

Trade name: Pamifos® 3 mg/ml

Status: 03.06.2008

Version: 2.0.0 / GB

Date of printing: 03.06.2008

1.) Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

Trade name

Pamifos® 3 mg/ml

Company/undertaking identification

Address

medac Gesellschaft für klinische Spezialpräparate mbH
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Telephone no. +49-4103-8006-0

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Information provided by / telephone

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Emergency telephone

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Advice on Safety Data Sheet

sdb_info@umco.de

2.) Hazards identification

Hazard symbols

- N O N E

Particular information pertaining specific risk for human / environment

Although this product is not subject to reporting requirements for hazardous products, we recommend compliance with the safety recommendations.

3.) Composition / information on ingredients

Hazardous ingredients

disodium dihydrogen (3-amino-1-hydroxypropylidene)bisphosphonate

EC no.	260-647-1	Index no.	-	CAS no.	57248-88-1
Concentration	< 0,5			%-b.w.	
Classification	Xn; R22				
Hazard symbols	Xn	R phrases	22		

4.) First aid measures

General information

In case of persisting adverse effects, consult a physician.

After inhalation

In the event of symptoms take medical treatment. Ensure supply of fresh air.

After skin contact

In case of contact with skin wash off immediately with soap and water.

After eye contact

In case of contact with eyes rinse thoroughly with plenty of water. If symptoms persist, seek medical advice.

After ingestion

Rinse out mouth and give plenty of water to drink.

5.) Fire-fighting measures

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases

No risks known.

Special protective equipment for fire-fighters

Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus.

6.) Accidental release measures

Personal precautions

Use personal protective clothing.

Methods for cleaning up/taking up

Pick up with absorbent material. Dispose of absorbed material in accordance with the regulations.

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7.) Handling and storage

Handling

Advice on protection against fire and explosion

No special measures necessary.

Classification of fires

B

Storage

Advice on storage assembly

Adhere to the drug storage ruling provisions.

Further information on storage conditions

Keep container tightly closed in a well-ventilated place.

8.) Exposure controls / personal protection

Exposure limit values

N O N E

Personal protective equipment

Hand protection

In case of intensive contact, wear protective gloves (EN 374). Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product . Before use, the protective glove should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Appropriate Material rubber

Eye protection

Safety glasses (EN 166)

Skin protection

Light protective clothing

General protective and hygiene measures

Avoid contact with eyes and skin. Keep away from foodstuffs and beverages.

9.) Physical and chemical properties

General information

Form	liquid
Colour	clear
Odour	characteristic

Important health, safety and environmental information

Solubility in water

Remarks miscible

10.) Stability and reactivity

Thermal decomposition

Remarks No decomposition if used as prescribed.

11.) Toxicological information

Acute toxicity

Acute oral toxicity

LD50 625 mg/kg

Species

mouse

Reference substance

Phosphonic acid, (3-amino-1-hydroxypropylidene)bis-, disodium salt

Acute dermal toxicity

Remarks No data available.

Acute inhalational toxicity

Remarks No data available.

Irritant/corrosive effects

Irritant effect on skin

Remarks No data available.

Irritant effect on eyes

Evaluation non-irritant

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Sensitisation

Remarks No data available.

Effects after repeated or prolonged exposition (subacute, subchronic, chronic)

Mutagenicity

Remarks No data available.

Reproduction toxicity

Remarks No data available.

Carcinogenicity

Remarks No experimental information on carcinogenic effects available.

12.) Ecological information

Ecotoxicity

Fish toxicity

Remarks No data available.

Daphnia toxicity

Remarks No data available.

Algae toxicity

Remarks No data available.

Bacteria toxicity

Remarks No data available.

Persistence and degradability

Biodegradability

Remarks No data available.

Other adverse effects

Do not discharge product unmonitored into the environment.

13.) Disposal considerations

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Uncontaminated packaging may be taken for recycling.
Packaging that cannot be cleaned should be disposed off as product waste.

14.) Transport information

Other information (chapter 14.)

No hazardous material as defined by the transport regulations.

15.) Regulatory information

Labelling in accordance with EC directives

The product does not require a hazard warning label in accordance with EC Directives.

The product is not subject to the chemicals act. However it has been classified according to the rules of the chemicals act, so that the precautionary measures comply with the procedures generally foreseen for chemicals handling and to make them comparable.

Hazard symbols

-

N O N E

National regulations

Other regulations, restrictions and prohibition regulations

Adhere to : TRGS 525 "Handling of hazardous substances in facilities for human medical care".

BGI 754: "Safer handling with dangerous substances in the pharmaceutical industry"

16.) Other information

Further information

Processing notes

Please read packing specification of the drug for additional drug related information.

The data of this safety data sheet reflect the actual state of knowledge. The safety data sheet describes the product in view of its handling and safety relevant requirements of the pharmaceutical ingredient as bulk ware (chemical).

The information is based on our current knowledge however it does not represent a guarantee of product properties nor does it create any legal obligation.

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Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 99/45/EC as amended in each case.

Regulation (EC) No 1907/2006 (REACH) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC as amended in each case.

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Relevant R-phrases (chapter 3):

22 Harmful if swallowed.

Department issuing safety data sheet

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Ready-made medical preparations are not ruled by the chemical's act, so that the submission of a safety data sheet is not obligatory. Medac, however, opts for this form because the safety data sheet constitutes a reliable source of information regarding the handling of hazardous substances and preparations, and because many occupational safety measures are basing on the safety data sheet structure.