

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

GUT-YODOFILM

Product type(s)

PT03: Veterinary hygiene

Authorisation number: ES/APP(NA)-2024-03-00938

R4BP asset number: ES-0032498-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	GUT-YODOFILM
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Tesis Galicia, S.L.
	Address	Alemparte de Arriba 29-A 36860 Ponteareas Spain
Authorisation number	ES/APP(NA)-2024-03-00938	
<i>R4BP asset number</i>	ES-0032498-0000	
Date of the authorisation	13/05/2024	
Expiry date of the authorisation	13/05/2034	

1.3. Manufacturer(s) of the product

Name of manufacturer	TESIS GALICIA, S.L.
Address of manufacturer	ALEMPARTE DE ARRIBA 29-A 36861 Ponteareas - PONTEVEDRA Spain
Location of manufacturing sites	TESIS GALICIA, S.L. site 1 ALEMPARTE 29-A 36861 Ponteareas - PONTEVEDRA Spain

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

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	ASHLAND Services B.V.
Address of manufacturer	Pesetrastraat 5, 2991 Barendrecht Netherlands (the)
Location of manufacturing sites	ASHLAND Services B.V. site 1 ISP Chemicals LLC, 455 North Main Street, KY 42029. Calvert City, United States (the)

Active substance	Iodine
Name of manufacturer	Ashland Services BV
Address of manufacturer	Pesetrastraat 5, 2991 XT Barendrecht, Netherlands (the)
Location of manufacturing sites	Ashland Services BV site 1 Sociedad Quimica y Minera (SQM) S.A Los militares 4290 Las Condes Santiago Chile Chile Ashland Services BV site 2 Cosayach S.A. Compañía de Salitre y yodo Amunátegui 178, 7th Floor, ---- Santiago Chile Chile Ashland Services BV site 3 Algorta Norte. Av. El Golf 99 Of. 703, Santiago, --- Las Condes Chile Almonte Chile 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
Isopropyl Alcohol	propan-2-ol	Non-active substance	67-63-0	200-661-7	0,85

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. P273: Avoid release to the environment. P280: Wear gloves/ protective clothing/eye protection/ face protection/ hearing 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 médico. P501: Dispose of contenido to contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – Post-milking teat disinfection by dipping

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Teat disinfection (non-medical) by dipping. Post milking application.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeast Common name: Yeast Development stage: no data
Field(s) of use	indoor use outdoor use Indoor and outdoor
Application method(s)	Method: inmersión manual Detailed description: inmersión manual
Application rate(s) and frequency	Application rate: 10 ml/animal/event of RTU after milking Number and timing of application: 2 events/day for manual milking, after each milking event..
Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	HEDP plastic containers of 10, 20, 200, 1000L

4.1.1. Use-specific instructions

See section General directions

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

See section General directions

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 section General directions

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

See section General directions

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

See section General directions

4.2. Use description

Table 2. Use # 2 – Post-milking teat disinfection by automatic dipping robot

Product type	PT03: Veterinary hygiene
Where relevant, an exact description of the authorised use	Teat disinfection (non-medical) after milking. Post milking application
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: no data Scientific name: Yeast Common name: Yeast Development stage: no data
Field(s) of use	indoor use outdoor use Indoor and outdoor
Application method(s)	Method: Robot de inmersión automático Detailed description: Automatic dipping robot
Application rate(s) and frequency	Application rate: 10 ml/animal/event of RTU after milking Number and timing of application: 3 events/day for milking systems, after each milking event
Category(ies) of users	trained professional ; professional
Pack sizes and packaging material	HEDP plastic containers of 10, 20, 200, 1000L

4.2.1. Use-specific instructions

See section General directions for use

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

See section 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 section General directions for use

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

See section 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 section 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.

This biocidal product is specially formulated to be applied for disinfection of the teat hole after milking. It is indicated for topical use in dairy cows, sheep and goats.

Apply the product on the udder nipple covering it homogeneously. Immerse the teat in the pure product immediately after milking. Before next milking remove the remains of the biocidal product.

Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).

Contact time: At least 5 minutes.

5.2. Risk mitigation measures

Avoid contact with eyes and skin.

During product handling phase, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information).

Personal protection equipment, at least chemical goggles is recommended.

It is recommended to design all work processes always so that the following is excluded: Inhalation of vapours or spray/mists. Use only in well-ventilated areas

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 to 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.

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

Environmental precautions:

Avoid at all cost any type of spillage into an aqueous medium. Contain the product absorbed appropriately in hermetically sealed

containers. Notify the relevant authority in case of exposure to the general public or the environment.

Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents.

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

Keep out of reach of children and non-target animals/pets.

Technical measures for storage

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

-Minimum Temp.: 5 °C

-Maximum Temp.: 30 °C

General conditions for storage

-Avoid sources of heat, radiation, static electricity and contact with food.

Shelf-life: 1 years from the date of manufacture

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.

In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexity of control measures.