Summary of product characteristics for a biocidal product

Product name: INTEROX AG Spray 25S

Product type(s): PT04 - Food and feed area (Disinfectants)

Authorisation number: EU-0027468-0000

R4BP 3 asset reference number: EU-0027468-0006

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Administrative information

1.1. Trade names of the product

INTEROX AG Spray 25S

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 1-4	

R4BP 3 asset reference number	EU-0027468-0006
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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Name of the manufacturer	Solvay Interox Produtos Peroxidados SA
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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	25,7

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	May intensify fire; oxidiser Harmful if swallowed. Causes 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)

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

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.