

Trade name: Sodiofolin® (folinic acid, sodium folinate)

Status: 03.06.2008

Version: 4.0.0 / 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

**Sodiofolin® (folinic acid, sodium folinate)**

Use of the substance/preparation

pharmaceutical products

### Company/undertaking identification

Address

medac Gesellschaft für klinische Spezialpräparate mbH

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Information provided by / telephone

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Emergency telephone

+49(0)551 / 19240 {Giftinformationszentrum Nord (GIZ-Nord)} (Service in english)

Advice on Safety Data Sheet

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## 2.) Hazards identification

Classification

R42/43 May cause sensitisation by inhalation and skin contact.

Hazard symbols

Xn Harmful

R phrases

42/43 May cause sensitisation by inhalation and skin contact.

## 3.) Composition / information on ingredients

Hazardous ingredients

sodium hydrogen N-[4-[[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridiny]methyl]amino]benzoyl]-L-glutamate

EC no.	255-839-7	Index no.	-	CAS no.	42476-21-1
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Concentration	5	%-b.w.
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Classification	Xi; R36/37/38	R42/43
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Hazard symbols	Xn	R phrases	36/37/38-42/43
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## 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.

Other information

Collect contaminated firefighting water separately, must not be discharged into the drains.

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## 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.

## 7.) Handling and storage

### Handling

#### Advice on protection against fire and explosion

No special measures necessary.

### 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

#### Respiratory protection

In case of aerosol and mist formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

#### 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		
Material thickness	>	0,2	mm

#### 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
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## 10.) Stability and reactivity

### Thermal decomposition

Remarks	No decomposition if used as prescribed.
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## 11.) Toxicological information

### Acute toxicity

#### Acute oral toxicity

Remarks	No data available.
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#### Acute dermal toxicity

Remarks	No data available.
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#### Acute inhalational toxicity

Remarks	No data available.
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## Irritant/corrosive effects

### Irritant effect on skin

Remarks No data available.

### Irritant effect on eyes

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 data available.

## Experience in practice

Irritates the eyes and the skin.

Irritates respiratory tract.

Allergic reactions possible ( analogy-reasons ).

## 12.) Ecological information

### Persistence and degradability

#### Biodegradability

Evaluation biodegradable

### Other adverse effects

Ecological data are not available.

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 is classified and labelled in accordance with EC Directive 1999/45/EC.

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

Xn Harmful

### Hazardous component(s) to be indicated on label, contains:

sodium hydrogen N-[4-[[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridiny]methyl]amino]benzoyl]-L-glutamate

### R phrases

42/43 May cause sensitisation by inhalation and skin contact.

### S phrases

23.4 Do not breathe spray.  
 24 Avoid contact with skin.  
 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
 36/37 Wear suitable protective clothing and gloves.

## 16.) Other information

### Further information

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.

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

Data in the safety data sheet refer to the substance in the tube.

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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):**

36/37/38

Irritating to eyes, respiratory system and skin.

42/43

May cause sensitisation by inhalation and skin contact.

**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.