

## Product Data Sheet

Product: eye wash saline solution

Version: 1.0

Status: Approved

Issue Date: 11.01.2024

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Aqua-NIT 250ml - Sterile isotonic sodium chloride solution

Product Type: Eye wash saline solution

Variants: --

Use: Rinsing the eyes, the conjunctival sac and the skin

Appearance: colourless liquid

Legal Manufacturer: Optima Medical Swiss AG, Bundesstrasse 7, 6300 Zug, Switzerland

Services: Optima Pharmazeutische GmbH, Ludwigstr. 49, 85399 Hallbergmoos, Germany

Tel.: +49 811 555 393 – 0, Fax: +49 811 555 393 – 29, Email: [info@optimapharma.de](mailto:info@optimapharma.de)

### 2. COMPOSITION

Sodium chloride 9 mg/ml, purified water

### 3. HAZARDS IDENTIFICATION

Health: No hazards in normal use.

Environment: No special precautions required.

### 4. FIRST AID MEASURES

<u>Eye Contact</u>	No specific treatment is necessary as the material is not hazardous by eye contact.
<u>Skin Contact</u>	No specific treatment is necessary as the material is not hazardous by skin contact.
<u>Ingestion</u>	No specific treatment is necessary as the material is not hazardous by ingestion.
<u>Inhalation</u>	No specific treatments necessary as the material is not hazardous by inhalation.

Read instruction for use.

### 5. FIRE FIGHTING MEASURES

Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

Not applicable

### 7. HANDLING AND STORAGE

<u>Handling</u>	No special requirements.
<u>Storage</u>	Do not freeze

### 8. EXPOSURE CONTROL AND PERSONAL PROTECTION

Respiratory Protection	Not required.
Hand Protection	Not required.
Eye Protection	Not required.
Skin Protection	Not required.
See also Section 7	
Not applicable under normal circumstances	

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<u>Physical state</u>	bottle containing liquid
<u>Appearance</u>	clear, colourless solution
<u>Odour</u>	odeurless
<u>Flashpoint</u>	Not applicable
<u>Solubility in water</u>	Miscible with water

## 10. STABILITY AND REACTIVITY

<u>Materials to Avoid</u>	Not applicable
<u>Hazardous Decomposition Products</u>	None known

## 11. TOXICOLOGICAL INFORMATION

See also Section 2 and 3; no significant hazard is considered to be present. The product possesses no known toxicological hazards when used as directed and all precautions followed. The product has been assessed in line with the relevant regulatory requirements applicable to medical devices for safety and toxicology.

## 12. ECOLOGICAL INFORMATION

None available, no hazard expected. See also Sections 6,7,13 and 15

## 13. DISPOSAL CONSIDERATIONS

According to local requirements.

## 14. TRANSPORT INFORMATION

No special labelling required for Road, Sea and Air. Not classified as hazardous for transport.  
The supply chain temperature limits provided in Section 7 must be adhered to during transportation.

## 15. REGULATORY INFORMATION

This product is classified as a Medical Device.  
Product should be stored in a cool and dry place at room temperature (between 2°C and 25°C)  
Before use please read enclosed instruction for use.

## 16. OTHER INFORMATION

Data sources: Technical documentation

This document complements the instruction for use but does not replace them. The information contained herein is based on our best current technical knowledge of the product concerned, and is given in good faith. The attention of recipients is drawn to (amongst other things) the element of risk consequent to use of the product for a purpose other than that for which it was intended.

In no way does this document remove the need of the recipient of the product to fully understand and apply statutory requirements. It is the recipient's sole responsibility to take due precautions relative to the use made of the product.

All information contained herein is included only to assist the recipient in fulfilling his or her statutory duty connected with the use of hazardous materials.

This list of information must not be considered as exhaustive, and does not exonerate the recipient from taking other precautions described in documents other than those mentioned, concerning the storage and use of the product, for which he or she remains the sole person responsible.