

Summary of product characteristics for a biocidal product

Product name: POVI IODINE 100

Product type(s): PT01 - Human hygiene (Disinfectants)

Authorisation number: IT/2021/00714/AUT

R4BP 3 asset reference number: IT-0014770-0000

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Administrative information

1.1. Trade names of the product

POVI IODINE 100

1.2. Authorisation holder

Name and address of the authorisation holder	Name	NUOVA FARMEC S.r.l.
	Address	Via W. Flemming 37026 Settimo di Pescantina - Verona Italy
Authorisation number	IT/2021/00714/AUT	
R4BP 3 asset reference number	IT-0014770-0000	
Date of the authorisation	29/01/2021	
Expiry date of the authorisation	31/08/2025	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	NUOVA FARMEC S.r.l.
Address of the manufacturer	Via W. Flemming 37026 Settimo di Pescantina - Verona Italy
Location of manufacturing sites	Via W. Flemming 37026 Settimo di Pescantina - Verona Italy

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

Active substance	1349 - Polyvinylpyrrolidone iodine
Name of the manufacturer	ASHLAND INC.
Address of the manufacturer	Pesetastraat 5 2991 Barendrecht Netherlands
Location of manufacturing sites	455 North Main Street 42029 Calvert City United States

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 (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		10

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	<p>May be corrosive to metals.</p> <p>Causes serious eye damage.</p> <p>Harmful to aquatic life with long lasting effects.</p>
Precautionary statements	<p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Immediately call a POISON CENTER.</p>

4. Authorised use(s)

4.1 Use description

Use 1 - Hands disinfection by hand-wash – professional users

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hands disinfection by hand-wash in healthcare settings by professional users
Target organism(s) (including development stage)	Scientific name: Escherichia coli K12 Common name: Bacteria Development stage: Scientific name: Enterococcus hirae Common name: Bacteria Development stage: Scientific name: Staphylococcus aureus Common name: Bacteria Development stage: Scientific name: Pseudomonas aeruginosa Common name: Bacteria Development stage: Scientific name: Murine norovirus Common name: Virus (limited spectrum) Development stage: Scientific name: Adenovirus Common name: Virus (limited spectrum) Development stage: Scientific name: Candida albicans Common name: Yeasts Development stage:
Field(s) of use	Indoor
Application method(s)	Method: Manual application Detailed description: RTU product. Wet hands with water. Apply the product directly on the palm of a hand and rub hands for at least 1 minute, then rinse thoroughly with clean water.
Application rate(s) and frequencies	Application Rate: Apply enough product (3 mL) so to lather evenly both hands and rub them easily for the necessary contact time. Dilution (%): 0 Number and timing of application: 1 to 10 applications per day
Category(ies) of users	Professional

Pack sizes and packaging material

125-250-500-1000 mL bottle (HDPE, opaque), with antisplash PE spout + PP screw cap

4.1.1 Use-specific instructions for use

Please refer to general directions for use.

4.1.2 Use-specific risk mitigation measures

Please refer to general 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

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.

5. General directions for use

5.1. Instructions for use

The product is ready-to-use.

Wet hands with water. Apply the product directly on the palm of a hand and rub hands for at least 1 minute, then rinse thoroughly with clean water.

Apply enough product (3 mL) so to lather evenly both hands and rub them easily for the necessary contact time).

1 to 10 applications per day

5.2. Risk mitigation measures

Always read the label or leaflet before use and follow all the instructions provided.
The use of eye protection during handling of the product is mandatory.

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

Likely direct or indirect adverse effects

Serious eye damage.

First aid instructions

- in the event of exposure by inhalation: Move the person away from the place of exposure and take him/her to fresh air.
- In the event of splashes or contact with eyes: If necessary, remove contact lenses. Rinse thoroughly with clean water for 15 minutes keeping the eyelids enlarged. Do not run the water towards the unaffected eye. If pain, redness or visual disturbance appears, consult an ophthalmologist. Show the container or label.
- in the event of splashes or skin contact: In case of skin irritation, consult a doctor.
- If swallowed: Rinse mouth, spit, do NOT induce vomiting. Get medical advice. Show the container or label.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER [INSERT LOCAL NUMBER HERE].

Emergency measures to protect the environment

Large spills: Contain and collect for disposal.

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

Do not discharge the biocidal product nor the diluted solution of the biocidal product into the sewage system or the environment.

Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Keep container tightly closed.

Store ONLY in the original container.

Do not store at temperature higher than 35°C.

Shelf-life: 2 years.

6. Other information

None