

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 <i>Council Directive 93/42/EEC of 14 June 1993 concerning medical devices</i> , they are certified by Notified Body, Presafe. 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 A/S 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 and 500ml) / Shower eye cup (1000 ml)



DUO eye cup (500 ml)



- Always wash with an ordinary eyewash solution 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.

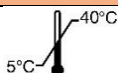
	200 ml bottle	500 ml bottle	1000 ml bottle
Bottle material	Polyethylene without additives	Polyethylene without additives	Polyethylene without additives
The bottle contains [ml]	201-207	505-512	1005-1020
Bottom Ø [mm]	58.5	78	90
Height [mm]	129.6	183	229

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 6471 2112, 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 pictogramm 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
1.0	19-11-2019	CL	New TDS

Other information

Additional information can be obtained by contacting info@plum.eu or by telephone +45 6471 2112.

TDS prepared by:

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