

DATI TECNICI / technical sheet	Soluzione lavaggio oculare BioPhos®74
	<i>Eye wash solution BioPhos® 74</i>

93/42/CEE - 2007/47/CEE

MATERIALI / components

1	Lavaggio oculare a PH neutro	<i>Eye wash solution PH neutral</i>
	Vedi scheda allegata	<i>see enclosed sheet</i>
2	doccetta oculare	polipropilene
	<i>Eye cup</i>	<i>polypropylene</i>
3	tappo protezione doccetta oculare	polipropilene
	<i>protection cap</i>	<i>polypropylene</i>



cod : ACQ406

PVS S.p.A. - Cassina de Pecchi - Italy	20/04/12
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EC Material safety data sheet (MSDS)

(according regulation (EC) No. 1907/2006)

GRAMM Eye wash solution BioPhos[®] 74 (250 ml)

Rev. 1.0 (as of: 01.02.2011)

1. Product and company description

- Trading name: GRAMM Eye wash solution BioPhos[®] 74 (250 ml)
- Art.-No.: 500.100.74200
- Field of application: First aid equipment – (chemical burns of eye and skin)
- Manufacturer/Supplier:
 - Company: GRAMM medical GmbH
 - Street: Werkstr. 13
 - Postcode, City: D-71384 Weinstadt
 - Tel: +49 (0)71 51 – 272 018 – 0
 - Fax: +49 (0)71 51 – 272 018 – 19
 - E-Mail: info@gramm-medical.de
 - Internet: www.gramm-medical.de

2. Potential dangers/risks

- Indication of danger: No hazardous product in terms of regulation 1999/45/EC.
- Specific danger warnings for humans and environment:
No hazardous product in terms of regulation 1999/45/EC.
- GHS characterization: n/a
- Additional information: Product is not suitable for infusion, injection or other internal application on humans and animals. Product may not be mixed, blended or used in the same time with pharmaceutical or other third-party products according to the destined specific function.
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3. Composition / Ingredient information

Chemical characterization by ingredients:	CAS-Nr.:	EC-No.:	Gew.-%
• Water (Aqua)	7732-18-5	231-791-2	95,2
• Buffered salt mixture, consisting of :			4,8 ^(*)
(a) di-sodiumhydrogenphosphate dihydrate	10028-24-7	231-448-7	
(b) Sodiumhydrogenphosphate dihydrate	13472-35-0	231-449-2	
(c) Potassiumhydrogenphosphate	7778-77-0	231-913-4	

() calculated to the anhyd salt mixture.*

Workplace guide and limit value according to regulation 2000/39/EC: None

4. First aid measure

- General advice: No special actions necessary. As the circumstances require, contact a doctor of medicine and show label.
- In case of eye contact: The solution is used for neutralization of pH-value in the eye after chemical burns (caused by acids and alkaline solution). After neutralization the eye should be rinsed with a sterile sodium chloride solution 0,9% or water for minimum 15 minutes and turn to a doctor immediately. If possible, any contact lenses should be removed from the eyes.
- In case of skin contact: The solution is used for neutralization of pH-value of the skin after chemical burn (caused by acids or alkaline solution). As the circumstances require, turn to a doctor after neutralization.



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- By taking (swallowing): No specific action necessary. In case of inadvertently swallowing drink a plenty of water and contact a doctor if any troubles occur.
- By inhalation: No specific action necessary. In case of long exposition take care of fresh air supply as required and contact a doctor if any troubles occur.

5. Measures for firefighting

- Precautional measures: Unnecessary
- Special risks: No danger by preparation through combustion products or gases. Eventual fire load through polymeric parts of the packaging should be heeded separately.
- Suitable extinguishing agent: Method to blow out a fire should be adapted to the surrounding fire.

6. Measures in case of inadvertent exposition

- Environment: No specific action necessary. In case of exposition of large quantity it's recommended that to make sure that these quantities do not come undiluted in drain water, bodies of water and/or sewerage.
- Personal protection: n/a

7. Storage and handling

- Handling: No special precautions necessary. For application please note instructions for use.
- Storage: Store unopened, dry and free of damage in original packing by 5 – 25° C. To avoid embrittlement of the material and plastic packing protect the product against sunlight and/or UV light.
- Storage class: 10–13 / Miscellaneous liquids and solids
- Classification according to ordinance on Industrial Safety and Health (BetrSichV): -

8. Limit of exposition and personal protective equipment

- Additional indications for the configuration of technical equipment and constructions: No further information, see point 7.
- Workplace-related elements, to controlled limit values: n/a
- Personal protective equipment (PPE): n/a
- General precautionary measure and sanitary regulation: Product may only be used if it's sterile (unscathed original packing ensured) and if the expiry date is not exceeded.

10. Physical and chemical characteristics

Color:	Colorless, clear, transparent
Form:	Liquid
Scent:	neutral (odorless)
Melting point / Melting range:	< 0 °C
Boiling point / Boiling range:	100 °C
Flashpoint:	Product is not combustible
Ignition temperature:	Product is not flammable
Explosion hazard:	Product is not explosive
Density by 20 °C:	1,037 ± 0,002 g/cm ³



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Solubility in / Miscibility with
Water by 20 °C: Easy and optional miscible and dilutable
pH-value by 20 °C: 7,4 ± 0,2

11. Stability and reactivity

- Conditions to avoid: See point 7 (Storage).
- Solids to avoid: See punkt 16 (Safety instructions).
- Danger reeactions: n/a
- Danger products of decomposition: n/a

12. Toxicological information

- Acute toxicology: None
- Relevant classification LD-50-values of the contained salts as solids in preparation.
(a) Oral LD50: ~ 1700 mg/kg * (Mouse)
(b) Dermal LD50: ~ 4640 mg/kg * (rabbit)
() related to the pure substance (potassiumhydrogenphosphate) with the highest toxicity*
- Primarystimulation effect in case of:
 - (a) Skin contact: None, not irritant
 - (b) Eye contact: Due to the higher tension of salt of the solution compared to the tension of a healthy eye it's possible that by longer exposition a slight stimulation effect or a flush of the eye occurs.
 - (c) Inhalation: None, not irritant when breathing in
 - (d) Taking: By swallowing larger quantities nausea and comiting can occur.
- Sensitization: No sensitizing effect known.

14. Ecology information

- Mobility: Soluble in water, optional miscible and dilutable
- Degradability: 100 %
- Accumulation: None
- Ecotoxic effect:
Aquatic toxicity:
Fisht toxicity * LC50 467 mg/l/48 h (Gambusia affinis)
Daphnia toxicity * EC50 1089 mg/l/48 h (Daphnia magna)
() related to the pure substance (di-Sodiumhydrogenphosphate) with the highest aquatically toxicity*
Notice: Phosphates can promote algal growth. By exposition of larger quantities an fertilizing effect is possible.
- Water hazard class: No classification
Manufacturers recommendation: Make sure that these quantities do not come undiluted in drain water, bodies of water and/or sewerage.

15. Disposal note

- Product: There are no common regulations in the member states of the European Community re the disposal of preparations which contain chemical substances. The way of disposal may be made in strict accordance with the local official Regulations and taking into account that small quantities can be disposed through the regular drain water.



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- Packing: Disposal of untreated packaging material only in accordance with the official regulations. Cleaned packing can be recycled.

16. Transport regulation

The product is no hazardous material in ground, sea or air freight in terms of valid legal positions and applicable regulations. Special directions for transport are not required.

17. Legal provisions

- EC: The product is classified, according to regulation 1999/45/E, as nonhazardous.
- National: Not classified in the Ordinance on Industrial Safety and health (BetrSchV).
- Storage class: 10-13 / Transport class: None / Water hazard class: None

18. Other specifications

- Field of application: Solution is used for rinsing of eye and skin in case of chemical burns when acid or alkaline solutions get in touch with eyes or the skin surface. In any injury and/or chemical burn seek medical advice immediately. The rinsing should be continued with sodium chloride solution of 0,9% during the transport to the doctor.
 - Type of application:
 1. Turn the cap resp. the spray nozzle by 180° in direction of the arrow.
 2. Rinse the eye or the affected skin areas until the bottle is empty.
 3. Continue rinsing with a conventional solution (e.g. sodium chloride 0,9%) for minimum 15 minutes.
 4. Seek medical advice.
 - Durability: The bottles can be used up to three years after manufacturing date (See expiry date on the label).
Opened eye wash bottles and remaining quantities shall not be used, because sterility is not ensured anymore.
19. Safety notes: Not suitable for rinsing liquids which contain calcium and liquids which build poorly soluble compounds with phosphates. Moreover, the product may not be used for infusion, injection and other inner application on humans or animals. Product may not be mixed, blended or used in the same time with pharmaceutical or other third-party products according to the destined specific function.

Legal notices:

All data and information of the present EC safety data sheet is based on our best current knowledge and is intended to provide information on specific properties of the product, safety precaution and its application. The information provided does not represent any warranty or guarantee, be it explicit or implicit, regarding in particular the nature of the product, its merchantability or its suitability for specific purposes and does not constitute a legal relationship.

It is the responsibility of the user if this product is not used as directed, used without the related instructions for use, used without the present safety data sheet, used in combination with any other products or process.