Summary of product characteristics for a biocidal product family

Family name: Interox Biocidal Product Family 1

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0027468-0000

R4BP 3 asset reference number: EU-0027468-0000

Table Of Contents

Part I.- First information level

1. Administrative information

1.1. Family name

Interox Biocidal Product Family 1

1.2. Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
PT03 - Veterinary hygiene (Disinfectants)
PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	SOLVAY CHEMICALS INTERNATIONAL
	Address	RUE DE RANSBEEK 310 B-1120 BRUXELLES Belgium
Authorisation number	EU-0027468-0000	

R4BP 3 asset reference number	EU-0027468-0000
Date of the authorisation	08/08/2022
Expiry date of the authorisation	31/07/2032

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer	Solvay Interox Limited
Address of the manufacturer	Baronet Road, Solvay House WA4 6HA Warrington United Kingdom
Location of manufacturing sites	Solvay Interox Limited, Baronet Road, Solvay House WA4 6HA Warrington United Kingdom

Name of the manufacturer	Solvay Chemicals Finland Oy
Address of the manufacturer	YRJONOJANTIE 2 45910 VOIKKAA Finland
Location of manufacturing sites	Solvay Chemicals Finland Oy, YRJONOJANTIE 2 45910 VOIKKAA Finland

Name of the manufacturer	Solvay Chemicals GmbH Germany
Address of the manufacturer	KOETHENSCHE STRASSE 1-3 06406 DE BERNBURG Germany
Location of manufacturing sites	Solvay Chemicals GmbH Germany, KOETHENSCHE STRASSE 1-3 06406 DE BERNBURG Germany

Name of the manufacturer	Solvay Chemie BV Netherlands
Address of the manufacturer	SCHEPERSWEG, 1 6049 CV HERTEN Netherlands
Location of manufacturing sites	Solvay Chemie BV Netherlands, SCHEPERSWEG, 1 6049 CV HERTEN Netherlands

Name of the manufacturer	Solvay Chimica Italia SpA Italy
Address of the manufacturer	VIA PIAVE, 6 Rosignano SOLVAY LI 57013 Rosignano Italy
Location of manufacturing sites	Solvay Chimica Italia SpA Italy, VIA PIAVE, 6 Rosignano SOLVAY LI 57013 Rosignano Italy

Name of the manufacturer	Solvay Chimie SA Belgium
Address of the manufacturer	Rue de Ransbeek 310 1120 BE Brussels Belgium
Location of manufacturing sites	Solvay Chimie SA Belgium, RUE SOLVAY, 39 5190 BE JEMEPPE-SUR-SAMBRE Belgium
	Solvay Chimie SA Belgium, SCHELDELAAN 600 – HAVEN 725 2040 BE Antwerp Belgium

Name of the manufacturer	Solvay Interox Produtos Peroxidados SA
Address of the manufacturer	RUA ENG. CLEMENT DUMOULIN 2625-106 POVOA DE SANTA IRIA Portugal
Location of manufacturing sites	Solvay Interox Produtos Peroxidados SA, RUA ENG. CLEMENT DUMOULIN 2625-106 POVOA DE SANTA IRIA Portugal

1.5. Manufacturer(s) of the active substance(s)

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Interox Limited
Address of the manufacturer	Baronet Road, Solvay House WA4 6HA Warrington United Kingdom
Location of manufacturing sites	Solvay Interox Limited, Baronet Road, Solvay House WA4 6HA Warrington United Kingdom

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chemicals Finland Oy
Address of the manufacturer	YRJONOJANTIE 2 45910 VOIKKAA Finland
Location of manufacturing sites	Solvay Chemicals Finland Oy, YRJONOJANTIE 2 45910 VOIKKAA Finland

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chemicals GmbH Germany
Address of the manufacturer	KOETHENSCHE STRASSE 1-3 06406 BERNBURG Germany
Location of manufacturing sites	Solvay Chemicals GmbH Germany, KOETHENSCHE STRASSE 1-3 06406 BERNBURG Germany

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chimica Italia SpA Italy
Address of the manufacturer	VIA PIAVE, 6 ROSIGNANO SOLVAY LI 57013 ROSIGNANO Italy
Location of manufacturing sites	Solvay Chimica Italia SpA Italy, VIA PIAVE, 6 ROSIGNANO SOLVAY LI 57013 ROSIGNANO Italy

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chimie SA Belgium
Address of the manufacturer	Rue de Ransbeek 310 1120 Brussels Belgium
Location of manufacturing sites	Solvay Chimie SA Belgium, RUE SOLVAY 39 5190 BE JEMEPPE-SUR-SAMBRE Belgium
	Solvay Chimie SA Belgium, SCHELDELAAN 600 – HAVEN 725 2040 BE Antwerp Belgium

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Interox Produtos Peroxidados SA
Address of the manufacturer	RUA ENG. CLEMENT DUMOULIN 2625-106 POVOA DE SANTA IRIA Portugal
Location of manufacturing sites	Solvay Interox Produtos Peroxidados SA, RUA ENG. CLEMENT DUMOULIN 2625-106 POVOA DE SANTA IRIA Portugal

2. Product family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	13 - 49,9

2.2. Type(s) of formulation

SL - Soluble concentrate

AL - Any other liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 1

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	13 - 13,5

2.2. Type(s) of formulation of the meta SPC

Formulation(s)	AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements	May intensify fire; oxidiser Causes serious eye damage.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Wear eye protection. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. In case of fire:Use water to extinguish. Dispose of contents to in accordance with local/regional/national/international regulation. Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Surface disinfection of closed spaces by aerosolised hydrogen peroxide

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant

Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Viruses Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Bacterial spores Development stage:
Field(s) of use	Indoor Indoor, closed spaces. Industrial/pharmaceutical industry or cosmetics industry, for example clean rooms. Medical - healthcare facilities, hospitals and emergency vehicles. Institutional. Disinfection of non-porous surfaces
Application method(s)	Method: - Detailed description: Automated, non-directed aerosolization (e.g. fogging or spraying)
Application rate(s) and frequencies	Application Rate: 13% hydrogen peroxide (undiluted product) applied via aerosolization in closed rooms. Dilution (%): Number and timing of application: Frequency - as required by user, for example up to 3 times per day. Treatment time depends on machine type, size of room or area of surfaces to be disinfected. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes (L) **:** 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L Packaging material: Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system. 13% (w/w) hydrogen peroxide (undiluted product) is applied via aerosolization by automated device in a sealed room. Rooms may be dehumidified to achieve higher hydrogen peroxide concentrations on surfaces.

Remove barriers that may hinder aerosolized product from reaching the surfaces to be disinfected.
The disinfected surfaces should be non-porous and cleaned before application of the product. The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs.
The user should 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. Each device or specific installation is systematically validated when it is set up. The optimal operating conditions are validated on site (temperature, hygrometry, product to be used, diffusion time, extraction time, etc.). Besides biological validation chemical validation should be performed.

Efficacy of room disinfection was demonstrated according to norm NF T 72-281 by nebulization of 1 g of hydrogen peroxide per cubic meter of room volume in 22 min followed by 180 min contact time at room temperature.

Volume of disinfected space should be 30 - 150 m^3.

Median particle size should be 0.5 µm in aerosols used for disinfection

Prevent entry during disinfection process

4.1.2 Use-specific risk mitigation measures

Surfaces in the treatment area must be clean and dry prior to application.
Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels.
Ensure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m3). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. In case of the room has to be entered when the hydrogen peroxide concentration is still above 1.25 mg/m^3 it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).
Place warning signs on all entrances to the treatment enclosure.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.

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

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.

• Methods and materials for containment and cleaning up:

Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40 °C. Keep away from combustible materials and sources of ignition and heat.

Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX SG 12	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	13,5

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 2

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35 - 35,7

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements	May intensify fire; oxidiser Harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Avoid breathing vapours. Wash hands thoroughly after handling. Do no eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell. IF ON SKIN:Wash with plenty of water. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Rinse mouth. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. Take off contaminated clothing.And wash it before reuse. In case of fire:Use water to extinguish. Store in a well-ventilated place.Keep container tightly closed. Store locked up.

	Dispose of contents to ...in accordance with all local, regional, national and international regulations.. Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Surface disinfection of closed spaces by aerosolised hydrogen peroxide

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage: Scientific name: Common name: bacterial spores Development stage:
Field(s) of use	Indoor Indoor, closed spaces Industrial – pharmaceutical industry or cosmetics industry, for example clean rooms. Medical– healthcare facilities, hospitals, emergency vehicles. Institutional. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated, non-directed aerosolization (e.g. fogging or spraying)
Application rate(s) and frequencies	Application Rate: 35% hydrogen peroxide (undiluted product) applied via aerosolization in closed rooms. Dilution (%): Number and timing of application: Frequency - as required by user, for example up to 3 times per day. Treatment time depends on machine type, size of room or area of surfaces to be disinfected.

	Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes (L): 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L Packaging material: Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system.
35% (w/w) hydrogen peroxide (undiluted product) is applied via aerosolization by automated device in a sealed room. Rooms may be dehumidified to achieve higher hydrogen peroxide concentrations on surfaces.
Remove barriers that may hinder aerosolized product from reaching the surfaces to be disinfected.
The disinfected surfaces should be non-porous and cleaned before application of the product. The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs.
The user should 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. Each device or specific installation is systematically validated when it is set up. The optimal operating conditions are validated on site (temperature, hygrometry, product to be used, diffusion time, extraction time, etc.). Besides biological validation chemical validation should be performed.

Efficacy of room disinfection was demonstrated according to norm NF T 72-281 by nebulization of 1 g of hydrogen peroxide per cubic meter of room volume in 22 min followed by 180 min contact time at room temperature.

Volume of disinfected space should be 30 - 150 m^3.

Median particle size should be 0.5 µm in aerosols used for disinfection.

Prevent entry during disinfection process.

4.1.2 Use-specific risk mitigation measures

Surfaces in the treatment area must be clean and dry prior to application.
Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels.
Ensure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m3). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. In case the room has to be entered when the hydrogen peroxide concentration is still above 1.25 mg/m^3 it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).
Place warning signs on all entrances to the treatment enclosure.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: bacterial spores Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor Indoor. Industrial – aseptic chambers in aseptic filling applied in pharmaceutical or cosmetics industry. Disinfection of non-porous surfaces.
Application method(s)	Method: -

	Detailed description: Automated, non-directed aerosolization (e.g. fogging or spraying, flash evaporation)
Application rate(s) and frequencies	Application Rate: 35% hydrogen peroxide (undiluted product) applied via flash evaporation or aerosolization in filling isolators. Dilution (%): Number and timing of application: Frequency – as required by user, for example 1 or 2 times per day/week.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes (L): 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L. Packaging material: Approved grades of HDPE

4.2.1 Use-specific instructions for use

Use an automated loading system.

35% (w/w) hydrogen peroxide (undiluted product) is applied via flash evaporation or aerosolization by automated device connected to an filling isolator. Filling isolators may be dehumidified to achieve higher hydrogen peroxide concentrations on surfaces.

The disinfected surfaces should be non-porous and cleaned before application of the product. The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs.

The user should carry out a microbiological validation of the disinfection in the enclosures to be disinfected with the devices to be used, after which a protocol for disinfection of these enclosures can be made and used thereafter. Each device or specific installation is systematically validated when it is set up. The optimal operating conditions are validated on site (temperature, hygrometry, product to be used, diffusion time, extraction time, etc.). Besides biological validation chemical validation should be performed.

Efficacy of use against bacterial spores was demonstrated by flash evaporation of hydrogen peroxide at a rate of 0.35 g/m3/min for 51 min (18 g hydrogen peroxide / m3 / treatment).

Volume of disinfected enclosure should be 15 - 150 m3.

Median particle size should be 0.5 µm in aerosols used for disinfection.

Prevent entry during disinfection process.

4.2.2 Use-specific risk mitigation measures

Surfaces in the treatment area must be clean and dry prior to application.
Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels.
Ensure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m^3).
After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. In case the room has to be entered when the hydrogen peroxide concentration is still above 1.25 mg/m^3 it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).

Place warning signs on all entrances to the treatment enclosure.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.

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

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
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 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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.

• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40 °C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX SG 35	Market area: EU
Authorisation number		

(R4BP 3 asset reference number - National Authorisation)	EU-0027468-0002 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

Trade name(s)	INTEROX SG 35 PLUS	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0003 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 3

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	49 - 49,9

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

May intensify fire; oxidiser

Harmful if swallowed.

Causes severe skin burns and eye damage.

May cause respiratory irritation.

Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.

Keep away from clothing and other combustible materials.

Do not breathe vapours.

Wash hands thoroughly after handling.

Do no eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Avoid release to the environment.

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water.

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor.

Wash contaminated clothing before reuse.

In case of fire:Use water to extinguish.

Store in a well-ventilated place.Keep container tightly closed.

Store locked up.

Dispose of contents to ...in accordance with all local, regional, national and international regulations.

Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Surface disinfection of closed spaces by aerosolised hydrogen peroxide

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage: Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Indoor, closed spaces. Industrial – pharmaceutical industry or cosmetics industry, for example clean rooms. Medical– healthcare facilities, hospitals, emergency vehicles. Institutional. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated, non-directed aerosolization (e.g. fogging or spraying).
Application rate(s) and frequencies	Application Rate: 49% hydrogen peroxide (undiluted product) applied via aerosolization in closed rooms. Dilution (%): Number and timing of application: Frequency - as required by user, for example up to 3 times per day. Treatment time depends on machine type, size of room or area of surfaces to be disinfected. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes (L): 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L Packaging material: Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system.
49% (w/w) hydrogen peroxide (undiluted product) is applied via aerosolization by automated device in a sealed room. Rooms may be dehumidified to achieve higher hydrogen peroxide concentrations on surfaces.
Remove barriers that may hinder aerosolized product from reaching the surfaces to be disinfected.
The disinfected surfaces should be non-porous and cleaned before application of the product. The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs.
The user should 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. Each device or specific installation is systematically validated when it is set up. The optimal operating conditions are validated on site (temperature, hygrometry, product to be used, diffusion time, extraction time, etc.). Besides biological validation chemical validation should be performed.

Efficacy of room disinfection was demonstrated according to norm NF T 72-281by nebulization of 1 g of hydrogen peroxide per cubic meter of room volume in 22 min followed by 180 min contact time at room temperature.

Volume of disinfected space should be 30 - 150 m^3.
Median particle size should be 0.5 µm in aerosols used for disinfection.
Prevent entry during disinfection process.

4.1.2 Use-specific risk mitigation measures

Surfaces in the treatment area must be clean and dry prior to application.
Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels.
Ensure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m3). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. In case the room has to be entered when the hydrogen peroxide concentration is still above 1.25 mg/m^3 it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).
Place warning signs on all entrances to the treatment enclosure.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Surface disinfection of enclosures in filling isolators by aerosolised or vaporised hydrogen peroxide (VHP)

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: bacterial spores Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor Indoor. Industrial – aseptic chambers in aseptic filling applied in pharmaceutical or cosmetics industry. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated, non-directed aerosolization (e.g. fogging or spraying, flash evaporation)
Application rate(s) and frequencies	Application Rate: 49% hydrogen peroxide (undiluted product) applied via flash evaporation or aerosolization in filling isolators. Dilution (%): Number and timing of application: Frequency – as required by user, for example 1 or 2 times per day/week.
Category(ies) of users	Professional
Pack sizes and packaging material	Pack sizes (L): 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L. Packaging material: Approved grades of HDPE.

4.2.1 Use-specific instructions for use

Use an automated loading system.
49% (w/w) hydrogen peroxide (undiluted product) is applied via flash evaporation or aerosolization by automated device connected to an filling isolator. Filling isolators may be dehumidified to achieve higher hydrogen peroxide concentrations on surfaces.

The disinfected surfaces should be non-porous and cleaned before application of the product. The product is not intended to be used on surfaces that may come into contact with food or feeding stuffs.

The user should carry out a microbiological validation of the disinfection in the enclosures to be disinfected with the devices to be used, after which a protocol for disinfection of these enclosures can be made and used thereafter. Each device or specific installation is systematically validated when it is set up. The optimal operating conditions are validated on site (temperature, hygrometry, product to be used, diffusion time, extraction time, etc.). Besides biological validation chemical validation should be performed.

Efficacy of use against bacterial spores was demonstrated by flash evaporation of hydrogen peroxide at a rate of 0.35 g/m3/min for 51 min (18 g hydrogen peroxide / m3 / treatment).

Volume of disinfected enclosure should be 15 - 150 m3.

Median particle size should be 0.5 µm in aerosols used for disinfection.

Prevent entry during disinfection process.

4.2.2 Use-specific risk mitigation measures

Surfaces in the treatment area must be clean and dry prior to application.
Seal the treatment enclosure (e.g. with tape) to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels.
Ensure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food. Re-entry is only permitted once the air concentration has dropped below the reference value (1.25 mg/m^3).
After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment. In case the room has to be entered when the hydrogen peroxide concentration is still above 1.25 mg/m^3 it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).

Place warning signs on all entrances to the treatment enclosure.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.

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

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
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 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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.
• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40 °C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	Interox SG 50	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0004 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	49,9

Trade name(s)	INTEROX SG 50 PLUS	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0005 1-3	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	49,9

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 4

1.2. Suffix to the authorisation number

1-4

1.3 Product type(s)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	25 - 25,7

2.2. Type(s) of formulation of the meta SPC

Formulation(s)	AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements	May intensify fire; oxidiser Harmful if swallowed. Causes serious eye damage. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Wash hands thoroughly after handling. Do no eat, drink or smoke when using this product. Avoid release to the environment. Wear eye protection. IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Rinse mouth. In case of fire:Use water to extinguish.

	Store in a well-ventilated place.Keep container tightly closed. Store locked up. Dispose of contents to ….in accordance with all local, regional, national and international regulations.. Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Disinfection of polyethylene terephthalate food packages by vaporised hydrogen peroxide (VHP)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Industrial use - food and feed area. Disinfection of food package material.
Application method(s)	Method: - Detailed description: Automated vaporization in aseptic filling machines
Application rate(s) and frequencies	Application Rate: Undiluted product (25 % w/w hydrogen peroxide) vaporized 400 g/h/packaging machine. Dilution (%): Number and timing of application: Number and timing of applications as required by user. Machines typically operate up to 120 hours per week.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system.
Use undiluted product (25 % w/w hydrogen peroxide) to disinfect polyethylene terephthalate food packages used in aseptic packaging in food industry..
Follow machine operating instructions for disinfection period, extraction of hydrogen peroxide and re-entry. Prevent entry during disinfection process. Efficacy was demonstrated with a packaging machine running at 12480 bottles per hour with a production consumption rate of 400 g/h.
Disinfection performance of each packaging machine should be validated using biological and chemical indicators.
After sterilisation, blow-dry the packaging with hot sterile air.

4.1.2 Use-specific risk mitigation measures

During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
2. 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.
3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, 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.

Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.
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5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.
• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40°C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX AG Spray 25S	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0006 1-4	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	25,7

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 5

1.2. Suffix to the authorisation number

1-5

1.3 Product type(s)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35 - 35,7

2.2. Type(s) of formulation of the meta SPC

Formulation(s)	AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements	May intensify fire; oxidiser Harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Avoid breathing vapours. Wash hands thoroughly after handling. Do no eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell. IF ON SKIN:Wash with plenty of water. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Rinse mouth. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. Take off contaminated clothing.And wash it before reuse.

	In case of fire:Use water to extinguish. Store in a well-ventilated place.Keep container tightly closed. Store locked up. Dispose of contents to ….in accordance with all local, regional, national and international regulations.. Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Disinfection of food packaging material (aseptic packaging) by immersion or aerosolised or vaporised hydrogen peroxide (VHP)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Industrial use - food and feed area. Disinfection of food package material.
Application method(s)	Method: - Detailed description: Automated immersion of packaging material into bath of heated product in aseptic filling machine. Automated vaporisation or aerosolisation of product in sealed area in aseptic filling machine.
Application rate(s) and frequencies	Application Rate: Undiluted product (35 % w/w hydrogen peroxide) is used. Product consumption in vapour and aerosol applications 0.1 – 1 mL per second per packaging line while the machine is operating. Dilution (%): Number and timing of application: Number and timing of applications as required by user. Machines typically operate up to 120 hours per week.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC).

Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system.
Immersion: immerse clean packaging material in undiluted product according to packaging machine operating instruction Disinfection efficacy is determined by immersion time and temperature and packaging material.
Efficacy was demonstrated by immersion of carton food packages in 80 °C bath for 2.5 s.
If concentration of hydrogen peroxide in the bath drops to less than 32% during operation, replace solution with fresh product.
Vaporization: vaporize and apply undiluted product to clean packaging material according to packaging machine operating instructions. Product vaporized at 100-250 °C. Efficacy was demonstrated with polyethylene terephthalate packages flushed with 100 °C air containing 1.1% (w/w) of product for 5.5 s.
After sterilisation, blow-dry the packaging with hot sterile air.
Suitable packaging materials included paperboard, polyethylene terephthalate, polystyrene and aluminium.
Disinfection performance of each packaging machine should be validated using biological and chemical indicators.
Follow machine operating instructions for disinfection period, extraction of hydrogen peroxide and re-entry. Prevent entry during disinfection process.

4.1.2 Use-specific risk mitigation measures

During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
2. 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.
3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, 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

Aerosolised or vaporised application should be use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Disinfection of closed areas in aseptic packaging machines by aerosolised and vaporised hydrogen peroxide (VHP)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Industrial use - food and feed area. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated vaporisation or aerosolization in closed areas in aseptic filling machines.
Application rate(s) and frequencies	Application Rate: Undiluted product (35 % w/w hydrogen peroxide) is used. 100 – 800 mL product consumed per machine in one disinfection cycle. Dilution (%): Number and timing of application: Frequency – as required by user, typically once every 24 hours.

Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.2.1 Use-specific instructions for use

Use an automated loading system.
Automated disinfection of closed areas in aseptic filling machines.
Flash evaporation 130-250 °C or aerosolization (room temperature) of undiluted product using automated equipment integrated to the packaging machine. From 100 to 800 mL product required for one disinfection cycle. Minimum contact time 7 minutes starting from beginning of application.
Disinfection performance of each packaging machine should be validated using biological and chemical indicators.
Follow machine operating instructions for disinfection period, volume of disinfectant extraction of hydrogen peroxide and re-entry.
Prevent entry during disinfection process.

4.2.2 Use-specific risk mitigation measures

During operation, ensure adequate ventilation along the machines (LEV) and in the industrial halls (technical ventilation).
During manual maintenance tasks, ensure adequate ventilation inside the machine (LEV) before opening the doors of the aseptic area.

1. The product shall only be transferred in closed pipes after mixing and loading. Open product and waste water flows are not allowed.
2. 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.
3. In case of maintenance of the aseptic packaging plant (e.g. manual cleaning, technical incidents or repair) appropriate PPE (respiratory protective equipment, 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.

Use only in closed aseptic packaging machines with no emission to water and negligible emission to air. Hydrogen peroxide emission to air should be controlled by the machine e.g. with catalytic treatment or through a gas scrubber.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.

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

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
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 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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.
• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40°C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX AG Spray 35	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0007 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

Trade name(s)	INTEROX AG Spray 35S	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0008 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

Trade name(s)	INTEROX AG Bath 35S	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0009 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

Trade name(s)	INTEROX AG Bath 35	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0010 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

Trade name(s)	INTEROX AG Dual 35	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0011 1-5	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 6

1.2. Suffix to the authorisation number

1-6

1.3 Product type(s)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35 - 35,7

2.2. Type(s) of formulation of the meta SPC

Formulation(s)	SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements	May intensify fire; oxidiser Harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Avoid breathing vapours. Wash hands thoroughly after handling. Do no eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell. IF ON SKIN:Wash with plenty of water. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Rinse mouth. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. Take off contaminated clothing.And wash it before reuse.

	In case of fire:Use water to extinguish. Store in a well-ventilated place.Keep container tightly closed. Store locked up. Dispose of contents to ….in accordance with all local, regional, national and international regulations.. Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Disinfection of distribution and storage systems for drinking water

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage: Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Industrial use - drinking water systems for human and animals drinking water. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Flooding of pipes Automated spraying (CIP)
Application rate(s) and frequencies	Application Rate: Use concentration 13% w/w hydrogen peroxide. Dilution (%): Number and timing of application: Apply at room temperature. Frequency: once per week.

	Use following installation, maintenance or cleaning.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system.
Dilute the product to reach the needed hydrogen peroxide concentration stated below.
Effective hydrogen peroxide (w/w) concentration and contact time:
Bactericidal – 13%, 10 min
Yeasticidal and fungicidal – 13%, 15 min
Sporicidal – 13 %, 60 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min
Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:
A product with 35 % hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L).

Apply diluted product at room temperature on pre-cleaned surfaces. Add as aqueous solution to pipes as needed for flooding. Spray application to tanks until run-off. Surface need to be wet with disinfectant for the allocated contact time.

4.1.2 Use-specific risk mitigation measures

CIP and automated spraying:
The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.
The use is limited to distribution and storage systems with volume ≤ 15 000 L. Rinse well with potable water.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Surface disinfection in food and feed processing by liquid application

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed for humans and animals.
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage: Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Industrial use - food & feed area. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated spraying on surfaces Cleaning-in-Place (CIP) Immersion of equipment and utensils
	Application Rate: Use concentration 13% w/w hydrogen peroxide.

Application rate(s) and frequencies	Dilution (%): Number and timing of application: • CIP (cleaning-in-place): volume of diluted product needed to fill the system to be disinfected • Automated spraying: 50 – 100 mL diluted product/m^2 • Immersion: make solution and dip items As required by user - up to 1 or 2 times per day, often once per week. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.2.1 Use-specific instructions for use

Disinfection of pre-cleaned, non-porous surfaces such as tables, floors, walls, machinery, equipment and utensils in food & feed areas in production, transport, storage or preparation and handling. CIP (cleaning in place) disinfection (terminal disinfection after cleaning) – pipes, tanks, mixer, other machine which comes into contact with food. Soaking of pre-cleaned items – dishes, cutlery, equipment, small machinery, machine items, crates, boxes.

Use an automated loading system for CIP and automated spraying.
Dilute the product to reach the needed hydrogen peroxide concentration stated below.
Effective hydrogen peroxide (w/w) concentration and contact time:
Bactericidal, yeasticidal, fungicidal – 13%, 15 min
Sporicidal – 13 %, 60 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:
A product with 35% hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L).

Apply at room temperature.
Precleaning of surfaces required before using disinfectants.

Dosing
- Automated spraying 50 – 100 mL/m2

Surface need to be wet with disinfectant for the allocated contact time. Rinse well with potable water and allow to drain or dry with hot air.

4.2.2 Use-specific risk mitigation measures

CIP:
The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.

Automated spraying:
In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing.
Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries.

Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

Immersion:
The use of eye protection during handling of the product is mandatory.
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN 13034) shall be worn in loading.
For stationary processes, a local exhaust ventilation (LEV) with a capture efficiency of at least 85% shall be specified.
If no LEV, use respiratory protective equipment (RPE) providing a protection factor of 20 in loading and 5 for immersion.
After use, immersion baths must be emptied or covered to prevent further evaporation.

The waste water from breweries should not be discharged direct to surface water after simple on-site treatment. The waste water from breweries should be discharged to the sewer connected to the sewage treatment plant (STP).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.
Ensure adequate ventilation during the application.

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

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
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 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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.
• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40°C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX FCC 35	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0012 1-6	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 7

1.2. Suffix to the authorisation number

1-7

1.3 Product type(s)

PT04 - Food and feed area (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	49 - 49,9

2.2. Type(s) of formulation of the meta SPC

Formulation(s)	SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements	May intensify fire; oxidiser Harmful if swallowed. Causes severe skin burns and eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Do not breathe vapours. Wash hands thoroughly after handling. Do no eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment.

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water.

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor.

Wash contaminated clothing before reuse.

In case of fire:Use water to extinguish.

Store in a well-ventilated place.Keep container tightly closed.

Store locked up.

Dispose of contents to ….in accordance with all local, regional, national and international regulations..

Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Disinfection of distribution and storage systems for drinking water

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage:

	Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Industrial use - drinking water systems for human and animals drinking water. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Flooding of pipes Automated spraying (CIP)
Application rate(s) and frequencies	Application Rate: Use concentration 13% w/w hydrogen peroxide. Dilution (%): Number and timing of application: Apply at room temperature. Frequency: once per week. Use following installation, maintenance or cleaning.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system.
Dilute the product to reach the needed hydrogen peroxide concentration stated below.
Effective hydrogen peroxide (w/w) concentration and contact time:
Bactericidal – 13%, 10 min
Yeasticidal and fungicidal – 13%, 15 min
Sporicidal – 13 %, 60 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:
A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1L).

Apply diluted product at room temperature on pre-cleaned surfaces. Add as aqueous solution to pipes as needed for flooding. Spray

application to tanks until run-off. Surface need to be wet with disinfectant for the allocated contact time.

4.1.2 Use-specific risk mitigation measures

CIP and automated spraying:
The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.
The use is limited to distribution and storage systems with volume ≤ 15 000 L. Rinse well with potable water.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Surface disinfection in food and feed processing by liquid application

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed for humans and animals.
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage:

	Scientific name: Common name: Bacterial Spores Development stage:
Field(s) of use	Indoor Industrial use - food & feed area. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated spraying on surfaces Cleaning-in-Place (CIP) Immersion of equipment and utensils
Application rate(s) and frequencies	Application Rate: Use concentration 13% w/w hydrogen peroxide. Dilution (%): Number and timing of application: • CIP (cleaning-in-place): volume of diluted product needed to fill the system to be disinfected • Automated spraying: 50 – 100 mL diluted product/m2 • Immersion: make solution and dip items As required by user - up to 1 or 2 times per day, often once per week. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.2.1 Use-specific instructions for use

Disinfection of pre-cleaned, non-porous surfaces such as tables, floors, walls, machinery, equipment and utensils in food & feed areas in production, transport, storage or preparation and handling. CIP (cleaning in place) disinfection (terminal disinfection after cleaning) – pipes, tanks, mixer, other machine which comes into contact with food. Soaking of pre-cleaned items – dishes, cutlery, equipment, small machinery, machine items, crates, boxes. Use an automated loading system for CIP and automated spraying. Dilute the product to reach the needed hydrogen peroxide concentration stated below. Effective hydrogen peroxide (w/w) concentration and contact time: Bactericidal, yeasticidal, fungicidal – 13%, 15 min Sporicidal – 13%, 60 min Virucidal – 13%, 30 min All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:

A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1L).

Apply at room temperature.
Precleaning of surfaces required before using disinfectants.

Dosing
- Automated spraying 50 – 100 mL/m2

Surface need to be wet with disinfectant for the allocated contact time.
Rinse well with potable water and allow to drain or dry with hot air.

4.2.2 Use-specific risk mitigation measures

CIP:
The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.

Automated spraying:
In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing.
Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries.
Air concentrations must be monitored to ensure that no leakage occurs during operations and levels are safe before entering the area. For re-entry, the undercut of AECinhalation of 1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

Immersion:
The use of eye protection during handling of the product is mandatory.
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN 13034) shall be worn in loading.
For stationary processes, a local exhaust ventilation (LEV) with a capture efficiency of at least 85% shall be specified.
If no LEV, use respiratory protective equipment (RPE) providing a protection factor of 20 in loading and 5 for immersion.
After use, immersion baths must be emptied or covered to prevent further evaporation.

The waste water from breweries should not be discharged direct to surface water after simple on-site treatment. The waste water from breweries should be discharged to the sewer connected to the sewage treatment plant (STP).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.
Ensure adequate ventilation during the application.

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

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
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 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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.
• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40°C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX FCC 50	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0013 1-7	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	49,9

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 8

1.2. Suffix to the authorisation number

1-8

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35 - 35,7

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements	May intensify fire; oxidiser Harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Avoid breathing vapours. Avoid breathing spray. Wash hands thoroughly after handling. Do no eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell. IF ON SKIN:Wash with plenty of water. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor. Rinse mouth. If skin irritation occurs:Get medical advice. If skin irritation occurs:Get medical attention. Take off contaminated clothing.And wash it before reuse. In case of fire:Use water to extinguish. Store in a well-ventilated place.Keep container tightly closed.

	Store locked up. Dispose of contents to ….in accordance with all local, regional, national and international regulations.. Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Surface disinfection by liquid application in industrial and institutional areas

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage: Scientific name: Common name: Bacterial spores Development stage:
Field(s) of use	Indoor Industrial or institutional use. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated spraying on surfaces Cleaning-in-Place (CIP) Immersion of equipment and utensils
Application rate(s) and frequencies	Application Rate: Use concentration 13% w/w hydrogen peroxide. Dilution (%): Number and timing of application: • CIP (cleaning-in-place): volume of diluted product needed to fill the disinfected system • Automated spraying: 50 -100 mL diluted product/m2 • Immersion: make solution and dip items Frequency - as required by the user. Apply at room temperature.

Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.1.1 Use-specific instructions for use

Use an automated loading system for CIP and automated spraying.
Dilute the product to reach the needed hydrogen peroxide concentration stated below.

Effective hydrogen peroxide concentration (w/w) and contact time:
Bactericidal - 13 %, 10 min
Sporicidal – 13%, 60 min
Yeasticidal and fungicidal – 13%, 15 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:

A product with 35% hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L).

Precleaning of surfaces required before using disinfectants.

Automated spraying of diluted product 50 -100 mL /m2 on non-porous surfaces. Surface needs to stay wet for the allocated contact time.

Immerse instruments in diluted product for the allocated contact time. Allow to drain and dry.

4.1.2 Use-specific risk mitigation measures

CIP:
The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.

Automated spraying:
In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing.
Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries.
Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of

AECinhalation of 1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).
Immersion:
The use of eye protection during handling of the product is mandatory.
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN 13034) shall be worn in loading.
For stationary processes, a local exhaust ventilation (LEV) with a capture efficiency of at least 85% shall be specified.
If no LEV, use respiratory protective equipment (RPE) providing a protection factor of 20 in loading and 5 for immersion.
After use, immersion baths must be emptied or covered to prevent further evaporation.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Disinfection of surfaces associated with animal housing by spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage:

Field(s) of use

	Indoor Disinfection of non-porous materials and surfaces associated with the housing of animals.
Application method(s)	Method: - Detailed description: Spraying with automated or manual equipment
Application rate(s) and frequencies	Application Rate: Use concentration 9.5-13 % w/w hydrogen peroxide. Dilution (%): Number and timing of application: Spraying: 50 -100 mL diluted product/m2. Frequency depends on life-cycle of animals - as required by user.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.2.1 Use-specific instructions for use

Dilute the product to reach the needed hydrogen peroxide concentration stated below.

Effective hydrogen peroxide concentration (w/w) and contact time:

Bactericidal and yeasticidal - 9.5%, 30 min

Fungicidal – 13%, 60 min

Virucidal – 13%, 30 min

All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:

A product with 35% hydrogen peroxide concentration: The product should be diluted to 39% w/v (390 g or 340 mL of product, add water up to 1L).

Remove animals from spaces to be disinfected. Precleaning of surfaces required before using disinfectants.

Spray diluted product 50 -100 mL /m2 on non-porous surfaces. Surface needs to stay wet for the allocated contact time. Allow to drain and dry.

4.2.2 Use-specific risk mitigation measures

Automated spraying systems:
During the operation worker must leave the area and access must be denied by appropriate barriers or locked doors. After operation efficient ventilation (10 ACH) must be used to reach a safe level. During this period access must also be denied. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

For manual spraying:
The use of eye protection during handling of the product is mandatory.
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN 13034) shall be worn.
Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
Only operators wearing the specified RPE should be present while spraying or fumigating.
The operator must walk backward towards the exit while spraying the surfaces so always walking away from sprayed areas.
Efficient ventilation (10 ACH) must be used during spraying and access must be denied by appropriate barriers and notices. Also after operation efficient ventilation (10 ACH) must be used to reach a safe level. During this period access must also be denied. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of

1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

No secondary exposure is expected because of rapid decomposition of hydrogen peroxide.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.
Ensure adequate ventilation during the application.

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

Particulars of likely direct or indirect adverse effects:

• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.

• In case of skin contact: Redness, swelling of tissue, skin irritation.

• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.

• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:

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 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.

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.

Emergency measures to protect environment in case of accident:

• Environmental precautions:

Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.

• Methods and materials for containment and cleaning up:

Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40°C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX BT 35	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0014 1-8	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35,7

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 9

1.2. Suffix to the authorisation number

1-9

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	49 - 49,9

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements

May intensify fire; oxidiser

Harmful if swallowed.

Causes severe skin burns and eye damage.

May cause respiratory irritation.

Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.

Keep away from clothing and other combustible materials.

Do not breathe vapours.

Do not breathe spray.

Wash hands thoroughly after handling.

Do no eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Avoid release to the environment.

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water.

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor.

Wash contaminated clothing before reuse.

In case of fire:Use water to extinguish.

Store in a well-ventilated place.Keep container tightly closed.

Store locked up.

Dispose of contents to ….in accordance with all local, regional, national and international regulations..

Dispose of container to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Surface disinfection by liquid application in industrial and institutional areas

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts

	Development stage: Scientific name: Common name: Viruses Development stage: Scientific name: Common name: Bacterial spores Development stage:
Field(s) of use	Indoor Industrial or institutional use. Disinfection of non-porous surfaces.
Application method(s)	Method: - Detailed description: Automated spraying on surfaces Cleaning-in-Place (CIP) Immersion of equipment and utensils
Application rate(s) and frequencies	Application Rate: Use concentration 13% w/w hydrogen peroxide. Dilution (%): Number and timing of application: • CIP (cleaning-in-place): volume of diluted product needed to fill the disinfected system • Automated spraying: 50 -100 mL diluted product/m2 • Immersion: make solution and dip items Frequency - as required by the user. Apply at room temperature.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.1.1 Use-specific instructions for use

4.1.1 Use-specific instructions for use

Use an automated loading system for CIP and automated spraying.
Dilute the product to reach the needed hydrogen peroxide concentration stated below.

Effective hydrogen peroxide concentration (w/w) and contact time:
Bactericidal - 13%, 10 min
Sporicidal – 13%, 60 min
Yeasticidal and fungicidal – 13%, 15 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:
A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1 L).

Precleaning of surfaces required before using disinfectants.

Automated spraying of diluted product 50 -100 mL /m^2 on non-porous surfaces. Surface needs to stay wet for the allocated contact time.
Immerse instruments in diluted product for the allocated contact time. Allow to drain and dry.

4.1.2 Use-specific risk mitigation measures

CIP:
The processes must be fully automated and enclosed with no exposure in the case of tanks or piping systems.

Automated spraying:
In the case of automated spraying of surfaces such as conveyors or other fixed installations workers must leave the room before processing.
Disinfection can only be processed after the end of a shift with all workers having left the room. The process must be started from outside the room. Warning notices indicating that entry is denied and temporary barriers must be placed on all entries.
Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

Immersion:
The use of eye protection during handling of the product is mandatory.
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN 13034) shall be worn in loading.
For stationary processes, a local exhaust ventilation (LEV) with a capture efficiency of at least 85% shall be specified.
If no LEV, use respiratory protective equipment (RPE) providing a protection factor of 20 in loading and 5 for immersion.
After use, immersion baths must be emptied or covered to prevent further evaporation.

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

See general directions for use

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

See general directions for use.

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

See general directions for use.

4.2 Use description

Use 2 - Disinfection of surfaces associated with animal housing by spraying

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant.
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Fungi/yeasts Development stage: Scientific name: Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of non-porous materials and surfaces associated with the housing of animals.
Application method(s)	Method: - Detailed description: Spraying with automated or manual equipment
Application rate(s) and frequencies	Application Rate: Use concentration 9.5-13 % w/w hydrogen peroxide. Dilution (%): Number and timing of application: Spraying: 50 -100 mL diluted product/m2

	Frequency depends on life-cycle of animals - as required by user.
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE packaging: 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L (IBC). Approved grades of HDPE.

4.2.1 Use-specific instructions for use

Dilute the product to reach the needed hydrogen peroxide concentration stated below.

Effective hydrogen peroxide concentration (w/w) and contact time:
Bactericidal and yeasticidal - 9.5%, 30 min
Fungicidal – 13%, 60 min
Virucidal – 13%, 30 min
All claimed microbes - 13%, 60 min

Each product label should give information on how the dilution should be made, e.g. to reach 13% (w/w) hydrogen peroxide concentration:

A product with 50% hydrogen peroxide concentration: The product should be diluted to 28% w/v (280 g or 230 mL of product, add water up to 1L).

Remove animals from spaces to be disinfected. Precleaning of surfaces required before using disinfectants.

Spray diluted product 50 -100 mL /m2 on non-porous surfaces. Surface needs to stay wet for the allocated contact time. Allow to drain and dry.

4.2.2 Use-specific risk mitigation measures

Automated spraying systems:

During the operation worker must leave the area and access must be denied by appropriate barriers or locked doors. After operation efficient ventilation (10 ACH) must be used to reach a safe level. During this period access must also be denied. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

For manual spraying:
The use of eye protection during handling of the product is mandatory.
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN 13034) shall be worn.
Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory. At least a powered air purifying

respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
Only operators wearing the specified RPE should be present while spraying or fumigating.

The operator must walk backward towards the exit while spraying the surfaces so always walking away from sprayed areas. Efficient ventilation (10 ACH) must be used during spraying and access must be denied by appropriate barriers and notices, Also after operation efficient ventilation (10 ACH) must be used to reach a safe level. During this period access must also be denied. Air concentrations must be monitored to ensure that no leakage occurs during operations. For re-entry, the undercut of AECinhalation of 1.25 mg/m3 shall be ensured with technical and organisational measures (e.g. sensor, defined ventilation period).

No secondary exposure is expected because of rapid decomposition of hydrogen peroxide.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. General directions for use of the meta SPC

5.1. Instructions for use

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5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.
Wear face shield where splashing is possible.

Ensure adequate ventilation during the application.

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

Particulars of likely direct or indirect adverse effects:
• In case of inhalation: Breathing difficulties, cough, pulmonary oedema, nausea, vomiting.
• In case of skin contact: Redness, swelling of tissue, skin irritation.
• In case of eye contact: Redness, lachrymation, swelling of tissue, severe burns.
• In case of ingestion: Nausea, abdominal pain, bloody vomiting, diarrhoea, suffocation, cough, severe shortness of breath, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach. Risk of respiratory disorder.

First aid instructions:
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 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.

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.

Emergency measures to protect environment in case of accident:
• Environmental precautions:
Should not be released into the environment. If the product contaminates rivers and lakes or drains inform respective authorities.
• Methods and materials for containment and cleaning up:
Dilute with plenty of water. Dam up. Do not mix waste streams during collection. Soak up with inert absorbent material. Keep in properly labelled containers. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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

Do not allow undiluted product to enter the sewer. Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains.. Only pass on empty containers/packaging for recycling. Disposal of packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Storage: Hydrogen peroxide should be stored in properly designed bulk storage tanks or in original vented container in upright position away from incompatible products. Use only approved materials of construction for equipment or approved packs. Store in a cool, ventilated area and protect from damage and direct sunlight. Do not store at temperatures above 40°C. Keep away from combustible materials and sources of ignition and heat.
Shelf-life: 12 months in HDPE packs at ambient temperature.

6. Other information

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 this product.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	INTEROX BT 50	Market area: EU
Authorisation number **(R4BP 3 asset reference number - National Authorisation)**	EU-0027468-0015 1-9	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	49,9