

Technical Data Sheet

Plum Eyewash pH Neutral 4.9% Phosphate

1. Identification of the product and the company

1.1. Product identifier and intended use.

| | |
|----------------------|---|
| Trade Name: | Plum Eyewash pH Neutral 4.9% Phosphate |
| Intended Use: | The products are intended to be used as first aid products for eye irrigation after accidents involving acids and alkali. |
| Expiry date: | Printed on the bottle label. |

1.2. Details of the supplier of the data sheet

Manufacturer

| | |
|------------------|--|
| Company: | Plum A/S |
| Address: | Frederik Plums Vej 2 |
| Zip code: | 5610 |
| City: | Assens |
| Country: | DENMARK |
| E-mail: | info@plum.eu |
| Phone: | +45 64712112 |
| Fax: | +45 64712125 |

1.3 Legislative information

General information: As the products are class 1s sterile medical devices according to *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*, they are certified by Notified Body, Presafe. 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 A/S is certified according to *ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes*.

1.4 Instructions for use:

Mono eye cup (200 and 500ml) / Shower eye cup (1000 ml)



DUO eye cup (500 ml)



- Always wash with Plum Eyewash 0.9% Sodium Chloride after using Plum Eyewash pH Neutral 4.9% Phosphate!
- Do not reuse.
- Do not use if damaged.
- Recommended temperature when used



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2. General information about the product

Material requirements: The materials in these products have been judged biocompatible according to the requirements of *ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.

Bottle, label and eye cup dimensions.

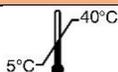
| | 200 ml bottle | 500 ml bottle | 1000 ml bottle |
|--------------------------|--------------------------------|--------------------------------|--------------------------------|
| Bottle material | Polyethylene without additives | Polyethylene without additives | Polyethylene without additives |
| The bottle contains [ml] | 201-207 | 505-512 | 1005-1020 |
| Bottom Ø [mm] | 58.5 | 78 | 90 |
| Height [mm] | 129.6 | 183 | 229 |

3. Side effects and malfunction

Side effects and malfunction: The products are designed as a first aid product for eye irrigation. If side effects or malfunctions are experienced, please report these to Plum A/S, 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:



Mounting stations and boxes:

Please visit <https://plum.eu/products/firstaid/eye-wash>

5. Other information

Version history and indication of changes

| Version | Revision date | Responsible | Changes |
|---------|---------------|-------------|---------|
| 1.2 | 30-09-2020 | CL | 5 |
| 1.1 | 03-06-2020 | CL / VWB | 3, 5 |
| 1.0 | 14-04-2020 | CL /VWB | |

Other information

Additional information can be obtained by contacting info@plum.eu or by telephone +45 6916 9600.

TDS prepared by:

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