

Summary of product characteristics for a biocidal product

Product name: ARVO XY PE

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

PT04 - Food and feed area (Disinfectants)

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

PT04 - Food and feed area (Disinfectants)

Authorisation number: IE/BPA 70796

R4BP 3 asset reference number: IE-0026285-0000

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Administrative information

1.1. Trade names of the product

O2 SAFE 7.4
SPRAY OXY PAE

1.2. Authorisation holder

Name and address of the authorisation holder	Name	STOCKMEIER FRANCE SAS
	Address	3 rue de la Buhotière 35091 RENNES France
Authorisation number	IE/BPA 70796	
R4BP 3 asset reference number	IE-0026285-0000	
Date of the authorisation	01/07/2019	
Expiry date of the authorisation	05/06/2029	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	STOCKMEIER FRANCE SAS
Address of the manufacturer	3 rue de la Buhotière - Saint-Jacques de la Lande BP 89152 35091 Rennes CEDEX 9 France
Location of manufacturing sites	3 rue de la Buhotière - Saint-Jacques de la Lande BP 89152 35136 RENNES France
	rue des Criquiers 60220 Formerie France

Name of the manufacturer	STOCKMEIER Chemie Eilenburg
Address of the manufacturer	Gustav-Adolf-Ring 5 04838 Eilenburg Germany
Location of manufacturing sites	Gustav-Adolf-Ring 5 04838 Eilenburg Germany

Name of the manufacturer	STOCKMEIER Chemie GmbH & Co. KG
Address of the manufacturer	Am Stadtholz 37 33609 Bielefeld Germany
Location of manufacturing sites	Am Stadtholz 37 33609 Bielefeld Germany

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

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	SOLVAY CHEMICALS INTERNATIONAL SA
Address of the manufacturer	Rue de Ransbeek 310 1120 Bruxelles Belgium
Location of manufacturing sites	Solvay Interox Limited, Baronet Road, Solvay House WA4 6HA Warrington, Cheshire United Kingdom
	Solvay Chemicals Finland Oy, YRJONOJANTIE 2 45910 VOIKKAA Finland
	Solvay Chemicals GmbH Germany, KOETHENSCHER STRASSE 13, 06406 BERNBURG Germany
	Solvay Chemie BV Netherlands, SCHEPERSWEG, 1 6049 CV HERTEN Netherlands
	Solvay Chimica Italia SpA Italy, VIA PIAVE, 6 57013 ROSIGNANO SOLVAY LI Italy
	Solvay Chemie SA Belgium, RUE SOLVAY, 39 5190 Jemeppe-sur-Sambre Belgium
	Solvay Chemie SA Belgium, SCHELDELAAN 600, HAVEN 725 2040 ANTWERPEN Belgium
	Solvay Interox Produtos Peroxidados SA, RUA ENG. CLEMENT DUMOULIN 2625106 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	7,44

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Causes serious eye irritation.

Precautionary statements

Wash hands thoroughly after handling.

Wear protective gloves, protective clothing, eye protection.

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

If eye irritation persists: Get medical advice.

Dispose of contents to be in accordance with local/regional/national/international regulations..

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

4. Authorised use(s)

4.1 Use description

Use 1 - Spray disinfectant, PT2

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

Disinfectants for sanitary, surfaces, equipment and furniture without direct contact with food or feedstuff in medical and hospital environments, paramedical, institutional, tertiary sector, hotels, sports halls and changing rooms, etc. Disinfectants for sanitariums, bathrooms, etc.

Target organism(s) (including development stage)

Scientific name: Listeria
Common name: Bacteria
Development stage:

Scientific name: Salmonella
Common name: Bacteria
Development stage:

Scientific name:
Common name: Bacteria
Development stage:

Scientific name: B.cereus
Common name: Bacteria
Development stage: Bacterial spores

Scientific name: C.sporogenes
Common name: Bacteria
Development stage: Bacterial spores

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Scientific name: M. terrae
Common name: Mycobacteria
Development stage:

Field(s) of use

Indoor

Medical sector and collectivities (no food contact)

Application method(s)

Method: Spraying
Detailed description:
Surface spraying

Application rate(s) and frequencies

Application Rate: -
Dilution (%): 0
Number and timing of application:
Ready to use (100 % v/v)

Contact time

Bacteria, yeasts and fungi : 15 min

Bacterial spores : 60 min

Mycobacteria (*M. terrae*) : 60 min

	<p>Room temperature</p> <p>Medical sector : clean conditions</p> <p>Collectivities : dirty conditions except sporicidal and tuberculocidal activities</p>
<p>Category(ies) of users</p>	<p>Professional</p>
<p>Pack sizes and packaging material</p>	<p>500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle</p> <p>1L Opaque bottle with nebulization equipment</p> <p>5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment</p>

4.1.1 Use-specific instructions for use

- Apply the product uniformly by spraying (if needed spread with a wipe/soaked cloth on the entire surfaces to be treated) in sufficient quantity so that the surface remains wet during the requested contact time.
- The product is not intended to be used in dirty conditions for health care area (medical / dental / veterinary hospitals equipments) therefore clean carefully the surfaces, followed by a rinsing step with drinking water before application of the product in this area.
- For medical area, due to the contact time superior to 5 minutes, do not use this product for surfaces that are likely to come into contact with the patient and/or the medical staff and surfaces which are frequently touched by different people.
- Only clean conditions are validated for sporicidal and tuberculocidal activities therefore clean carefully the surfaces, followed by a rinsing step with drinking water before application of the product both in medical sector and collectivities.

4.1.2 Use-specific risk mitigation measures

- During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:
 - o Minimisation of splashes and spills (during loading of the product);
 - o Eye protection (chemical goggles);
 - o Training for staff on good practice.
 - Prohibit access to the general public during the application.
 - After required contact time, wipe treated surfaces or rinse treated surfaces with potable water or let the surfaces dry well.
- For hospitals:
- Wear respiratory protective equipment (minimum APF 4, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.
 - For the general public: Access to treated area is not restricted after the end of the rinsing, wiping or drying step.
- For medical practices:
- Wear respiratory protective equipment (minimum APF 4, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.
 - For the general public: Observe a re-entry time of minimum 58 min in the treated room after the end of the rinsing, wiping or

drying step.

Or

Ensure that the ambient air concentration is below 1.25 mg / m³ by using an H₂O₂ detector before allowing re-entry in the room.

For hotels and nurseries:

- Wear respiratory protective equipment (minimum APF 40, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.
- For the general public: Observe a re-entry time of minimum 125 min in the treated room after the end of the rinsing, wiping or drying step.

Or

Ensure that the ambient air concentration is below 1.25 mg/ m³ by using an H₂O₂ detector before allowing re-entry in the room.

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

Please refer to general directions for use

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

Please refer to 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

Please refer to general directions for use

4.2 Use description

Use 2 - Spray disinfectant, PT4

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Disinfectants of rooms (including collective central kitchens) and equipments for the production of food and feedstuff (including drinking water) for human and animal consumption.
Target organism(s) (including development stage)	<p>Scientific name: Listeria Common name: Bacteria Development stage:</p> <p>Scientific name: Salmonella Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: B.cereus Common name: Bacteria Development stage: Bacterial spores</p> <p>Scientific name: C.sporogenes Common name: Bacteria</p>

Development stage: Bacterial spores

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Field(s) of use

Indoor

Agro-food industry and collective central kitchens (food contact)

Application method(s)

Method: Spraying
Detailed description:
Surface spraying

Application rate(s) and frequencies

Application Rate: -
Dilution (%): 0
Number and timing of application:
Ready to use (100 % v/v)

Contact time

Bacteria, yeasts and fungi : 15 min

Bacterial spores : 60 min

Room temperature

Dirty conditions except sporicidal activity

Category(ies) of users

Professional

Pack sizes and packaging material

500mL, 750mL or 1L HDPE Prefilled trigger spray opaque bottle

1L Opaque bottle with nebulization equipment

5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment

4.2.1 Use-specific instructions for use

- Apply the product uniformly by spraying (and if needed spread the product with a wipe/soaked cloth on the entire surfaces to be treated) in sufficient quantity so that the surface remains wet during at during the requested contact time.
- Only clean conditions are validated for sporicidal activity therefore clean carefully the surfaces before application of the product.

4.2.2 Use-specific risk mitigation measures

- During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:
 - o Minimisation of spills and splashes (during loading of the product);
 - o Eye protection (chemical goggles);
 - o Training for staff on good practice.
- Prohibit access to the general public during the application.
- After required contact time, wipe treated surfaces or rinse treated surfaces with potable water or let the surfaces dry well.

For small kitchens:

- Wear respiratory protective equipment (minimum APF 10, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.
- For the general public: Observe a re-entry time of minimum 29 min in the treated room after the end of the rinsing, wiping or drying step.

Or

Ensure that the ambient air concentration is below 1.25 mg/ m3 by using an H2O2 detector before allowing re-entry in the room.

For canteens:

- Wear respiratory protective equipment (minimum APF 10, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.
- For the general public: Observe a re-entry time of minimum 39 min in the treated room after the end of the rinsing or wiping or drying step.

Or

Ensure that the ambient air concentration is below 1.25 mg/ m3 by using an H2O2 detector before allowing re-entry in the room.

For food processing industry:

- Wear respiratory protective equipment (minimum APF 4, type of equipment to be specified by the applicant) during the application of the product including the rinsing or wiping step.
- For the general public: Observe a re-entry time of minimum 15 min in the treated room after the end of the rinsing or wiping or drying step.

Or

Ensure that the ambient air concentration is below 1.25 mg/ m3 by using an H2O2 detector before allowing re-entry in the room.

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

Please refer to general directions for use

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

Please refer to 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

Please refer to general directions for use

4.3 Use description

Use 3 - Fogger disinfectant, PT2

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

Room disinfection

Target organism(s) (including development stage)

Scientific name: Listeria
Common name: Bacteria
Development stage:

Scientific name: Salmonella
Common name: Bacteria
Development stage:

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Bacteria
Development stage: Bacterial spores

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Field(s) of use

Indoor

Medical sector and collectivities (no food contact)

Application method(s)

Method: Fogging
Detailed description:
Airborne diffusion (fogging) disinfection

Application rate(s) and frequencies

Application Rate: 12 mL of product /m³
Dilution (%): 0
Number and timing of application:
12 mL of product /m³ in combination with a fogger equipment with the following characteristics:
Droplet size: 5-10 µm
Pump speed: 1.2 L/h
Room volume between 30 and 150 m³ (diffusion time between 18 and 90 min)

Contact time:
2H for bacteria, yeasts and fungi
3H for additional bacteria (L.monocytogenes and S.Thyphimurium) and bacterial spores

Room temperature
Humidity: 40 -80 %

Medical sector: clean conditions
Collectivities: dirty conditions

Category(ies) of users

Professional

Pack sizes and packaging material

1L Opaque bottle with nebulization equipment

5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment

4.3.1 Use-specific instructions for use

- The product is not intended to be used in dirty conditions for health care area (medical / dental / veterinary hospitals equipments), therefore clean carefully the surfaces, followed by a rinsing step with drinking water before application of the product in this area.

4.3.2 Use-specific risk mitigation measures

- During the loading of the fogger device, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:
 - o Minimisation of spills and splashes;
 - o Eye protection (chemical goggles);
 - o Training for staff on good practice;
 - o Good standard of personal hygiene.
- Prohibit access to the general public during the application.
- Apply the product in rooms made airtight.
- A re-entry period is required for professionals and for general public entering the treated room:
 - o a minimum of 3h09 (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
 - o a minimum of 2h37 (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

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

Please refer to general directions for use

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

Please refer to general directions for use

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

Please refer to general directions for use

4.4 Use description

Use 4 - Fogger disinfectant, PT4

Product type

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

Room disinfection

Target organism(s) (including development stage)

Scientific name: Listeria
Common name: Bacteria
Development stage:

Scientific name: Salmonella
Common name: Bacteria
Development stage:

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Bacteria
Development stage: Bacterial spores

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Field(s) of use

Indoor

Agro-food industry and collective central kitchens (food contact)

Application method(s)

Method: Fogging
Detailed description:
Airborne diffusion (fogging) disinfection

Application rate(s) and frequencies

Application Rate: 12 mL of product /m³
Dilution (%): 0
Number and timing of application:
12 ml of product /m³ in combination with a fogger equipment with the following characteristics:
Droplet size: 5-10 µm
Pump speed: 1.2 L/h
Room volume between 30 and 150 m³ (diffusion time between 18 and 90 min)

Contact time:
2H for bacteria, yeasts and fungi
3H for additional bacteria (L.monocytogenes and S.Thyphimurium) and bacterial spores
Room temperature
Humidity: 40 -80 %

Dirty conditions

Category(ies) of users

Professional

Pack sizes and packaging material

1L Opaque bottle with nebulization equipment
5L, 10L or 20L HDPE Opaque Jerrycan with nebulization equipment

4.4.1 Use-specific instructions for use

Please refer to general directions for use

4.4.2 Use-specific risk mitigation measures

- To prevent food, feed or drinking water contamination, after required contact time, wipe treated surfaces or rinse treated surfaces with potable water well , before reusing the surfaces.
- During the loading of the fogger device, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:
 - o Minimisation of spills and splashes;
 - o Eye protection (chemical goggles);
 - o Training for staff on good practice;
 - o Good standard of personal hygiene.
- Prohibit access to the general public during the application.
- Apply the product in rooms made airtight.

- A re-entry period is required for professionals and for general public entering the treated room:
 - o a minimum of 3h09 for “kitchens and canteens” uses and 3h30 “food processing industry” uses (after the product contact time) if the ventilation system cannot be re-activated without entering the treated room;
 - o a minimum of 20 min for “kitchens and canteens” uses and 6 min for “food processing industry” uses (after the product contact time) if the ventilation system can be re-activated without entering the treated room.

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

Please refer to general directions for use

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

Please refer to general directions for use

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

Please refer to general directions for use

5. General directions for use

5.1. Instructions for use

- Always read the label or leaflet before use and respect follow all the instructions provided.
- Respect the conditions of use of the product (concentration, contact time, temperature, etc.).
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved.
- Inform the registration holder if the treatment is ineffective.

5.2. Risk mitigation measures

Please refer to specific directions for use

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

- Inhalation (spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested
- In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.
- Keep the container or label available.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

2 years at ambient temperature.
Mitigation measure to be added: Protect from frost.

6. Other information

- The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).