

Summary of product characteristics for a biocidal product

Product name: INTEROX SG 35

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

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

Authorisation number: EU-0027468-0000

R4BP 3 asset reference number: EU-0027468-0002

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Administrative information

1.1. Trade names of the product

INTEROX SG 35

1.2. 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 1-2

R4BP 3 asset reference number

EU-0027468-0002

Date of the authorisation

08/08/2022

Expiry date of the authorisation

31/07/2032

1.3. 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
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Location of manufacturing sites

Solvay Interox Limited, Baronet Road, Solvay House WA4 6HA Warrington United Kingdom
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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	KOETHENSCHER STRASSE 1-3 06406 DE BERNBURG Germany
Location of manufacturing sites	Solvay Chemicals GmbH Germany, KOETHENSCHER 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

1.4. 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	KOETHENSCHER STRASSE 1-3 06406 BERNBURG Germany
Location of manufacturing sites	Solvay Chemicals GmbH Germany, KOETHENSCHER 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 composition and formulation

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

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

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

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 not 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)

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)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Fungi/yeasts Development stage:</p> <p>Scientific name: Common name: Viruses Development stage:</p> <p>Scientific name: Common name: bacterial spores Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>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.</p>
Application method(s)	<p>Method: - Detailed description: Automated, non-directed aerosolization (e.g. fogging or spraying)</p>
Application rate(s) and frequencies	<p>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.</p>

	<p>Treatment time depends on machine type, size of room or area of surfaces to be disinfected.</p> <p>Apply at room temperature.</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Pack sizes (L): 0.25, 1, 2.5, 5, 10, 20, 22, 30, 60, 200, 220 and 1000 L</p> <p>Packaging material: Approved grades of HDPE.</p>

4.1.1 Use-specific instructions for use

<p>Use an automated loading system.</p> <p>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.</p> <p>Remove barriers that may hinder aerosolized product from reaching the surfaces to be disinfected.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Volume of disinfected space should be 30 - 150 m³.</p> <p>Median particle size should be 0.5 µm in aerosols used for disinfection.</p> <p>Prevent entry during disinfection process.</p>
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4.1.2 Use-specific risk mitigation measures

<p>Surfaces in the treatment area must be clean and dry prior to application.</p> <p>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.</p> <p>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/m³ it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).</p> <p>Place warning signs on all entrances to the treatment enclosure.</p>
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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 algacides 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

<p>Use an automated loading system.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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).</p> <p>Volume of disinfected enclosure should be 15 - 150 m³.</p> <p>Median particle size should be 0.5 µm in aerosols used for disinfection.</p> <p>Prevent entry during disinfection process.</p>

4.2.2 Use-specific risk mitigation measures

<p>Surfaces in the treatment area must be clean and dry prior to application.</p> <p>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.</p> <p>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).</p> <p>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/m³ it is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).</p> <p>Place warning signs on all entrances to the treatment enclosure.</p>

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

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.