Summary of product characteristics for a biocidal product

Product name: PEROXYDE D'HYDROGENE 7,4% PRÊTE A L'EMPLOI

Product type(s):

 $\mbox{\sc PT02}$ - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

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

animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: FR-2019-0056

R4BP 3 asset reference number: FR-0017466-0000

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Administrative information

1.1. Trade names of the product

PEROXYDE D'HYDROGENE 7,4% PRÊTE A L'EMPLOI

1.2. Authorisation holder

Name and address of the authorisation holder

Name	GFB COM 18
Address	95 cours Lafayette 69006 LYON France

Authorisation number

FR-2019-0056

R4BP 3 asset reference number

FR-0017466-0000

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

QUARON SAS

Address of the manufacturer

 $3\ \mathrm{rue}$ de la Buhotière - Saint-Jacques de la Lande BP 89152 35091 Rennes CEDEX 9 RENNES France

Location of manufacturing sites

3 rue de la Buhotière 35136 Saint-Jacques de la Lande France

rue des Criquiers 60220 Formerie France

Name of the manufacturer	HYDRACHIM	
Address of the manufacturer	ZA du piquet 35370 Etrelles France	
Location of manufacturing sites	Route de Saint Poix 35370 Le Pertre France	
	ZA La Pointe 35380 Plelan Le Grand France	
Name of the manufacturer	EYREIN INDUSTRIE	
Address of the manufacturer	ZAC de La Montane, Allée des Iris 19800 Eyrein France	
Location of manufacturing sites	ZI La Croix Saint Pierre 19800 Eyrein France	
Name of the manufacturer	LABORATOIRE CEETAL	
Address of the manufacturer	1 rue des Touristes CS 10039 42001 Saint Etienne France	
Location of manufacturing sites	LABORATOIRE MERIEL 12 rue de Malacussy 42100 Saint Etienne France	
	Zone Industrielle du Broteau Rue du Broteau 69540 Irigny France	
	CMPC SA Route de Cahors 46100 Cambes France	
Name of the manufacturer	HYGIENE ET NATURE	
Address of the manufacturer	12 Boulevard Eiffel BP 86 21600 Longvic Cedex France	
Location of manufacturing sites	12 Boulevard Eiffel 21600 Longvic France	
Name of the manufacturer	SANOGIA	
Address of the manufacturer	Parc d'activités de Signes BP 50774 83030 Toulon Cedex France	

PA du plateau de Signes, Allée d'Helsinki 94 83870 Signes France

Location of manufacturing sites

Name of the manufacturer	SOPRODIS
Address of the manufacturer	RN 113 11204 Lezignan-Corbieres France
Location of manufacturing sites	RN 113 11204 Lezignan-Corbieres France

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	Belgium
Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Arkema
Address of the manufacturer	420 rue d'Estienne d'Orves 92705 Colombes Cedex France
Location of manufacturing sites	France

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 - all other liquid

3. Hazard and precautionary statements

Hazard statements

Causes serious eye irritation.

Precautionary statements

Wash thoroughly after handling.

Wear .

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.

Dispose of to .

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

Target organism(s) (including development stage)

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 sanitaries, bathrooms, etc.

Scientific name: Common name: Bacteria (including Listeria, Salmonella) Development stage:

Scientific name: Common name: bacterial spores Development stage:

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: 100

Dilution (%): 0

Number and timing of application: Ready for use (100 % v/v)

Contact time

bacteria, yeasts and fungi: 15 min bacterial spores: 60 min mycobacteria (M.terrae): 60 min

Room temperature

Medical sector: clean conditions

Collectivities: dirty conditions except sporicidal and tuberculosidal activities

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

4.1.1 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 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 rincing 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 rincing 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:

- Minimisation of splashes and spills (during loading of the product);
- Eye protection (chemical goggles);
- 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		

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
-
4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
-
4.2 Use description
Lico 2 Spray disinfactant DT4

Use 2 - Spray disinfectant, P14

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)

Scientific name: Common name: Bacteria (including Listeria, Salmonella) Development stage:

Scientific name: Common name: Bacterial spores Development stage:

Scientific name: Common name: Yeasts Development stage:

Scientific name: Common name: Fungi Development stage:

Field(s) of use

Indoor

Professional use in 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: 100

Dilution (%): 0

Number and timing of application:

Ready for 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:

- Minimisation of spills and splashes (during loading of the product);
- 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, 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, 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.
1.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
1.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
-
.2.5 Where specific to the use, the conditions of storage and shelf-life of the product inder normal conditions of storage
-
1.3 Use description

Use 3 - Fogger 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

Room disinfection

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: Yeasts Development stage:

Scientific name: Common name: Fungi Development stage:

Field(s) of use

Indoor

Professional use in medical sector and collectivities (no food contact)

Application method(s)

Airbone diffusion Detailed description:

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 additionnal 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 rincing 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		
-		
4.3.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its	
-		
4.3.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage	
-		
4.4 Use description		
Use 4 - Fogger disinfectant, PT	4	
Product type	PT04 - Food and feed area (Disinfectants)	
Where relevant, an exact description of the authorised use	Room disinfection	
Target organism(s) (including	Scientific name: Common name: Bacteria (including Listeria, Salmonella)	

development stage)

	Scientific name: Common name: Bacterial spores Development stage:
	Scientific name: Common name: Yeasts Development stage:
	Scientific name: Common name: Fungi Development stage:
Field(s) of use	Indoor
	Professional use in agro-food industry and collective central kitchens (food contact)
Application method(s)	Airbone diffusion Detailed description: -
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 additionnal 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 instruction - 4.4.2 Use-specific risk mitig	

Development stage:

	d or drinking water contamination, after required contact time, wipe treated surfaces or rinse treated surfaces /ell , before reusing the surfaces.
	of the fogger device, facial exposure to generated aerosols has to be limited by the use of PPE and application of isational RMM such as:
	spills and splashes; chemical goggles);
o Training for staff	on good practice; of personal hygiene.
	ne general public during the application. rooms made airtight.
o a minimum of 3h the ventilation syster o a minimum of 20	required for professionals and for general public entering the treated room: 109 for "kitchens and canteens" uses and 3h30 "food processing industry" uses (after the product contact time) if m cannot be re-activated without entering the treated room; 10 min for "kitchens and canteens" uses and 6 min for "food processing industry" uses (after the product contact n system can be re-activated without entering the treated room.
-	ecific to the use, the particulars of likely direct or indirect effects, first aid and emergency measures to protect the environment
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	ecific to the use, the conditions of storage and shelf-life of the product conditions of storage
_	emantione of otoring
. General dir	ections for use
.1. Instruction	s for use
	label or leaflet before use and respect follow all the instructions provided. ditions 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. ration holder if the treatment is ineffective.
5.2. Risk mitiga	ation measures
-	

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).