Summary of product characteristics for a biocidal product

Product name: INTEROX BT 35

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

PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0027468-0000

R4BP 3 asset reference number: EU-0027468-0014

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Administrative information

1.1. Trade names of the product

INTEROX BT 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 1-8	

R4BP 3 asset reference number	EU-0027468-0014
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
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

1.4. 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	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
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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

SL - Soluble concentrate

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. 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)

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.
	Method: -

Application method(s)	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

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.