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

93/42/CEE - 2007/47/CEE

MATERIALI / components

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





GRAMM Eye wash solution BioPhos® 74 (250 ml)

Rev. 1.0 (as of: 01.02.2011)

Product and company description

GRAMM Eye wash solution BioPhos® 74 (250 ml) Trading name:

Art.-No.: 500.100.74200

First aid equipment – (chemical burns of eye and skin) Field of application:

Manuacturer/Supplier:

Company: GRAMM medical GmbH

Street: Werkstr. 13

Postcode, City: D-71384 Weinstadt

Tel: +49 (0)71 51 - 272 018 - 0 +49 (0)71 51 - 272 018 - 19 Fax: E-Mail: info@gramm-medical.de www.gramm-medical.de Internet:

2. Potential dangers/risks

Indication of danger: No hazardous product in terms of regulation 1999/45/EC.

Specific danger warnings for humans an 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.

3. Composition / Ingredient information

Chemical characterization by ingredients: CAS-Nr.: EC-No.: Gew.-% 7732-18-5 231-791-2 95,2 Water (Aqua) 4.8 (*) Buffered salt mixture, consisting of : (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

First aid measure

General advice: No special actions necessary. As the circumstances require,

contact a doctor of medicine and show label.

The solution is used for neutralization of pH-value in the eye In case of eye contact:

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.

The solution is used for neutralization of pH-value of the In case of skin contact:

skin after chemical burn (caused by acids or alkline solution). As the circumstances require, turn to a

doctor after neutralization.

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No specific action necessary. In case of inadvertently By taking (swallowing):

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.

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.

Method to blow out a fire should be adapted to the Suitable extinguishing agent:

surrounding fire.

Measures in case of inadvertent exposition

Environment: No specific action necessary. In case of exposition of

large quantity it's recommeded that to make sure that these quantities do not come undilated in drain water, bodies of water

and/or sewerage.

Persnal protection: n/a

7. Storage and handling

Handling: No special precautions necessary. For application please note instructions

for use.

Store unopened, dry and free of damage in original packing by 5 – 25° C. To Storage:

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): -

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 100 °C Boiling point / Boiling range:

Flashpoint: Product is not combustible Ignition temperature: Product is not flammable Explosion hazard: Product is not explosive Density by 20 °C: $1,,037 \pm 0,002 \text{ g/cm}^3$

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Solubility in / Miscibility with

Easy and optional miscible and dilutable Water by 20 °C:

 7.4 ± 0.2 pH-value by 20 °C:

11. Stability and reactivity

Conditions to avoid: See point 7 (Storage).

Solids to avoid: See punkt 16 (Safety instructions).

Danger reeactions: 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.

LD50: ~ 1700 mg/kg * (Mouse) (a) Oral ~ 4640 mg/kg * (rabbit) (b) Dermal LD50:

(*) 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

Phosphates can promote algal growth. By exposition of larger Notice:

quantities an fertilizing effect is possible.

Water hazard class: No classification

Manufacturers recommendation: Make sure that these quantities do not come

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

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.

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 eve wash bottles and remaining quantities shall not be

used, because sterility is not ensured anymore.

Not suitable for rinsing liquids which contain calcium and liquids which 19. Safety notes:

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 quarantee, 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.