**EN**

***ANNEX***

# SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

AOPACK 35%

**Product type(s)**

PT04: Food and feed area

**Authorisation number:** ES/APP(NA)-2024-04-00928

**R4BP asset number:** ES-0022262-0000

## 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

| | |
|---|---|
| Trade name(s) | AOPACK 35%<br>CLARMARIN® 350 CORK<br>DUROX LRA<br>DUROX LRD<br>DUROX LRA TIPO S<br>DUROX LRA ADVANCED |

### 1.2. Authorisation holder

| | | |
|---|---|---|
| Name and address of the authorisation holder | Name | Evonik Operations GmbH |
| | Address | Rellinghauser Straße 1-11 45128 Essen Germany |
| Authorisation number | | ES/APP(NA)-2024-04-00928 |
| *R4BP asset number* | | ES-0022262-0000 |
| Date of the authorisation | | 16/04/2024 |
| Expiry date of the authorisation | | 16/04/2034 |

### 1.3. Manufacturer(s) of the product

| | |
|---|---|
| Name of manufacturer | Evonik España y Portugal SA |
| Address of manufacturer | c/ Afueras s/n 50784 La Zaida (Zaragoza) Spain |
| Location of manufacturing sites | Evonik Peroxide Spain s.l.u site 1 c/ Afueras s/n 50784 La Zaida (Zaragoza) Spain |

| | |
|---|---|
| Name of manufacturer | Evonik Peroxid GmbH |
| Address of manufacturer | Industriestraße 1 AT-9721 Weißenstein Austria |
| Location of manufacturing sites | Evonik Peroxid GmbH site 1 Industriestraße 1 9721 Weißenstein Austria |

| | |
|---|---|
| Name of manufacturer | Evonik Antwerpen N.V. |
| Address of manufacturer | Tijsmanstunnel West 4 2040 Antwerpen Belgium |
| Location of manufacturing sites | Evonik Antwerpen N.V. site 1 Tijsmanstunnel West 4 2040 Antwerpen Belgium |

| | |
|---|---|
| Name of manufacturer | Evonik Operations GmbH |
| Address of manufacturer | Untere Kanalstraße 3 79618 Rheinfelden Germany |
| Location of manufacturing sites | Evonik Operations GmbH site 1 Untere Kanalstraße 3 79618 Rheinfelden Germany |

| | |
|---|---|
| Name of manufacturer | RNM Produtos Químicos, S.A. |
| Address of manufacturer | Rua Da Fabrica Nº123 4765-080 Carreira (Famalicão) Portugal |

| | |
|---|---|
| Location of manufacturing sites | RNM Produtos Químicos, S.A. site 1 Avenida das Searas, s/n 4760-329 Landim (Vila Nova de Famalicão) Portugal |

## 1.4. Manufacturer(s) of the active substance(s)

| | |
|---|---|
| Active substance | Hydrogen peroxide |
| Name of manufacturer | Evonik España y Portugal SA |
| Address of manufacturer | c/ Afueras s/n 50784 La Zaida (Zaragoza) Spain |
| Location of manufacturing sites | Evonik Peroxide Spain s.l.u site 1 c/ Afueras s/n 50784 La Zaida (Zaragoza) Spain |

| | |
|---|---|
| Active substance | Hydrogen peroxide |
| Name of manufacturer | Evonik Peroxid GmbH |
| Address of manufacturer | Industriestraße 1 AT-9721 Weißenstein Austria |
| Location of manufacturing sites | Evonik Peroxid GmbH site 1 Industriestraße 1 AT-9721 Weißenstein Austria |

| | |
|---|---|
| Active substance | Hydrogen peroxide |
| Name of manufacturer | Evonik Antwerpen N.V. |
| Address of manufacturer | Tijsmanstunnel West 4 2040 Antwerpen Belgium |
| Location of manufacturing sites | Evonik Antwerpen N.V. site 1 Tijsmanstunnel West 4 2040 Antwerpen Belgium |

| | |
|---|---|
| Active substance | Hydrogen peroxide |
| Name of manufacturer | Evonik Operations GmbH |
| Address of manufacturer | Untere Kanalstraße 3 79618 Rheinfelden Germany |
| Location of manufacturing sites | Evonik Operations GmbH site 1 Untere Kanalstraße 3 79618 Rheinfelden Germany |

## 2. PRODUCT COMPOSITION AND FORMULATION

### 2.1. Qualitative and quantitative information on the composition of the product

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|---|---|---|---|---|---|
| Hydrogen peroxide | | active substance | 7722-84-1 | 231-765-0 | 35,6 % (w/w) |

### 2.2. Type(s) of formulation

SL Soluble concentrate

## 3. HAZARD AND PRECAUTIONARY STATEMENTS

| | |
|---|---|
| Hazard statements | H272: May intensify fire; oxidiser.<br><br>H302: Harmful if swallowed.<br><br>H315: Causes skin irritation.<br><br>H318: Causes serious eye damage.<br><br>H335: May cause respiratory irritation.<br><br>H412: Harmful to aquatic life with long lasting effects. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br><br>P220: Keep away from clothing or other combustible materials.<br><br>P261: Avoid breathing dust.<br><br>P261: Avoid breathing fume.<br><br>P261: Avoid breathing gas.<br><br>P261: Avoid breathing mist.<br><br>P261: Avoid breathing vapours.<br><br>P261: Avoid breathing spray.<br><br>P271: Use only outdoors or in a well-ventilated area.<br><br>P304+P340: IF INHALED: Remove person to fresh ai r and keep comfortable for breathing.<br><br>P312: Call a POISON CENTRE/doctor/… if you feel unwell.<br><br>P264: Wash hands thoroughly after handling.<br><br>P270: Do not eat, drink or smoke when using this prod uct.<br><br>P273: Avoid release to the environment.<br><br>P280: Wear protective gloves.<br><br>P280: Wear protective clothing.<br><br>P301+P312: IF SWALLOWED: Call a POISON CEN TRE/doctor/… if you feel unwell.<br><br>P330: Rinse mouth.<br><br>P310: Immediately call a poison centre in case of swal low/inhalation .<br><br>P302+P352: IF ON SKIN: Wash with plenty of water. |

| | |
|---|---|
| | P332+P313: If skin irritation occurs: Get medical advi ce.<br><br>P362+P364: Take off contaminated clothing and wash it before reuse.<br><br>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if pr esent and easy to do. Continue rinsing.<br><br>P370+P378: In case of fire: Use water to extinguish.<br><br>P403+P233: Store in a well-ventilated place. Keep con tainer tightly closed.<br><br>P405: Store locked up.<br><br>P501: Dispose of contents to and/or container as hazar dous waste to a registered establishment or undertakin g, in accordance with current regulations.. |

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Use # 1 – Aseptic packaging by automated immersion in closed system.**

| | |
|---|---|
| Product type | PT04: Food and feed area |
| Where relevant, an exact description of the authorised use | Not relevant. |
| Target organism(s) (including development stage) | Common name: Bacterias<br>Development stage: no data<br><br>Common name: Yeast<br>Development stage: no data<br><br>Common name: Bacterial spores<br>Development stage: bacterial spores |
| Field(s) of use | indoor use |
| Application method(s) | Method: Inmersion<br><br>Detailed description: Automated immersion in closed system. |
| Application rate(s) and frequency | Application rate: 35% (w/w) hydrogen peroxide.<br><br>Dilution (%): -<br><br>Number and timing of application:<br>Temperature and contact time: ≥65 °C for ≥6.6 seconds or ≥80 °C for ≥2.5 seconds Conditions depend on the aseptic packaging machine.<br>One application.<br>Waiting period: until packaging material is dry. |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L<br>Drum, Plastic: HDPE; 220 L<br>IBC (intermediate bulk container), Plastic: HDPE; 1000 L |

#### 4.1.1. Use-specific instructions

The aseptic filling systems 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 material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. The packaging material in the form of (sheet) reels passes through a deep bath filled with hydrogen peroxide solutions by dipping. The temperature and contact time depend on the machine (usually ≥65 °C for ≥6.6 seconds or ≥80 °C for ≥2.5 seconds). After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air. The receptacle is then filled and sealed.
Use in accordance with the instructions of the aseptic packaging machine. The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.
Please refer to general direction of use for further information.

### 4.1.2. Use-specific risk mitigation measures

Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.
During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.
In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.
Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

## 4.2. Use description

### Table 2. Use # 2 – Aseptic packaging by automated spraying in closed system.

| | |
|---|---|
| Product type | PT04: Food and feed area |
| Where relevant, an exact description of the authorised use | No relevante. |
| Target organism(s) (including development stage) | Common name: Bacteria<br>Development stage: no data<br><br>Common name: Yeast<br>Development stage: no data<br><br>Common name: bacterial spores. |

| | |
|---|---|
| | Development stage: bacterial spores |
| Field(s) of use | indoor use |
| Application method(s) | Method: spraying<br><br>Detailed description: Automated spraying in closed system. |
| Application rate(s) and frequency | Application rate: 35% (w/w) hydrogen peroxide. 0.1-1 mL/ package<br><br>Dilution (%): -<br><br>Number and timing of application:<br>Temperature: 75-85ºC<br>Contact time: ≥20 seconds.<br>Conditions depend on the aseptic packaging machine.<br>One application.<br>Waiting period: until packaging material is dry. |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L<br>Drum, Plastic: HDPE; 220 L<br>IBC (intermediate bulk container), Plastic: HDPE; 1000 L |

### 4.2.1. Use-specific instructions

The aseptic filling systems 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 material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. Then, hydrogen peroxide solution is sprayed to the packaging material stepwise via a nozzle (0.1-1mL).The temperature and contact time depend on the machine (usually 75-85ºC, ≥20seconds). After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air. The receptacle is then filled and sealed.
Use in accordance with the instructions of the aseptic packaging machine. The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.
Please refer to general direction of use for further information.

### 4.2.2. Use-specific risk mitigation measures

Workplace release measurements with suitable measurement equipment shall be performed upon implementation of the aseptic packaging plant, at regular intervals (annual intervals recommended) and after any change in relevant boundary conditions. The national regulations for workplace measurements have to be followed.
During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.
During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.
In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the

authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.
Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

## 4.3. Use description

**Table 3. Use # 3 – Surface disinfection by VHP process in food processing facilities.**

| | |
|---|---|
| Product type | PT04: Food and feed area |
| Where relevant, an exact description of the authorised use | Not relevant. |
| Target organism(s) (including development stage) | Common name: Bacteria<br>Development stage: no data<br><br>Common name: Yeast<br>Development stage: no data |
| Field(s) of use | indoor use |
| Application method(s) | Method: Vaporization<br><br>Detailed description: Automated disinfection with Vaporized Hydrogen Peroxide, generated with aid of a VHP generator. |
| Application rate(s) and frequency | Application rate: 1092 mg/m3 (780 ppm) hydrogen peroxide in air generated by the VHP generator. Contact time: ≥ 4 hours Daily if required Maximum 3 times per day.<br><br>Dilution (%): 0<br><br>Number and timing of application:<br>1092 mg/$m^3$ (780 ppm) hydrogen peroxide in air generated by the VHP generator.<br>Contact time: ≥ 4 hours<br>Daily if required<br>Maximum 3 times per day. |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L |

| | |
|---|---|
| | Drum, Plastic: HDPE; 220 L<br>IBC (intermediate bulk container), Plastic: HDPE; 1000 L |

### 4.3.1. Use-specific instructions

Prepare the area for decontamination by removing standing liquids and visible soils by wiping down. Clean the area before disinfection. Cupboard doors should be opened, surfaces should be dried and wet areas (such as sinks and toilet bowls) should be disinfected with suitable alternative products. Install biological and chemical indicators to validate the disinfection cycle.
Specially instructed users replace and seal the cap of the package as delivered by the supplier with a special cap that has a degassing valve and a fast connector. The fast connector is connected to a pipe that connects to the VHP machine. Seal the enclosed space or room and make sure that access to the vapour-treated area is denied during the whole procedure.
Efficacy of use was demonstrared by flash evaporation of hydrogen peroxide at rate of 1092 mg/$m^3$ for 4h.
Apply only on non-porous surfaces.
Room volume ranging from 30 up to 150 $m^3$. For room enclosures greater than 150 $m^3$ use multiple generator units to achieve the target concentration.
Diffusion speed can vary from 1.5 up to 20 g product /min.
Starting temperature of 20°C ± 2°C.
Relative humidity between 40 and 80 %.
During the disinfection cycle the VHP machine adjusts the hydrogen peroxide concentration up to the effective levels of 1092 mg/$m^3$ (780 ppm) and keeps it at this level for ≥ 4 hours. Concentration of hydrogen peroxide is monitored during the disinfection. After disinfection, the aeration of the sealed area is required to reduce the concentration of hydrogen peroxide below 1.25 mg /$m^3$ before entering the area. This step can be quick but can also last several hours resulting in a total decontamination cycle of 5 – 8 hours.
The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter.
In case there are methods available for chemically monitoring the active substance in the air or on surfaces, chemical validation should be performed besides biological validation, e.g. with test strips or with a device that measures ppm $H_2O_2$ in the air.
When it concerns a “standard room” for which a protocol is available, the validation may be limited to only a chemical validation.
Please refer to general direction of use for further information.

### 4.3.2. Use-specific risk mitigation measures

No access of persons to the treated area is permitted during treatment.
During aeration and before permitting re-entry to the treated area it should be checked that the undercut of $AEC_{inhalation}$ of 1.25 mg/$m^3$ or the corresponding national reference value shall be ensured with technical and organisational measures (e.g. sensor/test strip, defined ventilation period).
The professional user may only enter the room in emergency situations or to reactivate the ventilation considering RPE with APF 40 against vapour (Type of RPE to be specified by the authorisation holder within the product information). The re-entry is therefore only possible when the hydrogen peroxide level has dropped below 36 ppm (50 mg/ $m^3$) or below 40x the national reference value.
Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

## 4.4. Use description

### Table 4. Use # 4 – Disinfection of inner surfaces in human drinking water systems

| | |
|---|---|
| Product type | PT04: Food and feed area |
| Where relevant, an exact description of the authorised use | Not relevant. |
| Target organism(s) (including development stage) | Common name: Bacteria<br>Development stage: no data<br><br>Common name: Fungi<br>Development stage: no data |
| Field(s) of use | indoor use |
| Application method(s) | Method: Cleaning In Place (CIP)<br><br>Detailed description: Disinfecting the interior surfaces of closed systems by CIP |
| Application rate(s) and frequency | Application rate: 4.0% (w/w) hydrogen peroxide.<br><br>Number and timing of application:<br>Contact time: 15 min (Bacteria), 180 min (Fungui).<br>One application.<br>Temperature: 20ºC |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L<br>Drum, Plastic: HDPE; 220 L<br>IBC (intermediate bulk container), Plastic: HDPE; 1000 L |

### 4.4.1. Use-specific instructions

Remove the content (drinking water) before cleaning deposits and distribution systems. Clean the deposits mechanically before disinfection starts. For disinfection of bacteria and fungi the product should be diluted to 4% (w/w) of hydrogen peroxide.
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 4% of hydrogen peroxide Circulate the diluted product through the system. The process involves the jetting or spraying of surfaces or circulation of cleaning solutions through the plant under conditions of increased turbulence and flow velocity. After 15 min (Bacteria) and 180 min (Fungi) contact time, pipelines and tanks are rinsed with water before refilled with drinking water.
Please refer to general direction of use for further information.

### 4.4.2. Use-specific risk mitigation measures

In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the

authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.
Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

## 4.5. Use description

### Table 5. Use # 5 – Disinfection of inner surfaces by CIP

| | |
|---|---|
| Product type | PT04: Food and feed area |
| Where relevant, an exact description of the authorised use | Not relevant. |
| Target organism(s) (including development stage) | Common name: Bacteria<br>Development stage: no data<br><br>Common name: Yeast<br>Development stage: no data<br><br>Common name: Fungi<br>Development stage: no data |
| Field(s) of use | indoor use |
| Application method(s) | Method: Cleaning In Place (CIP)<br><br>Detailed description: Disinfecting the interior surfaces of closed systems by CIP |
| Application rate(s) and frequency | Application rate: 5.0% (w/w) hydrogen peroxide.<br><br>Number and timing of application:<br>Contact time: 15 min (Bacteria and yeast), 180 min (Fungi).<br>One application.<br>Temperature: 20ºC |
| Category(ies) of users | professional |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L<br>Drum, Plastic: HDPE; 220 L<br>IBC (intermediate bulk container), Plastic: HDPE; 1000 L |

### 4.5.1. Use-specific instructions

Empty the pipework and tanks, and clean tanks mechanically before disinfection starts.
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 5% of hydrogen peroxide. The process is carried out by circulating the disinfection solution of 5% (w/w) hydrogen peroxide through the system under conditions of increased turbulence and flow velocity. The application is automated and a closed process. Rinse the surface with water after 15 min (Bacteria and yeast), 180 min (Fungi) contact time for deposits and pipes under closed system conditions as well.
Please refer to general direction of use for further information.

### 4.5.2. Use-specific risk mitigation measures

In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.
Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

## 4.6. Use description

### Table 6. Use # 6 – Disinfection of cork stoppers by automated spraying in closed systems

| | |
|---|---|
| Product type | PT04: Food and feed area |
| Where relevant, an exact description of the authorised use | No relevante. |
| Target organism(s) (including development stage) | Common name: Bacteria<br>Development stage: no data<br><br>Common name: Yeast<br>Development stage: no data<br><br>Common name: Fungi<br>Development stage: no data |
| Field(s) of use | indoor use |
| Application method(s) | Method: spraying |

| | |
|---|---|
| | Detailed description: Automated spraying in closed system. |
| Application rate(s) and frequency | Application rate: 35% (w/w) hydrogen peroxide. 1mL/cork stopper<br><br>Dilution (%): -<br><br>Number and timing of application:<br><br>One application.<br>Spraying time: 20-50 seconds.<br>Contact time: 30 minutes.<br>Waiting period: until packaging material is dry.<br>Temperature: 20ºC |
| Category(ies) of users | trained professional ; professional |
| Pack sizes and packaging material | Jerry can, Plastic: HDPE; 5, 20, 25, 30 and 60 L<br>Drum, Plastic: HDPE; 220 L<br>IBC (intermediate bulk container), Plastic: HDPE; 1000 L |

### 4.6.1. Use-specific instructions

Cleaning is required prior to disinfection. Use in accordance with the requirements for the disinfection machine. Load the product as received to the system (automatic process). Inject the product (1 mL/cork stopper) by spraying into the rotary drums (20-50 seconds) and assure a minimum contact time of 30 minutes. Make sure to wet surfaces completely. Then rinse the cork stoppers with water and let them dry by applying hot air. Do not open the system until the stoppers are completely dry.
Make sure that the content of peroxide residues in cork is lower than 0.2 mg/stopper.
Please refer to general direction of use for further information.

### 4.6.2. Use-specific risk mitigation measures

In case of maintenance (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment (APF = 10), chemical protective gloves, chemical protective coverall (at least type 6), eye protection) is required. The type of RPE and the filter type (code letter, colour) are to be specified by the authorisation holder within the product information. Glove material to be specified by the authorisation holder within the product information.
Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

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

Please refer to general direction of use for further information.

## 5. GENERAL DIRECTIONS FOR USE[1]

### 5.1. Instructions for use

Intended only for professional use.
Always read the label or leaflet before use and follow all the instructions provided.
Precleaning of surfaces required before using disinfectants. Surfaces should be meticously cleaned/rinsed/dried before the disinfection step. Rinse treated equipment with drinking water after application.
Respect the conditions of use of the product (concentration, contact time, temperature, etc.).
Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
Inform the authorisation holder if the treatment is ineffective.
Further specific information for each use can be found in respective section of the use.

### 5.2. Risk mitigation measures

Wear protective chemical resistant gloves meeting the requirements of European Standard EN 374 during product handling phase (glove material to be specified by the authorisation holder within the product information).
Wear a protective coverall (at least type 6, EN 13034) which is impermeable for the biocidal product (coverall material to be specified by the authorisation holder within the product information).
The use of eye protection during handling of the product is mandatory.
Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during M&L phase. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with gas filter is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
Avoid contact with eyes/skin.
Do not use on clothing.
Avoid inhalation of vapours.
Do not eat, drink or smoke while working.
Operate in a well-ventilated area.
Keep away from heat sources and combustible materials.
Further specific information for each use can be found in respective section of the use.

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

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

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

Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.
Code the waste according Decision 2014/955/EU.

[1]Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Do not release to soil, ground, surface water or any kind of sewer.

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

Keep only in the original container in a cool, well-ventilated place. Protect from direct sunlight.
Keep away from heat sources (e.g. hot surfaces), sparks and open flames. Keep away from combustible material.
Keep in container tightly closed, fitted with safety valve or vent. Have a ventilation system in place.
Keep away from incompatible materials: acids, bases, metals, salts of metals, reducing agents, organic materials, flammable substances. Storage area should be made of non-combustible, impermeable materials.
Shelf-life of the product under normal conditions of storage:

- HDPE packagings: 24 months
- Stainless steel tanks: 3 months.

## 6. OTHER INFORMATION

Do not mix with other chemicals.
“Protect from direct sunlight” sentence should be added to the label.
The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).
Please be aware of the European reference value of 1.25 mg/m³ for the active substance hydrogen peroxide (CAS No.: 7722-84-1) which was used for the risk assessment for Human Health in this product.