

Trade name: Urokinase HS medac (urokinase)

Status: 03.06.2008

Version: 3.0.0 / 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****Urokinase HS medac (urokinase)****Use of the substance/preparation**

pharmaceutical products

**Company/undertaking identification****Address**

medac Gesellschaft für klinische Spezialpräparate mbH

Fehlandtstrasse 3

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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**

sdb\_info@umco.de

**2.) Hazards identification****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****Chemical characterization**

Kinase (enzyme-activating), uro

**Substance / product identification**

CAS no. 9039-53-6

EC no. 232-917-9

**4.) First aid measures****General information**

If the patient is likely to become unconscious, place and transport in stable sideways position.

**After inhalation**

Take medical treatment. Ensure supply of fresh air.

**After skin contact**

In case of contact with skin wash off immediately with soap and water. Consult a doctor if skin irritation persists.

**After eye contact**

In case of contact with eyes rinse thoroughly with copious amounts of water and seek medical advice.

**After ingestion**

Induce vomiting if patient is conscious, seek medical advice. Seek medical attention.

**Advice to doctor****Treatment**

urokinase effect inhibiting effect: antifibrinolytics such as aprotinine, e-aminocaprone acid and tranexame acid

**5.) Fire-fighting measures****Suitable extinguishing media**

extinguishing powder; Carbon dioxide; Alcohol-resistant foam; Water spray jet

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

Fire gas of organic material has to be classed invariably as respiratory poison.

**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**

Keep people away and stay on the upwind side. Use personal protective clothing. Avoid dust formation.

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**Environmental precautions**

Do not allow to enter drains or waterways.

**Methods for cleaning up/taking up**

Take up mechanically and send for disposal.

**7.) Handling and storage**

**Handling**

**Advice on safe handling**

Avoid absolutely dust formation and dust deposition. Open and handle container with care. Only qualified and trained persons are authorised to handle

**Storage**

**Further information on storage conditions**

Keep container tightly closed in a well-ventilated place. Protect from heat and direct sunlight.

**8.) Exposure controls / personal protection**

**Exposure limit values**

N O N E

**Exposure controls**

**Occupational exposure controls**

See chapter 7; no measures exceeding the ones mentioned are necessary.

**Personal protective equipment**

**Respiratory protection**

If ventilation insufficient, use a respiratory protection apparatus.

Respiratory filter (part): min. P2

**Hand protection**

Disposable gloves with long gauntlet and, if possible, revolving sleeve made of natural Latex, PVC or synthetics with tight closing band around the gauntlet (i.e. Biogel®Standard; Biogel®Skinsense™ or Biogel®Indicator)

- unpowdered, poor protein content, close-fitting, firm surface
- quality requirements according to DIN EN 374
- finger area designed with double wall thickness
- advantageous: dyed gloves recommendation
- Wearing of two pairs of gloves (i.e. Biogel®Indicator™)

Material thickness > 0,2 mm

**Eye protection**

Safety glasses with side protection shield (EN 166)

**Skin protection**

Clothing as usual in the chemical industry.

**General protective and hygiene measures**

At work do not eat, drink, smoke or take drugs. Keep separated from food-stuffs and feed-stocks.

**9.) Physical and chemical properties**

**General information**

Form	Tablets
Colour	whitish
Odour	odourless

**10.) Stability and reactivity**

**Conditions to avoid**

No hazardous reactions known.

**Thermal decomposition**

Remarks No decomposition if used as prescribed.

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## 11.) Toxicological information

### Acute toxicity

#### Acute oral toxicity

LD50	>	2,727	mg/kg
Species		rat	
Source		RTECS	
Remarks		highest dose tested	
LD50	>	2,272	mg/kg
Species		mouse	
Source		RTECS	
Remarks		highest dose tested	
LD50	>	0,909	mg/kg
Species		dog	
Source		RTECS	

#### Acute dermal toxicity

Remarks No data available.

#### Acute inhalational toxicity

Remarks No data available.

#### Acute toxicity / further data

LD50	>	2,727	mg/kg
Species		rat	
Route of exposure		s.c.	
Source		RTECS	
LD50	>	2,727	mg/kg
Species		mouse	
Route of exposure		s.c.	
Source		RTECS	

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

#### Reproduction toxicity

Remarks No indications of toxic effects were observed in reproduction studies in animals.

#### Carcinogenicity

Remarks No experimental information on carcinogenic effects available.

#### Other information (chapter 11.)

Mortality has not been found with the tested concentrations. From an industrial toxicological point of view non-toxic properties can be assumed starting from practical experience.

## 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.

## 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

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

## 14.) Transport information

## 15.) Regulatory information

### Labelling 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.

### Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Remarks Annex I: not listed.

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**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**

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.

**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.

**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.