

Technical Data Sheet

Plum Eyewash 0.9% Sodium Chloride

1. Identification of the product and the company

1.1. Product identifier and intended use.

| | |
|---------------|--|
| Trade Name: | Plum Eyewash 0.9% Sodium Chloride and Plum Eyewash 0.9% Sodium Chloride QuickRinse |
| Intended Use: | The products are intended to be used as first aid products for eye irrigation. |
| Expiry date: | Printed on the bottle label/ampoule. |

1.2. Details of the supplier of the data sheet

| | |
|--------------|--|
| Manufacturer | |
| Company: | Plum Safety ApS |
| Address: | Mandelalleen 1 |
| Zip code: | 5610 |
| City: | Assens |
| Country: | DENMARK |
| E-mail: | info@plum.eu |
| Phone: | +45 6916 9600 |
| Fax: | +45 6916 9630 |

1.3 Legislative information

| | |
|----------------------|--|
| General information: | As the products are class 1s sterile medical devices according to <i>Council Directive 93/42/EEC of 14 June 1993 concerning medical devices</i> , they are certified by the Notified Body, DNV Product Assurance AS . No Safety Data Sheet is required for medical devices. |
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The products shall not be classified as hazardous according to the classification and labeling rules for substance and mixtures.

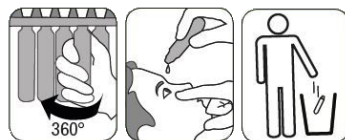
Plum Safety ApS is certified according to *ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes*.

1.4 Instruction for use:

Mono eye cup (200, 500, 1000 ml)

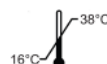


Duo eye cup (500, 1000 ml)



Ampoule (20 ml)

- 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.

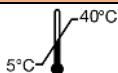
| | 20 ml ampoule | 200 ml bottle | 500 ml bottle | 1000 ml bottle |
|----------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| Bottle material | Polyethylene without additives | Polyethylene without additives | Polyethylene without additives | Polyethylene without additives |
| The bottle/ampoule contains [ml] | 20.0-20.5 | 201-207 | 505-512 | 1005-1020 |
| Bottom Ø [mm] | 21 | 58.5 | 78 | 90 |
| Height [mm] | 104 | 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 Safety ApS, 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 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 |
|---------|---------------|-------------|----------------|
| 1.3 | 25-05-2021 | CL | 1.2, 1.3, 3, 5 |
| 1.2 | 30-09-2020 | CL | 5 |
| 1.1 | 03-06-2020 | CL / VWB | 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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