

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

OXA-IOD FOAM

Product type(s)

PT03: Veterinary hygiene

Authorisation number: ES/APPF(NA)-2024-03-00929 1-2

R4BP asset number: ES-0021859-0002

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	OXA-IOD FOAM IODA MOUSSE
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	CYGYC BIOCON, S.L.
	Address	Po. Ind. Pla de Llerona C/Bélgica, 5 08520 Les Franqueses del Vallés Spain
Authorisation number	ES/APPF(NA)-2024-03-00929 1-2	
<i>R4BP asset number</i>	ES-0021859-0002	
Date of the authorisation	16/04/2024	
Expiry date of the authorisation	16/04/2034	

1.3. Manufacturer(s) of the product

Name of manufacturer	CYGYC BIOCON, S.L
Address of manufacturer	Pol. Ind. Pla de Llerona -C/Bélgica, 5 08520 Les Franqueses del Vallés Spain
Location of manufacturing sites	CYGYC BIOCON, S.L site 1 Pol. Ind. Pla de Llerona -C/Bélgica, 5 08520 Les Franqueses del Vallés Spain

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

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Laboratorios Montplet, SLU
Address of manufacturer	Via Trajana, 53-59 08020 Barcelona Spain
Location of manufacturing sites	Location Site 1 - ISP CHEMICALS LLC AFFILIATE OF ASHLAND 455 N. MAIN ST. (HWY 95) 42029 CALVERT CITY KY United States (the) Location site 2 - BASF Corporation BASF Corporation, P. O. Box 457 8404 River Road Geismar, Louisiana 70734-0457 USA 70734 Geismar, LA United States (the)

Active substance	Iodine
Name of manufacturer	Laboratorios Montplet, SLU
Address of manufacturer	Via Trajana, 53-59 08020 Barcelona Spain
Location of manufacturing sites	Location site 1 - Sociedad Quimica Minera Los Militares 4290 4290 Santiago de Chile Chile Location site 2 - Cosayach Nitratos S.A. Amunátegui 178, - Santiago de Chile Chile Location site 3 - ACF Minera S.A. Serrano 498, Iquique Chile - Iquique Chile

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		active substance	25655-41-8		2,5
Iodine		active substance	7553-56-2	231-442-4	0,25

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P264: Wash ... thoroughly after handling. P280: Wear eye protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice. P273: Avoid release to the environment. P501: Dispose of contents to /container as hazardous waste to a registered establishment or undertaking, in accordance with the current regulations..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 2.3 – Manual non-medical teat dipping disinfection. Pre- plus Post-milking

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Used in veterinary hygiene for the purpose of manual non-medical teat dipping disinfection before and after milking.
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacterias Development stage: no data Scientific name: no data Common name: Yeast Development stage: no data
Field(s) of use	indoor use
Application method(s)	Method: Manual dipping Detailed description:
Application rate(s) and frequency	Application rate: 6-8 ml/cow per treatment. Number and timing of application: Frequency: 2 events per day; (that is 4 applications per animal per day)
Category(ies) of users	professional
Pack sizes and packaging material	Bottle (1kg) (HDPE). Jerry can (10-25 kg) (HDPE). Drum (200 kg) (HDPE). IBC (1000 kg) (HDPE).

4.1.1. Use-specific instructions

See General Directions for use

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

See General Directions for use

4.1.4. 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

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

See General Directions for use

4.1.6. 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

Table 2. Use # 2.2 – Manual non-medical teat dipping disinfection. Post-milking

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Used in veterinary hygiene for the purpose of manual non-medical teat dipping disinfection after milking.
Target organism(s) (including development stage)	Common name: yeasts Development stage: No data Common name: bacteria Development stage: No data
Field(s) of use	indoor use
Application method(s)	Method: Manual dipping Detailed description:
Application rate(s) and frequency	Application rate: 6-8 ml/cow per treatment. Number and timing of application: Frequency: 2 events per day; (that is 2 applications per animal per day)
Category(ies) of users	professional
Pack sizes and packaging material	Bottle (1kg) (HDPE). Jerry can (10-25 kg) (HDPE). Drum (200 kg) (HDPE). IBC (1000 kg) (HDPE).

4.2.1. Use-specific instructions

See General Directions for use

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

See General Directions for use

4.2.4. 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

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

See General Directions for use

4.2.6. 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

4.3. Use description

Table 3. Use # 2.1 – Manual non-medical teat dipping disinfection. Pre-milking

Product type	PT03: Veterinary hygiene
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Where relevant, an exact description of the authorised use	Used in veterinary hygiene for the purpose of manual non-medical teat dipping disinfection before milking.
Target organism(s) (including development stage)	Common name: bacteria Development stage: No data Common name: yeasts Development stage: No data
Field(s) of use	indoor use
Application method(s)	Method: Manual dipping Detailed description:
Application rate(s) and frequency	Application rate: 6-8 ml/cow per treatment. Number and timing of application: Frequency: 2 events per day; (that is 2 applications per animal per day)
Category(ies) of users	professional
Pack sizes and packaging material	Bottle (1kg) (HDPE). Jerry can (10-25 kg) (HDPE). Drum (200 kg) (HDPE). IBC (1000 kg) (HDPE).

4.3.1. Use-specific instructions

See General Directions for use

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

See General Directions for use

4.3.4. 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

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

See General Directions for use

4.3.6. 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 USE¹

5.1. Instructions for use

- Please read the label or leaflet before use and follow all the instructions provided.
- Ready to use product for disinfection of milkable animal's teat by dipping treatment, before or/and after milking.
- The product must be tempered, ca. 20°C before use.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.)
- For hygienic reasons (in order to reduce the risk of possible cross contamination), it is standard practice to use gloves and protective clothing.
- The use of a dosing pump for filling the product into the application equipment is recommended.
- Fill the reservoir with the RTU product assuming 8 mL product per cow and screw the dip cup on top. Avoid discharges of surplus fluids.
- Fill the clean dip cup up to 3/4 and refill when needed. Exercise enough pressure on the reservoir to bring the product reaches the upper part of the dip cup.
- Clean the teats carefully by wiping with a single service paper towel/cloth immediately before treatment.
- Squeeze the reservoir and put the dip cup over each teat from below making sure that full length of the teats are immersed into the disinfectant.
- Make sure that have enough quantity of product to maintain the concentration: refill the cup of the dipping unit fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh product as needed.
- When finish the treatment, no return to the original container excess product. Empty the reservoir and clean reservoir and dip cup by rinsing with water.

Pre-milking teat disinfection: treat the teat with the product, let act 60 seconds and wipe teats dry using single-use towels to avoid any contamination.

Post-milking teat disinfection: treat the teat with the product after milking and leave it on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

5.2. Risk mitigation measures

- The use of eye protection during handling of these products is mandatory.
- Avoid contact with skin and eyes.

Protección Respiratoria: En caso de ventilación insuficiente, utilizar un equipo respiratorio adecuado.

Protección cutánea: Evítese el contacto con la piel. Se recomienda el uso de guantes (EN 374).

Protección de los ojos: En general, se recomienda utilizar gafas de seguridad con protectores laterales para protegerse contra la salpicadura de líquidos.

Equipos de protección individual: Utilizar equipos de protección individual adecuados de conformidad con el Reglamento (UE) 2016/425.

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor

IF SWALLOWED: Rinse mouth. Give something no drink, if exposed person is able to swallow. DO NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER

Primeros auxilios:

Ingestión: Enjuagar la boca con agua. Acuda inmediatamente al médico y muéstrela la etiqueta o el envase. Mantener en reposo. No provocar el vómito.

Contacto con los ojos: Quitar las lentes de contacto. Abra los párpados y aclárelos bien con agua limpia y fresca. Buscar ayuda médica.

Inhalación: Traslade a la persona afectada al aire libre, conserve la temperatura corporal y manténgala en reposo.

Contacto con la piel: Retirar la ropa contaminada. Lavar la piel con abundantes cantidades de agua y jabón neutro. Consulte con un médico si los síntomas persisten.

Medidas de emergencia para proteger al medio ambiente

Precauciones personales, equipo de protección y procedimientos de emergencia: Manipular el producto con guantes adecuados. Evitar respirar los vapores. Utilizar, si es preciso, un aparato respirador adecuado. Evitar todo contacto con los ojos y la piel. Mantener una ventilación adecuada en las áreas de trabajo después de derrame accidental.

Precauciones relativas al medio ambiente: Evite que los vertidos alcancen las alcantarillas municipales y conducciones de agua corriente.

Métodos y material de contención y de limpieza: Contener y absorber el vertido con material inerte, inorgánico y no combustible, tal como arena o tierra y trasladarlo a un contenedor para su eliminación según las reglamentaciones locales. Limpiar la superficie cuidadosamente para eliminar la contaminación residual.

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

- Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.
- Code the waste according to Decision 2014/955 / EU.
- Do not release to soil, ground, surface water or any kind of sewer.

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

Precautions for safe handling:

- Keep away from food, drink and animal feedingstuffs. Do not smoke.
- Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities:

- Keep the product in its original container well sealed, in a dry and ventilated area, away from potential sources of ignition and protected from light. Store in accordance with local/national regulations and follow the warnings on the label.
- Keep the product at temperature between 4-40°C.

Specific end use(s):

- Take care for general good housekeeping and good agricultural and livestock practice.

Shelf-life: 24 months

6. OTHER INFORMATION

ONLY for SPAIN:

In order to adapt the category of authorized users to its national legislation, ES CA will apply Art 37 of the BPR. Definitions (Users in Spain):

Professional: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.

Trained professional: pest control operators, having received specific training in biocides according to the national legislation in force.