

# Technical Data Sheet

## Plum Wound and Eyewash pH Neutral 4.9% Phosphate

### 1. Identification of the product and the company

#### 1.1. Product identifier and intended use

|                      |   |
|----------------------|---|
| <b>Trade Name:</b>   | Plum Wound and Eyewash pH Neutral 4.9% Phosphate  |
| <b>Intended Use:</b> | Plum Wound and Eyewash pH Neutral 4.9% Phosphate is a first aid product for wounds and eyes irrigation involving accidents with acids and alkali. |
| <b>Expiry date:</b>  | Printed on the bottle label.  |

#### 1.2. Details of the supplier of the data sheet

##### Manufacturer

|                  |  |
|------------------|--|
| <b>Company:</b>  | Plum Safety ApS                                |
| <b>Address:</b>  | Mandelalléen 1                                 |
| <b>Zip code:</b> | 5610   |
| <b>City:</b>     | Assens   |
| <b>Country:</b>  | DENMARK  |
| <b>E-mail:</b>   | <a href="mailto:info@plum.eu">info@plum.eu</a> |
| <b>Phone:</b>    | +45 6916 9600                                  |
| <b>Fax:</b>      | +45 6916 9630                                  |

#### 1.3 Legislative information

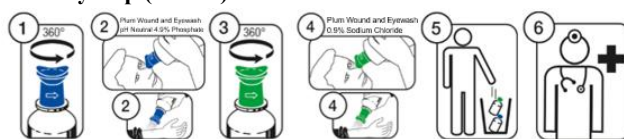
**General information:** As the products are class IIb medical devices according to *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*, they are certified by the Notified Body, **DNV Product Assurance AS**. No Safety Data Sheet is required for medical devices.

The products shall not be classified as hazardous according to the classification and labeling rules for substance and mixtures.

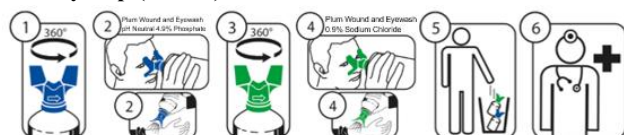
Plum Safety ApS is certified according to *ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes*.

#### 1.4 Instructions for use

##### Mono eyecup (200 ml)



##### DUO eyecup (500 ml)



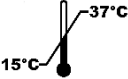






- Always wash with Plum Wound and Eyewash 0.9% Sodium Chloride after using Plum Wound and Eyewash pH Neutral 4.9% Phosphate

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### 1.5 Symbol explanation

- Do not reuse 
- Do not use if package is damaged 
- Recommended temperature when used 
- Warning Hydrofluoric acid (HF) 
- Warning Calcification (Ca) (only applies for eyes) 
- Warning Sodium Hypochlorite (NaClO) 
- Single sterile barrier system 

## 2. General information about the product

**Material requirements:** The materials in these products have been judged biocompatible according to the requirements of *EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

### Bottle, label and eyecup dimensions

|                          | 200 ml                         | 500 ml                         |
|--------------------------|--------------------------------|--------------------------------|
| Bottle material          | Polyethylene without additives | Polyethylene without additives |
| The bottle contains [ml] | 201-207                        | 505-512                        |
| Bottom Ø [mm]            | 58.5                           | 78                             |
| Height [mm]              | 165                            | 220                            |

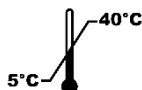
## 3. Side effects and malfunction

**Side effects and malfunction:** The products are designed as a first aid product for wounds and eyes irrigation involving accidents with acids and alkali. If side effects or malfunctions are experienced, please report these to Plum Safety ApS [info@plum.eu](mailto:info@plum.eu) or phone +45 6916 9600, so that necessary remedial measures can be initiated.

Serious adverse effects should always be reported to a relevant and competent authority.

## 4. Storage

**Storage:**



**Shelf life:** 42 months from manufacturing date.

**Installation:** Please refer to the pictogram on the label:



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### 5. Other information

#### Version history and indication of changes

| Version | Revision date (dd-mm-yyyy) | Responsible | Changes            |
|---------|----------------------------|-------------|--------------------|
| 2.0     | 06-11-2025                 | MAW         | 1.5 + 2            |
| 1.6     | 29-11-2024                 | MAW         | 1.4                |
| 1.5     | 17-10-2023                 | ANS         | 1.1, 1.3, 1.4, 2.0 |

*Information on earlier revisions to be found on document version 1.5 or earlier*

**Other information** Additional information can be obtained by contacting [info@plum.eu](mailto:info@plum.eu) or by telephone +45 6916 9600.

#### TDS prepared by:

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