydrogen peroxide is consumed before any medium reaches an anaerobic state in the manure storage pit. Since emissions of hydrogen peroxide are very low, it was not meaningful to estimate any environmental concentrations. |

## *Emission estimation*

### Scenario 2: Disinfection of animal housing

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Disinfection of animal housing (use 2) | | | |
| In-use concentration of hydrogen peroxide in the product ($C_{a.s.}$) | 0.1729 | kg/L | provided by the applicant |
| Degradation half-live (DT50) | 6 | min | CAR, 2015 |
| Fraction of hydrogen peroxide remaining after 1 day (F) | 7.5E-37 | - | CAR, 2015 |

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| Soil | negligible | Degradation in manure assumed as in CAR (2015) |

### General information

| | |
|---|---|
| Assessed PT | PT4 |
| Assessed scenarios | Scenario 3: Aseptic packaging |
| ESD(s) used | No harmonized scenario or TAB entry was available at the time of the assessment. Modified scenario used for approval of active substance was applied (CAR, 2015). |
| Approach | Scenario 3: Maximum in-use concentration |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No<br>Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied.<br><br>The degradation of hydrogen peroxide in the sewer ($F_{sewage}$) was considered same as it is detailed in CAR (2015), except the applicant assumed half-life of 6 minutes in raw sewage (instead of temperature corrected value of 11.2 minutes as in CAR) and a residence time in sewage of 30 minutes (instead of 60 minutes as in CAR). |

| | |
|---|---|
| | As obtained $F_{sewage}$ of 0.0313 is worst-case compared to 0.024 used in CAR, 0.0313 was accepted for the risk assessment:<br><br>$F_{sewage}$ = exp(- ln(2)/6 min · 30 min) = 0.0313 |

## *Emission estimation*

### **Scenario 3**: **Aseptic packaging**

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Aseptic packaging (use 3) | | | |
| In-use concentration of hydrogen peroxide in disinfectant solution ($C_{a.s.}$) | 0.35 | kg/kg | provided by the applicant |
| Amount of milk processed at a large-scale creamery, realistic worst case ($Q_{milk}$) | 3E+08 | kg/year | provided by the applicant |
| Working days per year, assumption ($T_{emission}$) | 260 | day/year | provided by the applicant |
| Consumption rate of disinfectant solution, realistic worst case ($R_{disinf}$) | 0.000571 | L/kg milk | CAR, 2015 |
| Bulk density of 35 % (w/w) hydrogen peroxide disinfectant solution ($\rho_{disinf}$) | 1.13 | kg/L | CAR, 2015 |
| Fraction of hydrogen peroxide remaining at discharge into sewage, realistic worst case ($F_{process}$) | 0.9 | - | CAR, 2015 |
| Fraction remaining after on-site wastewater treatment, conservatively ignored here ($F_{wwtp}$) | 1 | - | CAR, 2015 |
| Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst case ($F_{sewage}$) | 0.0313 | - | based on approach detailed in CAR, 2015 |

Calculations for Scenario 3

$Elocal_{water} = Q_{a.s.} \cdot F_{process} \cdot F_{wwtp} \cdot F_{sewage}$
$= Q_{milk} \cdot T_{emission}^{-1} \cdot R_{disinf} \cdot C_{a.s.} \cdot \rho_{disinf} \cdot F_{process} \cdot F_{wwtp} \cdot F_{sewage}$

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | 7.33E+00 | |

**General information**

| | |
|---|---|
| Assessed PT | PT4 |
| Assessed scenarios | Scenario 4: Cork stoppers disinfection |
| ESD(s) used | No harmonized scenario or TAB entry was available at the time of the assessment. Tailor-made calculations (by the applicant) were carried out. |
| Approach | Scenario 4: Maximum in-use concentration |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No<br>Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied.<br><br>The degradation of hydrogen peroxide in the sewer ($F_{sewage}$) was considered same as it is detailed in CAR (2015), except the applicant assumed half-life of 6 minutes in raw sewage (instead of temperature corrected value of 11.2 minutes as in CAR) and a residence time in sewage of 30 minutes (instead of 60 minutes as in CAR). As obtained $F_{sewage}$ of 0.0313 is worst-case compared to 0.024 used in CAR, 0.0313 was accepted for the risk assessment:<br><br>$F_{sewage}$ = exp(- ln(2)/6 min · 30 min) = 0.0313 |

## *Emission estimation*

**Scenario 4: Cork stoppers disinfection**

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Cork stoppers disinfection (use 4) | | | |
| In-use concentration of hydrogen peroxide in disinfectant solution ($C_{a.s.}$) | 0.35 | kg/kg | provided by the applicant |
| Amount of cork stoppers processed at a large-scale factory, realistic worst case ($Q_{cork}$) | 1E+09 | cork stopper/year | provided by the applicant |
| Working days per year, assumption ($T_{emission}$) | 260 | day/year | provided by the applicant |

| | | | |
|---|---|---|---|
| Consumption rate of disinfectant solution, realistic worst case ($R_{disinf}$) | 0.000188 | L/cork stopper | provided by the applicant |
| Bulk density of 35 % (w/w) hydrogen peroxide disinfectant solution ($\rho_{disinf}$) | 1.13 | kg/L | CAR, 2015 |
| Fraction of hydrogen peroxide remaining at discharge into sewage, realistic worst case ($F_{process}$) | 0.85 | - | provided by the applicant |
| Fraction remaining after on-site wastewater treatment, conservatively ignored here ($F_{wwtp}$) | 1 | - | provided by the applicant |
| Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst case ($F_{sewage}$) | 0.0313 | - | based on approach detailed in CAR, 2015 |

Calculations for Scenario 4

$Elocal_{water} = Q_{a.s.} \cdot F_{process} \cdot F_{wwtp} \cdot F_{sewage}$
$= Q_{cork} \cdot T_{emission}^{-1} \cdot R_{disinf} \cdot C_{a.s.} \cdot \rho_{disinf} \cdot F_{process} \cdot F_{wwtp} \cdot F_{sewage}$

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | 7.60E+00 | |

**General information**

| | |
|---|---|
| Assessed PT | PT4 |
| Assessed scenarios | Scenario 5: Surface disinfection in enclosed spaces by VHP process |
| ESD(s) used | No harmonized scenario or TAB entry was available at the time of the assessment. Modified scenario used for approval of active substance was applied (CAR, 2015). |
| Approach | Scenario 5: Maximum target concentration |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No<br>Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied. |

| | |
|---|---|
| | The degradation of hydrogen peroxide in the sewer ($F_{sewage}$) was considered same as it is detailed in CAR (2015), except the applicant assumed half-life of 6 minutes in raw sewage (instead of temperature corrected value of 11.2 minutes as in CAR) and a residence time in sewage of 30 minutes (instead of 60 minutes as in CAR). As obtained $F_{sewage}$ of 0.0313 is worst-case compared to 0.024 used in CAR, 0.0313 was accepted for the risk assessment:<br><br>$F_{sewage} = \exp(- \ln(2)/6 \text{ min} \cdot 30 \text{ min}) = 0.0313$<br><br>The residual hydrogen peroxide in the room air after the decomposition step ($F_{air}$) was estimated as the quotient of the maximum residual concentration in air after the decomposition step and the minimum target concentration in air, i.e. 1 ppm/360 ppm = 0.0028. |

Emission estimation for scenario 5 (use 5) is same to scenario 1 (use 1), as in both cases process applied is the same, except that in scenario 5 products are used in food and feed area (PT4), while in scenario 1 products are used in private and public health area (PT2).

**General information**

| | |
|---|---|
| Assessed PT | PT4 |
| Assessed scenarios | Scenario 6: Disinfection of inner surfaces of drinking water piping and tanks |
| ESD(s) used | No harmonized scenario or TAB entry was available at the time of the assessment. Modified scenario used for approval of active substance was applied (CAR, 2015). |
| Approach | Scenario 6: Maximum in-use concentration |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No<br>Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied.<br><br>The degradation of hydrogen peroxide in the sewer ($F_{sewage}$) was considered same as it is detailed in CAR (2015), except the applicant assumed half-life of 6 minutes in raw sewage (instead of temperature corrected value of 11.2 minutes as in CAR) and a residence time in sewage of 30 minutes (instead of 60 minutes as in CAR). As obtained $F_{sewage}$ of 0.0313 is worst-case compared to 0.024 used in CAR, 0.0313 was accepted for the risk assessment: |

| | |
|---|---|
| | $F_{sewage}$ = exp(- ln(2)/6 min · 30 min) = 0.0313 |

## *Emission estimation*

### Scenario 6: Disinfection of inner surfaces of drinking water piping and tanks

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Disinfection of inner surfaces of drinking water piping and tanks (use 6) | | | |
| In-use concentration of hydrogen peroxide in the disinfection solution ($C_{a.s.}$) | 0.0988 | kg/L | provided by the applicant |
| Volume of disinfection solution used ($V_{disinf}$) | 24500 | L | provided by the applicant |
| Fraction of hydrogen peroxide emitted to sewage ($F_{water}$) | 0.75 | - | CAR, 2015 |
| Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst case ($F_{sewage}$) | 0.0313 | - | based on approach detailed in CAR, 2015 |

Calculations for Scenario 6

$Elocal_{water} = C_{a.s.} \cdot V_{disinf} \cdot F_{water} \cdot F_{sewage}$

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | 5.67E+01 | |

### General information

| | |
|---|---|
| Assessed PT | PT4 |
| Assessed scenarios | Scenario 7: CIP of piping and tanks for beverages |
| ESD(s) used | Emission Scenario Document for Product Type 4 (2011): Assessment of entire plants (e.g. breweries, dairies, beverage processing plants) IHO (2006) (ESD Table 5) |
| Approach | Scenario 7: Average consumption |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No |

| | |
|---|---|
| | Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied.<br><br>The degradation of hydrogen peroxide in the sewer ($F_{sewage}$) was considered same as it is detailed in CAR (2015), except the applicant assumed half-life of 6 minutes in raw sewage (instead of temperature corrected value of 11.2 minutes as in CAR) and a residence time in sewage of 30 minutes (instead of 60 minutes as in CAR). As obtained $F_{sewage}$ of 0.0313 is worst-case compared to 0.024 used in CAR, 0.0313 was accepted for the risk assessment:<br><br>$F_{sewage}$ = exp(- ln(2)/6 min · 30 min) = 0.0313 |

## *Emission estimation*

### Scenario 7: CIP of piping and tanks for beverages

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: CIP of piping and tanks for beverages (use 7) | | | |
| Amount of hydrogen peroxide used per year in the local plant ($Q_{a.i.}$) | 191 | kg/yr | Default value (average annual amount of active substance (100 %) applied for hydrogen peroxide) |
| Number of emission days per year ($T_{emission}$) | 231 | d/yr | Default value |
| Fraction of substance disintegrated during or after application (before release to the sewer system) ($F_{dis}$) | 0 | - | Default value |
| Fraction of substance eliminated due to on-site pre-treatment of the plant wastewater ($F_{elim}$) | 0.9 | - | According to the AHEE-2 a default value of 0.9 for $F_{elim}$ can be applied for rapidly reacting substances like e.g. oxidizing substances for all scenarios in PT4. |
| Fraction of hydrogen peroxide emitted to sewage, worst case ($F_{water}$) | 1 | - | Default value |

| | | | |
|---|---|---|---|
| Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst case ($F_{sewage}$) | 0.0313 | - | based on approach detailed in CAR, 2015 |

Calculations for Scenario 7

$Elocal_{water} = Q_{a.i.} \cdot T_{emission}^{-1} \cdot (1 - F_{dis}) \cdot (1 - F_{elim}) \cdot F_{water} \cdot F_{sewage}$

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | 2.59E-03 | |

**General information**

| | |
|---|---|
| Assessed PT | PT5 |
| Assessed scenarios | Scenario 8: Drinking water disinfection |
| ESD(s) used | No harmonized scenario or TAB entry was available at the time of the assessment. Modified scenario used for approval of active substance was applied (CAR, 2015). |
| Approach | Scenario 8: Maximum permissible concentration |
| Distribution in the environment | Calculated based on ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) and EUSES 2.1.2 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No<br>Formulation: No<br>Use: Yes<br>Service life: No |
| Remarks | Additional guidance according to the TAB was applied.<br><br>The degradation of hydrogen peroxide in the sewer ($F_{sewage}$) was considered same as it is detailed in CAR (2015), except the applicant assumed half-life of 6 minutes in raw sewage (instead of temperature corrected value of 11.2 minutes as in CAR) and a residence time in sewage of 30 minutes (instead of 60 minutes as in CAR). As obtained $F_{sewage}$ of 0.0313 is worst-case compared to 0.024 used in CAR, 0.0313 was accepted for the risk assessment:<br><br>$F_{sewage} = \exp(- \ln(2)/6 \text{ min} \cdot 30 \text{ min}) = 0.0313$ |

## *Emission estimation*

### Scenario 8: Drinking water disinfection

| **Input parameters for calculating the local emission** | | | |
|---|---|---|---|
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Drinking water disinfection (use 8) | | | |
| Maximum permissible concentration of hydrogen peroxide in drinking water at the tap ($C_{tap}$) | 5 | mg/L | provided by the applicant |
| Influent volume at the local STP, TGD. Worst case to assume total influent containing residual hydrogen peroxide ($V_{inf}$) | 2E+06 | L/d | CAR, 2015 |
| Fraction of hydrogen peroxide emitted to sewage, worst case ($F_{water}$) | 0.75 | - | CAR, 2015 |
| Fraction of hydrogen peroxide remaining after degradation in sewage, realistic worst case ($F_{sewage}$) | 0.0313 | - | based on approach detailed in CAR, 2015 |

Calculations for Scenario 8

$Elocal_{water} = C_{tap} \cdot V_{inf} \cdot F_{water} \cdot F_{sewage} \cdot 10^{-6}$

| **Resulting local emission to relevant environmental compartments** | | |
|---|---|---|
| **Compartment** | **Local emission ($Elocal_{compartment}$) [kg/d]** | **Remarks** |
| STP | 2.35E-01 | |

## *Fate and distribution in exposed environmental compartments*

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water |
| Scenario 1 | yes | no | no | no | yes | yes | no | no |
| Scenario 2 | no | no | no | no | no | no | no | no |
| Scenario 3 | yes | no | no | no | yes | no | no | no |
| Scenario 4 | yes | no | no | no | yes | no | no | no |
| Scenario 5 | yes | no | no | no | yes | yes | no | no |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Scenario 6 | yes | no | no | no | yes | no | no | no |
| Scenario 7 | yes | no | no | no | yes | no | no | no |
| Scenario 8 | yes | no | no | no | yes | no | no | no |

| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
|---|---|---|---|
| Input | Value | Unit | Remarks |
| Molecular weight | 34.01 | g/mol | |
| Melting point | -0.43 | °C | 100% purity |
| Vapour pressure (at 25 °C) | 299 | Pa | 100% purity |
| Water solubility (at 25 °C) | 1E+05 | mg/L | The maximum set value in EUSES 2.1.2, as hydrogen peroxide is miscible in water in all proportions. |
| Log Octanol/water partition coefficient | -1.57 | Log 10 | Calculated |
| Organic carbon/water partition coefficient ($K_{oc}$) | 1.598 | L/kg | |
| Henry's Law Constant (at 20 °C) | 7.5E-04 | Pa $m^3$/mol | 100% purity |
| Biodegradability | | | As hydrogen peroxide is an anorganic substance, biodegradability classification does not apply. |
| Rate constant for STP | 499 | $day^{-1}$ | |
| DT50 for degradation in surface water | 5 | day | |
| DT50 for degradation in STP (at 20 °C) | 0.033 | hr | |
| DT50 for degradation in soil | 12 | hr | |
| DT50 for degradation in air | 24 | hr | |

| **Calculated fate and distribution in the STP (using Simple Treat 3.0)** | | |
|---|---|---|
| Compartment | Percentage [%] | Remarks |
| | All scenarios | |
| Air | $1.04 \cdot 10^{-4}$ | / |
| Water | 0.685 | |
| Sludge | 0.0144 | |
| Degraded in STP | 99.3 | |

### *Calculated PEC values*

| Summary table on calculated PEC values | | | |
|---|---|---|---|
| | **$PEC_{STP}$** | **$PEC_{water}$** | **$PEC_{soil}$** |
| | [mg/L] | [mg/L] | [$mg/kg_{wwt}$] |
| Scenario 1 | 1.52E-05 | 1.52E-06 | 2.86E-08 |
| Scenario 2 | not relevant | not relevant | negligible |
| Scenario 3 | 2.51E-02 | 2.51E-03 | 4.73E-05 |
| Scenario 4 | 2.60E-02 | 2.60E-03 | 4.90E-05 |
| Scenario 5 | 1.52E-05 | 1.52E-06 | 2.86E-08 |
| Scenario 6 | 1.94E-01 | 1.94E-02 | 3.66E-04 |
| Scenario 7 | 8.87E-06 | 8.87E-07 | 1.67E-08 |
| Scenario 8 | 8.04E-04 | 8.04E-05 | 1.52E-06 |

### *Primary and secondary poisoning*

Primary poisoning
The proposed uses of the products preclude any risk of primary poisoning.

Secondary poisoning
Substance is unlikely to bioaccumulate in aquatic or terrestrial environment. It has a low log $K_{ow}$ (–1.57), it is not highly adsorptive, it does not belong to a class of substances known to have a potential to accumulate in living organisms, its structural features does not indicate accumulation and has a short degradation half-life of 5 days in the surface water test. The low accumulation potential is supported by low BCF and BMF for fish and earthworms determined by EUSES 2.1.2. The bioconcentration factor for fish is 1.4 and a default BMF of 1. The bioconcentration factor for earthworms is 0.84 and a default BMF of 1. No further assessment of secondary exposure via the food chain is therefore considered necessary.

#### 2.2.8.3 Risk characterisation

### *Atmosphere*

According to the CAR (2015), emissions to air are not considered relevant for any of proposed uses. For surface disinfection by VHP process (PT2 and PT4), emissions to air from ventilation was calculated, although vaporisation only takes place in closed systems, and hydrogen peroxide remaining in process air is decomposed afterwards.

The resulting $PEC_{air}$ can be calculated following the ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) (equation 43), i.e. by multiplying the air emission of 7.87E-03 kg/day with the standard concentration at 100 m from the emission point calculated for a standard source of 1 kg/day (where $Cstd_{air}$ = 2.78E-04 $mg/m^3$). The resulting $PEC_{air}$ is 2.19E-03 $\mu g/m^3$. This is a worst case value, since the

emission estimate is a worst case, and since the standard concentration from the ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) is also based on worst case assumptions.

The estimated $PEC_{air}$ is well below the typical background concentrations of hydrogen peroxide in air that ranges from 0.14 to 1.4 µg/m$^3$, with a maximum concentration of 10 µg/m$^3$ (Document IIA, 2015). Therefore, the additional emissions constitute only a negligible contribution to the ambient air concentrations. Furthermore, the troposphere has a buffer capacity for hydrogen peroxide, which is part of the equilibrium system of photooxidants. Potential minor air emissions of hydrogen peroxide are therefore not expected to alter the existing tropospheric background concentrations to any relevant degree.

In conclusion, emissions to air from VHP process can be regarded negligible and probably don't alter existing background concentrations in the troposphere to any relevant degree. Therefore, further assessment of PECs in air and rainwater from emissions due to use of biocidal products is considered not relevant.

### *Sewage treatment plant (STP)*

| **Summary table on calculated PEC/PNEC values** | |
|---|---|
| | **$PEC/PNEC_{STP}$** |
| Scenario 1 | 3.25E-06 |
| Scenario 2 | not relevant |
| Scenario 3 | 5.39E-03 |
| Scenario 4 | 5.59E-03 |
| Scenario 5 | 3.25E-06 |
| Scenario 6 | 4.17E-02 |
| Scenario 7 | 1.90E-06 |
| Scenario 8 | 1.73E-04 |

For the emission pathway via STP, PEC/PNEC ratio values for all scenarios are below the trigger value of 1. Therefore, risk to the STP is considered as acceptable.

### *Aquatic compartment*

| **Summary table on calculated PEC/PNEC values** | |
|---|---|
| | **$PEC/PNEC_{water}$** |
| Scenario 1 | 1.20E-04 |
| Scenario 2 | not relevant |
| Scenario 3 | 1.99E-01 |

| | |
|---|---|
| Scenario 4 | 2.07E-01 |
| Scenario 5 | 1.20E-04 |
| Scenario 6 | 1.54E+00 |
| Scenario 7 | 7.04E-05 |
| Scenario 8 | 6.38E-03 |

For the emission pathways via surface water, PEC/PNEC ratio values are below the trigger value of 1 except for Scenario 6 (Disinfection of inner surfaces of drinking water piping and tanks). To resolve the indicated risk to the aquatic compartment from the respective use, it should be noted that distribution systems for drinking water are disinfected only intermittently and that risk assessment relies on the conservative assumption (reduction of only 25 % at discharge into sewer was assumed). Furthermore, permission or consent for disposal of any wastewater generated to a sewer must be obtained from the relevant water service company or environmental authority, as appropriate. Consequently, the risk to the aquatic compartment is assumed acceptable also for disinfection of inner surfaces of drinking water piping and tanks.

### *Terrestrial compartment*

| **Calculated PEC/PNEC values** | |
|---|---|
| | **PEC/PNEC$_{soil}$** |
| Scenario 1 | 1.59E-05 |
| Scenario 2 | negligible |
| Scenario 3 | 2.63E-02 |
| Scenario 4 | 2.72E-02 |
| Scenario 5 | 1.59E-05 |
| Scenario 6 | 2.03E-01 |
| Scenario 7 | 9.28E-06 |
| Scenario 8 | 8.42E-04 |

For the emission pathway via soil, PEC/PNEC ratio values for all scenarios are below the trigger value of 1. Therefore, risk to the soil organisms is considered as acceptable.

### *Groundwater*

At the WG II 2019 it was agreed that for rapidly reacting substances (e.g. substances reacting with organic matter) no groundwater assessment is needed since it is very unlikely that substance will reach the groundwater. For this reason, also no groundwater assessment for hydrogen peroxide is considered necessary.

## *Primary and secondary poisoning*

Primary poisoning
The proposed uses of the products preclude any risk of primary poisoning.

Secondary poisoning
There is a low risk for secondary poisoning from the use of products within the BELOX as hydrogen peroxide has a low log $K_{ow}$ (–1.57) and also low bioaccumulation factor being 1.4 for fish and 0.84 for earthworms. Thus, accumulation of hydrogen peroxide in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is considered negligible.

## *Mixture toxicity*

Not relevant for this product family as the products contain only one active substance and no substances of concern.

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

For hydrogen peroxide it was agreed at the WG V 2014 that aggregated risk assessment is not regarded relevant due to the high reactivity of the substance (Assessment Report, 2015).

| **Overall conclusion on the risk assessment for the environment of the product** |
|---|
| A number of worst-case assumptions have been applied in the assessment of the BELOX product family and acceptable risks to all environmental compartments have been predicted except for the Scenario 6 (Disinfection of inner surfaces of drinking water piping and tanks) as the $PEC/PNEC_{water}$ is greater than the trigger value of 1. To resolve the indicated risk to the aquatic compartment from the respective use, it should be noted that distribution systems for drinking water are disinfected only intermittently and that risk assessment relies on the conservative assumption (reduction of only 25 % at discharge into sewer was assumed). Furthermore, permission or consent for disposal of any wastewater generated to a sewer must be obtained from the relevant water service company or environmental authority, as appropriate. Consequently, the risk to the aquatic compartment is assumed acceptable also for disinfection of inner surfaces of drinking water piping and tanks.<br><br>In conclusion, acceptable uses to the environment have been demonstrated for this product for the proposed uses under PT2, PT3, PT4 and PT5. |

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

See relevant section in 2.1.4 Authorised use(s).

## 2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.
Not relevant as the biocidal products within the BELOX are not intended to be authorised for use with other biocidal products.

## 2.2.11 Comparative assessment

Not relevant as the active substance is not a candidate for substitution.

## 2.2.12 Endocrine disruption (ED) assessment

Based on available information the biocidal products in the BELOX biocidal product family are not considered to have ED properties. The conclusion from the CAR of hydrogen peroxide

(PTs 1-6, 2015) was that there is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier. In addition, there is no concern regarding ED properties of the co-formulants. Please see the Confidential annex to the PAR for further details of ED assessment for co-formulants.

# 3 ANNEXES

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

| Author(s) | Year | Title.<br>Source (where different from company)<br>Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
|---|---|---|---|---|
| Benetka, E. | 2019 | Determination of hydrogen peroxide in the product "BELOX 50"– long term storage stability study<br>Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria<br>LC 251/17-32k / Unpublished | yes | Belinka Perkemija d.o.o. |
| Benetka, E. | 2019 | Determination of hydrogen peroxide in the product "BELOX 35 SB, 155884"– long term storage stability study<br>Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria<br>LC 251/17-22k / Unpublished | yes | Belinka Perkemija d.o.o. |
| Benetka, E. | 2019 | Determination of hydrogen peroxide in the product "BELOX 50" - accelerated storage stability study<br>Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria<br>LC 251/17-3k / Unpublished | yes | Belinka Perkemija d.o.o. |
| Benetka, E. | 2019 | Determination of hydrogen peroxide in the product "BELOX 35 SB, 155884"– accelerated storage stability study<br>Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria<br>LC 251/17-2k / Unpublished | yes | Belinka Perkemija d.o.o. |
| Benetka, E. | 2019 | Determination of hydrogen peroxide in the product "BELOX 35 E, 155882" – method validation<br>Seibersdorf Labor GmbH 2444 Seibersdorf, Austria<br>LC 251/17-6 | yes | Belinka Perkemija d.o.o. |
| Crane, E. | 2007 | Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary field on non-porous surfaces<br>MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Chemical disinfectants and antiseptics - Basic bactericidal activity (Phase 1)<br>MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC |

| | | | | |
|---|---|---|---|---|
| Crane, E. | 2007 | Chemical disinfectants and antiseptics - Basic fungicidal activity (Phase 1). MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC |
| Crane, E. | 2007 | Chemical disinfectants and antiseptics - Basic sporicidal activity (Phase 1) MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC |
| Crane, E. | 2007 | Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary field on non-porous surfaces without mechanical action (Phase 2/Step 2) MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterniary field (Phase 2/Step 1) MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary field (Phase2/Step 1). MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Efficacy of antifungals as preservatives for aqueous-based products used in the paper industry (Phase 2/Step 2). MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Efficacy of antimicrobials as preservatives for aqueous-based products used in the paper industry (Phase 2/Step 2). MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants (Phase 2 / Step 2) | yes | CEFIC Peroxygen Sector Group, |

| | | | | |
|---|---|---|---|---|
| | | MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom<br>12319 / SO No: 1037/ Unpublished | | Hydrogen peroxide subgroup |
| Crane, E. | 2007 | Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants (Phase 2 / Step 2)<br>MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom<br>12319 / SO No: 1037/ Unpublished | yes | CEFIC Peroxygen Sector Group, Hydrogen peroxide subgroup |
| Crane, E. | 2007 | Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2/Step 1)<br>MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics (Phase 2/Step 1)<br>MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crane, E. | 2007 | Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants and antiseptics (Phase 2/Step 1)<br>MGS Laboratories Ltd, Unit 9 Brunei Science Centre, Coopers Hill Lane, Egham, Surrey, TW20 OJZ, United Kingdom / Unpublished | yes | CEFIC Peroxygen Sector Group |
| Crommelynck, F. | 1993 | Peroxyde d'hydrogène à usage industriel. Détermination de la teneur en peroxyde d'hydrogène. Methode titrimetrique. | yes | CEFIC Peroxygens Sector, Group Hydrogen peroxide subgroup |
| CEFIC | 2003 | Hydrogen peroxide for industrial use. Determination of hydrogen peroxide content. Titrimetric method.<br>CEFIC /Unpublished | yes | CEFIC Peroxygens Sector, Group Hydrogen peroxide subgroup |

| | | | | |
|---|---|---|---|---|
| Degussa, AG | 2005 | Analytical method for H2O2: Determination of chloride, phosphate, sulphate and nitrate<br>Degussa AG Dept<br>O2-AO-AT/ Unpublished | yes | CEFIC Peroxygens Sector Group, Hydrogen peroxide subgroup |
| Froschl, H. | 2019 | Persistent foaming<br>Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria<br>NO. LC 262/19/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Gabriel, H. | 2017 | Quantitative Non-Porous Surface Test for Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants and Antiseptics Used in Food, Industrial, Domestic and Institutional Areas (MF T 72-281: 2011; Phase 2/Step 2)<br>Dr. Brill + Partner GmbH, Stiegstück 34, 22339 Hamburg, Germany<br>L 16/0960.5t/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Henke W. | 2016 | Determination of the corrosion of metals by Hydrogen Peroxide 49.5% following method 37.4 C.1 of the UN Handbook<br>LAUS GmbH Auf der Schafweide 20 D-67489 Kirrweiler, Germany | yes | Kemira Oyj Porkkalankatu 3 00101 Helsinki, Finland |
| Kilgour, J.D. | 2001 | Hydrogen peroxide: feasibility study<br>Central toxicology laboratory, Alderley Park, Macclesfield, Cheshire, UK<br>Report no. CTL/TZ0357/SUM/REPT / Unpublished | yes | CEFIC Peroxygens Sector Group, Hydrogen peroxide subgroup |
| Klock, J.-H. | 2017 | Quantitative suspension test for the evaluation of bactericidal activity of BELOX 35 in the medical area according to DIN EN 13727:2015 (Phase 2, step 1)<br>Dr. Brill + Partner GmbH, Stiegstöck 34, 22339 Hamburg, Germany<br>L 16/0960.1/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Klock, J.-H. | 2017 | Quantitative carrier test for the evaluation of bactericidal activity of BELOX 35 for disinfection of instruments the medial area according to DIN EN 14561:2006 (Phase 2, step 2)<br>Dr. Brill + Partner GmbH, Stiegstück 34, 22339 Hamburg, Germany<br>L16/0960.2 / Unpublished | yes | Belinka Perkemija d.o.o. |

| | | | | |
|---|---|---|---|---|
| Radulović, A. | 2018 | Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action<br>Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia<br>D 39/18 / Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2018 | Chemical disinfectants and antiseptics. Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on non-porous surfaces without mechanical action.<br>Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia<br>D37/18/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2018 | Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area<br>Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia<br>D 38/18/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2018 | Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary<br>Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia<br>D 36/18/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2018 | Semi-field study with Geobacillus stearothermophilus for aseptic package<br>Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia<br>D 40a/18/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2018 | Quantitative Non-Porous Surface Test for Evaluation of Bactericidal and/or Fungicidal Activity of Chemical Disinfectants and Antiseptic Uses in Food, Industrial, Domestic and Industrial Areas (NF T72-281:2011, Phase 2/Step 3)<br>Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia<br>D 35/18/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2017 | Quantitative determination of the efficacy of drinking water disinfectants 2013/02<br>Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia | yes | Belinka Perkemija d.o.o. |

| | | | | |
|---|---|---|---|---|
| | | / Unpublished | | |
| Radulović, A. | 2018 | EN 14476:2005 "Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine" Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia D 41/18/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2018 | Anaylsis of BELOX 50 Batch No (209983) according to Cipac method MT 31-free acidity and alk Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia / Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2018 | Analysis of BELOX 50 Batch No 209983 according to CIPAC method MT 179 (Degree of dissolution and solution stability) and CIPAC method MT41.1 (Dilution Stability of Aqueuous Solutions) Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia / Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2017 | Analysis of BELOX 35 Batch No (2017012301) according to EN 1650 Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia / Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2017 | Quantitative determination of the efficacy of drinking water disinfectants: EN 1276 - BELOX 35 Batch No (2017012301) Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia / Unpublished | yes | Belinka Perkemija d.o.o. |
| Radulović, A. | 2017 | NF T 72-281:2011: Quantitative Non-Porous Surface Test of Bactericidal and Fungicidal Activity of BELOX 35 Institute of general and physical chemistry, Studentski Trg 12/V, Belgrade, Serbia / Unpublished | yes | Belinka Perkemija d.o.o. |
| Schlegl, P | 2017 | "BELOX 35". Relative Density / Viscosity / Surface tension / pH Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria SL-LC-006/17/ Unpublished | yes | Belinka Perkemija d.o.o. |
| Schlegl, P | 2017 | "BELOX 50". Relative Density / Viscosity / Surface tension / pH Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria SL-LC-007/17/ Unpublished | yes | Belinka Perkemija d.o.o. |

| | | | | |
|---|---|---|---|---|
| Woodall, C. | 2017 | Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - test method and requirements (phase 2/step 1) BluScientific Test Data School of Life Sciences Glasgow Caledonian University GLASGOW UK - G4 OBA /Unpublished | yes | CEFIC Peroxygen Sector Group |

## 3.2 Output tables from exposure assessment tools

### 3.2.1 Human Health Exposure Output Tables

#### Scenario 1 - Loading scenario for automated applications

# ART REPORT

Loading scenario for automated applications

| **Chemical details** | |
|---|---|
| Chemical | Hydrogen peroxide |
| CAS No. | 7722-84-1 |

| **Scenario details** | |
|---|---|
| Number of activities | 1 |
| Total duration (mins) | 30 |
| Nonexposure period (mins) | 0 |

**Details for Activity Scenario 1**

Emission sources: Near field ✓ Duration (mins): 30

Far field

**Near-field exposure**

***Operational Conditions***

| *Substance emission potential* | |
|---|---|
| Substance product type | Liquids |
| Process temperature | 293 K |
| Vapour pressure | 214 Pa |
| Liquid mole fraction | 0.3452 |
| Activity coefficient | 1 |

| *Activity emission potential* | |
|---|---|
| Activity class | Falling liquids |
| Situation | Transfer of liquid product with flow of 1 - 10 l/minute |
| Containment level | Open process |
| Loading type | Submerged loading, where the liquid dispenser remains below the fluid level reducing the amount of aerosol formation |

| *Surface contamination* | |
|---|---|
| Process fully enclosed? | No |
| Effective housekeeping practices in place? | Yes |

| *Dispersion* | |
|---|---|
| Work area | Indoors |
| Room size | Any size workroom |

***Risk Management Measures***

| *Localised controls* | |
|---|---|
| Primary | Medium level containment (99.00 % reduction) |
| Secondary | No localized controls (0.00 % reduction) |

| *Dispersion* | |
|---|---|
| Ventilation rate | Only good natural ventilation |

## Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

**Mechanistic model results**

The predicted 90th percentile full-shift exposure is 0.05 mg/m³.

The inter-quartile confidence interval is 0.024 mg/m³ to 0.1 mg/m³.

## Scenario 4 – Manual loading

| **Chemical details** | |
|---|---|
| Chemical | Hydrogen peroxide |
| CAS No. | 7722-84-1 |

| **Scenario details** | |
|---|---|
| Number of activities | 1 |
| Total duration (mins) | 30 |
| Nonexposure period (mins) | 0 |

**Details for Activity Scenario 2**

| | | | | |
|---|---|---|---|---|
| Emission sources: | Near field | ✓ | Duration (mins): | 30 |
| | Far field | | | |

**Near-field exposure**

***Operational Conditions***

| *Substance emission potential* | |
|---|---|
| Substance product type | Liquids |

| | |
|---|---|
| Process temperature | 293 K |
| Vapour pressure | 214 Pa |
| Liquid mole fraction | 0.3452 |
| Activity coefficient | 1 |
| *Activity emission potential* | |
| Activity class | Falling liquids |
| Situation | Transfer of liquid product with flow of 1 - 10 l/minute |
| Containment level | Handling that reduces contact between product and adjacent air. Note: This does not include processes that are fully contained by localised controls (see next questions). |
| Loading type | Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely |
| *Surface contamination* | |
| Process fully enclosed? | No |
| Effective housekeeping practices in place? | Yes |
| *Dispersion* | |
| Work area | Indoors |
| Room size | Any size workroom |

***Risk Management Measures***

| | |
|---|---|
| *Localised controls* | |
| Primary | No localized controls (0.00 % reduction) |
| Secondary | No localized controls (0.00 % reduction) |
| *Dispersion* | |
| Ventilation rate | Only good natural ventilation |

## Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

**Mechanistic model results**

The predicted 90th percentile full-shift exposure is 4.5 mg/m³.

The inter-quartile confidence interval is 2.2 mg/m³ to 9.4 mg/m³.

## Scenario 5

| **Chemical details** | |
|---|---|
| Chemical | Hydrogen peroxide |
| CAS No. | 7722-84-1 |
| **Scenario details** | |

| | |
|---|---|
| Number of activities | 1 |
| Total duration (mins) | 400 |
| Nonexposure period (mins) | 0 |

**Details for Activity Scenario 5**

Emission sources: Near field Duration (mins): 400

Far field ✓

**Far-field exposure**

***Operational Conditions***

| *Substance emission potential* | |
|---|---|
| Substance product type | Liquids |
| Process temperature | 293 K |
| Vapour pressure | 214 Pa |
| Liquid mole fraction | 0.09970356 |
| Activity coefficient | 1 |

| *Activity emission potential* | |
|---|---|
| Activity class | Surface spraying of liquids |
| Situation | Low application rate (0.03 – 0.3 l/minute) |
| Spray direction | In any direction (including upwards) |
| Spray technique | Spraying with no or low compressed air use |

| *Surface contamination* | |
|---|---|
| Process fully enclosed? | No |
| Effective housekeeping practices in place? | Yes |

| *Dispersion* | |
|---|---|
| Work area | Indoors |
| Room size | 3000 m³ |

***Risk Management Measures***

| *Localised controls* | |
|---|---|
| Primary | No localized controls (0.00 % reduction) |
| Secondary | No localized controls (0.00 % reduction) |
| Segregation | No segregation (0.00 % reduction) |
| Personal enclosure | No personal enclosure (0.00 % reduction) |

| *Dispersion* | |
|---|---|
| Ventilation rate | Only good natural ventilation |

# Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

**Mechanistic model results**

The predicted 90th percentile full-shift exposure is 16 mg/m³.

The 90% confidence interval is 2.8 mg/m³ to 110 mg/m³.

## Scenario 5 – Tier 2

| **Chemical details** | |
|---|---|
| Chemical | Hydrogen peroxide |
| CAS No. | 7722-84-1 |

| **Scenario details** | |
|---|---|
| Number of activities | 1 |
| Total duration (mins) | 400 |
| None exposure period (mins) | 0 |

**Details for Activity Scenario 5 refinement**

| | | | |
|---|---|---|---|
| Emission sources: | Near field | Duration (mins): | 400 |
| | Far field ✓ | | |

**Far-field exposure**

***Operational Conditions***

| *Substance emission potential* | |
|---|---|
| Substance product type | Liquids |
| Process temperature | 293 K |
| Vapour pressure | 214 Pa |
| Liquid mole fraction | 0.09970356 |
| Activity coefficient | 1 |

| *Activity emission potential* | |
|---|---|
| Activity class | Surface spraying of liquids |
| Situation | Low application rate (0.03 – 0.3 l/minute) |
| Spray direction | In any direction (including upwards) |
| Spray technique | Spraying with no or low compressed air use |

| *Surface contamination* | |
|---|---|
| Process fully enclosed? | No |

| | |
|---|---|
| Effective housekeeping practices in place? | Yes |

| *Dispersion* | |
|---|---|
| Work area | Indoors |
| Room size | 3000 m³ |

***Risk Management Measures***

| *Localised controls* | |
|---|---|
| Primary | No localized controls (0.00 % reduction) |
| Secondary | No localized controls (0.00 % reduction) |
| Segregation | No segregation (0.00 % reduction) |
| Personal enclosure | No personal enclosure (0.00 % reduction) |
| *Dispersion* | |
| Ventilation rate | 3 air changes per hour (ACH) |

## Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

**Mechanistic model results**

The predicted 90th percentile full-shift exposure is 7.8 mg/m³.

The 90% confidence interval is 1.4 mg/m³ to 55 mg/m³.

## 3.2.2 Environmental Exposure Output Tables

**$PEC_{air}$**

Emissions to air have been calculated only for surface disinfection by VHP process (PT2 and PT4) using the calculations laid out in the ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017) as follows:

$$Elocal_{air} = \max\left(Elocal_{air}, Estp_{air}\right) \cdot Cstd_{air} \quad \text{(eq. 43)}$$

Local concentration in the air has been calculated based on the maximum value of $Elocal_{air}$ being 7.87E-03 kg/d (see chapter 2.2.8.2 Exposure assessment) with the standard concentration at 100 m from the emission point calculated for a standard source of 1 kg/day ($Cstd_{air}$ = 2.78E-04 mg/m$^3$). The resulting $PEC_{air}$ is 2.19E-03 µg/m$^3$.

**$PEC_{STP}$ and $PEC_{water}$**

Taking the $Elocal_{water}$ values previously calculated (see chapter 2.2.8.2 Exposure assessment), the $PEC_{STP}$ values can be calculated using the following equations and default values taken from the ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017):

$$Clocal_{inf} = \frac{Elocal_{water} \cdot 10^6}{EFFLUENT_{stp}} \quad \text{(eq. 35)}$$

$$Clocal_{eff} = Clocal_{inf} \cdot Fstp_{water} \quad \text{(eq. 36)}$$

| Symbol | Explanation and unit |
|---|---|
| $Clocal_{inf}$ | concentration in untreated wastewater (mg/L) |
| $Elocal_{water}$ | local emission rate to water during episode (kg/d) |
| $EFFLUENT_{stp}$ | effluent discharge rate of STP (default of 2.00E+06 L/d) |
| $Clocal_{eff}$ | concentration of substance in the STP effluent (mg/L) |
| $Fstp_{water}$ | fraction of emission directed to water by STP (Simple Treat output of 6.85E-03) |

| **Calculation of $PEC_{STP}$** | | | |
|---|---|---|---|
| | **$Elocal_{water}$ (kg/d)** | **$Clocal_{inf}$ (mg/L)** | **$Clocal_{eff}$ = $PEC_{STP}$ (mg/L)** |
| Scenario 1 | 4.43E-03 | 2.21E-03 | 1.52E-05 |
| Scenario 2 | not relevant | not relevant | not relevant |
| Scenario 3 | 7.33E+00 | 3.66E+00 | 2.51E-02 |
| Scenario 4 | 7.60E+00 | 3.80E+00 | 2.60E-02 |
| Scenario 5 | 4.43E-03 | 2.21E-03 | 1.52E-05 |
| Scenario 6 | 5.67E+01 | 2.84E+01 | 1.94E-01 |

| | | | |
|---|---|---|---|
| Scenario 7 | 2.59E-03 | 1.29E-03 | 8.87E-06 |
| Scenario 8 | 2.35E-01 | 1.17E-01 | 8.04E-04 |

The local concentration in surface water is calculated as follows:

$$Clocal_{water} = \frac{Clocal_{eff}}{\left(1 + Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}\right) \cdot DILUTION} \quad \text{(eq. 48)}$$

Where $Kp_{susp} = Foc_{susp} \cdot Koc = 0.1\ kg/kg \cdot 1.598\ L/kg = 0.1598\ L/kg$ (eq. 26)

| Symbol | Explanation and unit |
|---|---|
| $Clocal_{water}$ | local concentration in surface water during emission episode (mg/L) |
| $Kp_{susp}$ | solids-water partition coefficient of suspended matter (0.1598 L/kg) |
| $Foc_{susp}$ | weight fraction of organic carbon in sediment (default of 0.1 kg/kg) |
| $K_{oc}$ | partition coefficient organic carbon-water (1.598 L/kg) |
| $SUSP_{water}$ | concentration of suspended matter in the river (default of 15 mg/L) |
| DILUTION | dilution factor (default of 10) |

| **Calculation of $PEC_{water}$** | |
|---|---|
| | **$PEC_{water}$ (mg/L)** |
| Scenario 1 | 1.52E-06 |
| Scenario 2 | not relevant |
| Scenario 3 | 2.51E-03 |
| Scenario 4 | 2.60E-03 |
| Scenario 5 | 1.52E-06 |
| Scenario 6 | 1.94E-02 |
| Scenario 7 | 8.87E-07 |
| Scenario 8 | 8.04E-05 |

**$PEC_{soil}$**

Levels of hydrogen peroxide reaching the terrestrial compartment will only be as a result of the fraction sorbed to sewage sludge as the contribution from air (via deposition) can be discounted.

The concentration of any active substance in dry sewage sludge can be calculated using ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017):

$$C_{sludge} = \frac{Fstp_{sludge} \cdot Elocal_{water} \cdot 10^6}{SLUDGERATE} \qquad \text{(eq. 39)}$$

Where $SLUDGERATE = \frac{2}{3} \cdot SUSPCONC_{inf} \cdot EFFLUENT_{stp} + SURPLUS_{sludge} \cdot CAPACITY_{stp}$

$$= \frac{2}{3} \cdot 0.45 \ kg/m^3 \cdot 2000 \ m^3/d + 0.019 \, kg/d \ eq \cdot 10000 \ eq = 790 \ kg/d \qquad \text{(eq. 40)}$$

| Symbol | Explanation and unit |
|---|---|
| $C_{sludge}$ | concentration in dry sewage sludge (mg/kg) |
| $Fstp_{sludge}$ | fraction of emission directed to sludge by STP (Simple Treat output of 1.44E-04) |
| $Elocal_{water}$ | local emission rate to water during episode (kg/d) |
| SLUDGERATE | rate of sewage sludge production (790 kg/d) |
| $SUSPCONC_{inf}$ | concentration of suspended matter in STP influent (default of 0.45 kg/m$^3$) |
| $EFFLUENT_{stp}$ | effluent discharge rate of STP (default of 2000 m$^3$/d) |
| $SURPLUS_{sludge}$ | surplus sludge per inhabitant equivalent (default of 0.019 kg/d eq) |
| $CAPACITY_{stp}$ | capacity of the local STP (default of 10000 eq) |

| **Calculation of $C_{sludge}$** | |
|---|---|
| | **$C_{sludge}$ (mg/kg)** |
| Scenario 1 | 8.08E-04 |
| Scenario 2 | negligible |
| Scenario 3 | 1.34E+00 |
| Scenario 4 | 1.39E+00 |
| Scenario 5 | 8.08E-04 |
| Scenario 6 | 1.04E+01 |
| Scenario 7 | 4.72E-04 |
| Scenario 8 | 4.29E-02 |

When rapid degradation in soil is taken into account (DT50 of 12 hr), the equivalent k rate would be 1.39 d$^{-1}$ and this would crudely represent removal rate of the a.s. from top soil. At the end of each year, a fraction of the initial concentration (Facc) may potentially remain in the top soil layer and this can be determined by use of the equation stating:

$$Facc = e^{-365 \, k} \qquad \text{(eq. 62)}$$

The fraction of initial concentration (Facc) remaining in the top soil layer after one year has therefore been determined as zero and clearly shows that the a.s. will not accumulate thus $Csludge_{soil\ 1}(0) = Csludge_{soil\ 10}(0)$.

In line with ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017), the concentration of a.s. in soil after the first year of manure application can be given as follows:

$$Csludge_{soil\ 1}\ (0) = \frac{C_{sludge} \cdot APPL_{sludge}}{DEPTH_{soil} \cdot RHO_{soil}} \qquad \text{(eq. 61)}$$

| Symbol | Explanation and unit |
|---|---|
| $Csludge_{soil\ 1}\ (0)$ | concentration in soil due to sludge in first year at t = 0 (mg/kg) |
| $C_{sludge}$ | concentration in dry sewage sludge (mg/kg) |
| $APPL_{sludge}$ | dry sludge application rate (default of 0.5 kg/m$^3$ y) |
| $DEPTH_{soil}$ | mixing depth of soil (default of 0.2 m) |
| $RHO_{soil}$ | bulk density of soil (default of 1700 kg/m$^3$) |

| **Calculation of $Csludge_{soil\ 1}$ (0)** | |
|---|---|
| | **$Csludge_{soil\ 1}$ (0) (mg/kg)** |
| Scenario 1 | 1.19E-06 |
| Scenario 2 | negligible |
| Scenario 3 | 1.97E-03 |
| Scenario 4 | 2.04E-03 |
| Scenario 5 | 1.19E-06 |
| Scenario 6 | 1.52E-02 |
| Scenario 7 | 6.95E-07 |
| Scenario 8 | 6.30E-05 |

The PEC for local soil has been calculated using ECHA guidance on the BPR: Volume IV Environmental Assessment and Evaluation (Parts B + C) (ECHA 2017):

$$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{k \cdot T} \cdot \left[C_{soil\ 10}\ (0) - \frac{D_{air}}{k}\right] \cdot \left[1 - e^{-kT}\right] \qquad \text{(eq. 66)}$$

| Symbol | Explanation and unit |
|---|---|
| $Clocal_{soil}$ | average concentration in soil over T days (mg/kg) |
| $D_{air}$ | aerial deposition flux per kg of soil (mg/kg d) (taken to be zero) |
| k | first order rate constant for removal from top soil (1.39 d$^{-1}$) |
| T | averaging time (30 d) |
| $C_{soil\ 10}\ (0)$ | initial concentration in soil (after sludge application) in year 10 (mg/kg) |

| Calculation of $PECloca l_{soil}$ | |
|---|---|
| | **$PECloca l_{soil}$ (mg/kg)** |
| Scenario 1 | 2.86E-08 |
| Scenario 2 | negligible |
| Scenario 3 | 4.73E-05 |
| Scenario 4 | 4.90E-05 |
| Scenario 5 | 2.86E-08 |
| Scenario 6 | 3.66E-04 |
| Scenario 7 | 1.67E-08 |
| Scenario 8 | 1.52E-06 |

## 3.3 New information on the active substance

No new information on the active substance has been submitted for the authorisation of the BELOX.

## 3.4 Residue behaviour

Not relevant.

## 3.5 Summaries of the efficacy studies (B.5.10.1-xx)[4]

The summaries of the efficacy studies are available in the IUCLID.

## 3.6 Confidential annex

See the separate document.

4 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.