

## TECHNICAL DATA SHEET

# POVI IODINE 100

## Biocide for hand antiseptis

(Povidone-iodine)

Date of first issue	12-05-2021	Internal code
Revision n°	01	<b>PF081</b>
Date of last issue	27-06-2022	

### 1. Composition

100 g solution contains:

<i>Components</i>		<i>g</i>
<b>Active substance</b>	Povidone-iodine (10% of free iodine)	10

<b>Excipients</b>	
Glycerine, co-formulants and purified water up to 100 g	

### 2. Product characteristics

**POVI IODINE 100** is a ready-to-use aqueous solution based on Povidone-iodine in a concentration of 10%.

### 3. Range of application and instructions for use

#### Range of application

Hands disinfection by hand-wash in healthcare settings by professional users.

#### Instructions for use

The product does not need to be diluted.

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 min.).

1 to 10 applications per day.

The use, especially if prolonged, of products for topical use, can give rise to hypersensitivity phenomena: stop treatment and consult a doctor.

Avoid the simultaneous use of other antiseptics and / or detergents.

### 4. Mechanism of Action and biocidal activity

Povidone-iodine is active against gram-positive, gram-negative, yeasts and viruses (Adenovirus and Murine norovirus). It contains about 10% of free available iodine which is released gradually upon contact with the substrate. The antiseptis is expressed by free iodine with a direct oxidizing action.

**POVI IODINE 100** has been tested by accredited laboratories in accordance with the European standards of efficacy. The product has a proven bactericidal, yeastocidal and virucidal efficacy.

Biocidal activity	Active concentration	Contact time
<b>Bactericidal</b>		
EN 13727	As it is	1 min
EN 1500	As it is	1 min
EN 1499	As it is	1 min
<b>Yeasticidal</b>		
EN 13624	As it is	1 min
<b>Virucidal</b>		
EN 14476 <i>(limited spectrum of virucidal activity: Adenovirus and Murine Norovirus)</i>	As it is	1 min

## 5. Packaging

<b>Primary packaging</b>	<b>Secondary packaging</b>
1000 ml bottle	Carton box with 12 bottles
500 ml bottle	Carton box with 20 bottles
250 ml bottle	Carton box with 24 bottles
125 ml bottle	Carton box with 24 bottles

All primary packaging materials do not contain latex, and they are perfectly compatible with the components of the formulation. The primary packaging is impenetrable to light.

## 6. Storage and stability

Keep the container tightly closed. Do not store at temperature higher than 35°C.

The product in its original sealed packaging is valid for **2 years**.

If the package is correctly opened and closed at the end of each disinfection operation, without contamination of the residual part, the product maintains its chemical-physical and microbiological characteristics for **90 days**.

## 7. Quality Control

The components (raw materials, containers, labels etc.) and production steps of each individual batch are carefully controlled in compliance with the SOP (Standard Operative Procedures) required by ISO 9001 and ISO 13485.

## 8. Holder of the registration

Nuova Farmec S.r.l. - Zona Industriale - Settimo di Pescantina (VR) - ITALY

## 9. Ministry of Health registration: BIOCIDAL PRODUCT (PT01) n° IT/2021/00714/AUT

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