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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

YODICURA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA

Product type(s)

PT01: Human hygiene

Authorisation number: ES/APPF(NA)-2024-01-00949 1-1

R4BP asset number: ES-0015293-0001

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	YODICURA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA ACOFAR POVIDONA IODADA 10% ANTISEPTICO PIEL SANA ALVITA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA AUCHAN POVIDONA IODADA 10% ANTISEPTICO PIEL SANA CARREFOUR POVIDONA IODADA 10% ANTISEPTICO PIEL SANA EROSKI POVIDONA IODADA 10% ANTISEPTICO PIEL SANA OPTISANA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA DR. S.O.S. POVIDONA IODADA 10% ANTISEPTICO PIEL SANA NOTADERM POVIDONA IODADA 10% ANTISEPTICO PIEL SANA SALVELOX POVIDONA IODADA 10% ANTISEPTICO PIEL SANA LISUBEL POVIDONA IODADA 10% ANTISEPTICO PIEL SANA DELITAS POVIDONA IODADA 10% ANTISEPTICO PIEL SANA IBERPOS POVIDONA IODADA 10% ANTISEPTICO PIEL SANA KERN PHARMA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA NEXADINE POVIDONA IODADA 10% ANTISEPTICO PIEL SANA AMIFAR POVIDONA IODADA 10% ANTISEPTICO PIEL SANA UNIDE POVIDONA IODADA 10% ANTISEPTICO PIEL SANA VECKIA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA BOTIQUIN SANS POVIDONA IODADA 10% ANTISEPTICO PIEL SANA BONTE POVIDONA IODADA 10% ANTISEPTICO PIEL SANA INTERAPOTHEK POVIDONA IODADA 10% ANTISEPTICO PIEL SANA IFA UNNIA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA BALNERIS POVIDONA IODADA 10% ANTISEPTICO PIEL SANA COALIMENT POVIDONA IODADA 10% ANTISEPTICO PIEL SANA HIPERDINO POVIDONA IODADA 10% ANTISEPTICO PIEL SANA LUSAN POVIDONA IODADA 10% ANTISEPTICO PIEL SANA YODAL 10 POVIDONA IODADA 10% ANTISEPTICO PIEL SANA
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	DISPOYOD POVIDONA IODADA 10% ANTISEPTICO PIEL SANA APOSAN POVIDONA IODADA 10% ANTISEPTICO PIEL SANA CUIDAPLUS POVIDONA IODADA 10% ANTISEPTICO PIEL SANA MONTPLET POVIDONA IODADA 10% ANTISEPTICO PIEL SANA APODINE POVIDONA IODADA 10% ANTISEPTICO PIEL SANA DESINPOV IODINE POVIDONA IODADA 10% ANTISEPTICO PIEL SANA POVIMARK POVIDONA IODADA 10% ANTISEPTICO PIEL SANA POVISOL POVIDONA IODADA 10% ANTISEPTICO PIEL SANA FORET POVIDONA IODADA 10% ANTISEPTICO PIEL SANA BETAPOVIDONA NUEVA FÓRMULA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA FARPLUS NUEVA FÓRMULA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA JVF NUEVA FÓRMULA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA BETAFAR NUEVA FÓRMULA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA RUEDA FARMA NUEVA FÓRMULA POVIDONA IODADA 10% ANTISEPTICO PIEL SANA
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratorios Montplet, S.L.U.
	Address	Via Trajana 53-59 08020 Barcelona Spain
Authorisation number	ES/APPF(NA)-2024-01-00949 1-1	
<i>R4BP asset number</i>	ES-0015293-0001	
Date of the authorisation	10/07/2024	
Expiry date of the authorisation	10/07/2034	

1.3. Manufacturer(s) of the product

Name of manufacturer	Alcoholes Montplet, S.A.
Address of manufacturer	Via Trajana 53-55 08020 Barcelona Spain
Location of manufacturing sites	Laboratorios Montplet, S.L.U. site 1 Via Trajana 53-59 08020 Barcelona 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	Site 1: ISP CHEMICALS LLC (AFFILIATE OF ASHLAND) 455 N. MAIN ST. (HWY 95) 42029 CALVERT CITY KY United States (the)

	Site 2: BASF 8404 River Road 70734 Geismar, Louisiana United States (the)
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Active substance	Iodine
Name of manufacturer	Laboratorios Montplet, SLU
Address of manufacturer	Via Trajana, 53-59 08020 Barcelona Spain
Location of manufacturing sites	<p>Location site 1 - Sociedad Quimica Minera Los Militares 4290 Santiago de Chile Chile</p> <p>Location site 2 - Cosayach Compañía de Salitre y yodo S. A. Amunátegui 178, 7th Floor - Santiago de Chile Chile</p> <p>Location site 3 - ACF Minera S.A. Faena Lagunas, KM. 1.722 Ruta A-5, - Pozo Almonte Chile</p> <p>Location Site 4. Ashland Services BV Algorta Norte. Av. El Golf 99 Of. 703, Santiago, --- Santiago Chile</p>

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		10 % (w/w)
Iodine		active substance	7553-56-2	231-442-4	1 % (w/w)

2.2. Type(s) of formulation

CL Contact liquid or gel

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H318: Causes serious eye damage. H373: May cause damage to organs (thyroid gland) through prolonged or repeated exposure .. H412: Harmful to aquatic life with long lasting effects.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P260: Do not breathe dust. P260: Do not breathe fume. P260: Do not breathe gas. P260: Do not breathe mist. P260: Do not breathe vapours. P260: Do not breathe spray. P280: Wear protective gloves/protective clothing/eye protection/face 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. P310: Immediately call a POISON CENTER or doctor/physician.. P314: Get medical vapours if you feel unwell. P501: Dispose of contents to and / or its container as hazardous waste according to the regulations in force (Non-professional users).. P501: Dispose of contents to and / or its container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations (Professional users)..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 – Hand disinfection (10% PVP-iodine)

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	The biocidal product is used to disinfect hands The product is not intended for surgical disinfection. Professionals users: (healthcare and institutional professionals).
Target organism(s) (including development stage)	Scientific name: Yeast Common name: Yeasts Development stage: no data Scientific name: Bacteria Common name: Bacteria Development stage: no data
Field(s) of use	indoor use Hospitals, other healthcare facilities, public and private houses
Application method(s)	Method: Apply the solution on the hands, rub on, and let dry. Detailed description: Apply the solution on the hands, rub on for 1 minute, and let dry. After the product can be washed off.
Application rate(s) and frequency	Application rate: 3 mL (drop cap = 3 mL; spray pump = 18 pumps) Dilution (%): 0 Number and timing of application: 3 mL of product is applied. One single application. The solution is allowed to dry for 1 minute. (drop cap = 3 mL; spray pump = 18 pumps)
Category(ies) of users	professional ; general public (non-professional)
Pack sizes and packaging material	HDPE round bottle with a dropping and screw cap of PP: 40 mL, 50 mL, 125 mL, 250 mL, 500 mL, 1000 mL spray pen 10 mL Box containing 5 LDPE vials for single use (of 10 mL). HDPE trigger spray bottle: 25 and 50 mL

4.1.1. Use-specific instructions

Apply approx. 3 mL solution on the hands, rub on, and let dry for a minimum of 1 minute. Then action can be undertaken, for which the hands need to be disinfected (e.g. patient handling). After the action, the hands can be washed, to wash off the disinfectant (brown colour).

4.1.2. Use-specific risk mitigation measures

See this point in Directions for use

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 this point in Directions for use

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

See this point in 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 this point in Directions for use

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Comply with the instructions for use

No apply more than 15 times per day and hospital personal.

5.2. Risk mitigation measures

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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: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow.

Do NOT induce vomiting. Call 112/ambulance for medical assistance

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 . If skin irritation or rash occur: Get medical advice. 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. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

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

Environmental precautions:

Do not allow the product to reach directly the environment (soil, ground- and surface water or any kind of sewer). Inform respective authorities in case of pollution to the environment caused by the product.

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

Professional:

Empty containers, unused product and containers 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 those 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 or surface water.

Non profesional:

Empty containers and unused product are considered hazardous waste. Dispose of in accordance with current regulations.

Do not release to soil, ground or surface water.

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

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

Store in accordance with state and local regulations, observe the precautions indicated on the label.

Keep in a cool, dry and well-ventilated place, away from sources of heat and direct sunlight, and incompatible materials

Do not store at temperatures above 30°C for long periods of time.

The long-term stability test of the meta-SPC1 10% povidone iodine confirms its stability for 3 years.

The long-term stability test of the meta-SPC2 7,5% povidone iodine confirms its stability for 30 months.

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

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. Professionals users in this biocidal product: (healthcare and institutional professionals).