

# EC safety data sheet

**Trade name:** Gliolan ® 30 mg/ml

**Product no.:** MED067

**Current version :** 1.1.0, issued: 17.04.2012

**Replaced version:** 1.0.0, issued: 18.12.2008

**Region:** GB

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

**Trade name**

**Gliolan ® 30 mg/ml**

**Identification numbers**

CAS no. 5451-09-2

EC no. 226-679-5

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

**Relevant identified uses of the substance or mixture**  
pharmaceutics

### 1.3 Details of the supplier of the safety data sheet

**Address**

medac Gesellschaft für klinische Spezialpräparate mbH  
Fehlandtstrasse 3  
20354 Hamburg

Telephone no. +49-4103-8006-0

Fax no. +49-4103-8006-100

**Information provided by / telephone**

Wedel site: Tel: +49 (4103)-8006-0; Fax: +49 (4103)-8006-100

**Advice on Safety Data Sheet**

sdb\_info@umco.de

### 1.4 Emergency telephone number

For medical advice (in German and English):  
+49 (0)551 192 40 (Giftinformationszentrum Nord)

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

**Classification information**

This product does not meet the classification and labelling criteria given in the Regulation (EC) No 1272/2008 (CLP).

This product does not meet the classification and labelling criteria given in the Dangerous Preparations Directive 67/548/EC (DSD)

### 2.2 Label elements

Not relevant

### 2.3 Other hazards

No data available.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

**Chemical characterization**

Substance name 5-amino-4-oxopentanoic acid

Formula C<sub>5</sub>H<sub>10</sub>CINO<sub>3</sub>

Molecular weight 167,61

**Identification numbers**

CAS no. 5451-09-2

EC no. 226-679-5

### 3.2 Mixtures

Not applicable. The product is not a mixture.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

**After inhalation**

Ensure supply of fresh air.

**After skin contact**

In case of contact with skin wash off with water.

**After eye contact**

In case of contact with eyes rinse thoroughly with water.

**After ingestion**

Let plenty of water be drunk in small gulps. Seek medical advice if you feel unwell.

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## 4.2 Most important symptoms and effects, both acute and delayed

No data available.

## 4.3 Indication of any immediate medical attention and special treatment needed

No data available.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Water; Foam; extinguishing powder

#### Unsuitable extinguishing media

No data available.

### 5.2 Special hazards arising from the substance or mixture

Combustion products of this material have to be classed invariably as respiratory poison. In the event of fire, the following can be released: Nitrous oxides (NOx); Hydrogen chloride (HCl); Carbon dioxide (CO<sub>2</sub>); Carbon monoxide (CO)

### 5.3 Advice for firefighters

Defeat developing combustible gases with water spray.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Avoid dust formation.

#### For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

### 6.2 Environmental precautions

Do not allow to enter soil, waterways or waste water canal.

### 6.3 Methods and material for containment and cleaning up

Take up mechanically. Send in suitable containers for recovery or disposal. Avoid raising dust. Clean thoroughly.

### 6.4 Reference to other sections

No data available.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

#### Advice on safe handling

Provide good ventilation of working area (local exhaust ventilation, if necessary).

#### General protective and hygiene measures

Remove soiled or soaked clothing immediately. Wash hands and skin before breaks and after work. Do not eat, drink or smoke during work time. Do not inhale dust.

#### Advice on protection against fire and explosion

Dust can form an explosive mixture with air. Take precautionary measures against static charges. Keep away from sources of heat and ignition.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Technical measures and storage conditions

Keep container tightly closed. Store in a dry place.

#### Advice on storage assembly

Do not store together with oxidizing agents.

### 7.3 Specific end use(s)

No data available.

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

No parameters available for monitoring.

### 8.2 Exposure controls

#### Appropriate engineering controls

No data available.

#### Personal protective equipment

##### Respiratory protection

In case of dust formation, use a fine dust face mask.

##### Eye / face protection

Safety glasses (EN 166)

##### Hand protection

Chemical resistant 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 gloves 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.

##### Other

Protective clothing

##### Environmental exposure controls

No data available.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Form/Colour</b>	
Powder	
white	
<b>Odour</b>	
odourless	
<b>Odour threshold</b>	
No data available	
<b>pH value</b>	
No data available	
<b>Boiling point / boiling range</b>	
No data available	
<b>Melting point / melting range</b>	
Value	150 - 156 °C

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## Decomposition point / decomposition range

No data available

## Flash point

No data available

## Auto-ignition temperature

No data available

## Oxidising properties

No data available

## Explosive properties

No data available

## Flammability (solid, gas)

No data available

## Lower flammability or explosive limits

No data available

## Upper flammability or explosive limits

No data available

## Vapour pressure

No data available

## Vapour density

No data available

## Evaporation rate

No data available

## Relative density

No data available

## Density

No data available

## Bulk density

Value	appr.	400	kg/m <sup>3</sup>
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## Solubility in water

Value	800	g/l
Reference temperature	20	°C

## Solubility(ies)

No data available

## Partition coefficient: n-octanol/water

No data available

## Viscosity

No data available

## 9.2 Other information

### Other information

No data available.

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available.

### 10.2 Chemical stability

No data available.

### 10.3 Possibility of hazardous reactions

No data available.

### 10.4 Conditions to avoid

Extreme heat

### 10.5 Incompatible materials

Reactions with strong oxidising agents.

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## 10.6 Hazardous decomposition products

Nitrous gases; Hydrogen chloride (HCl)

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

<b>Acute oral toxicity</b>	
Remarks	No data available.
<b>Acute dermal toxicity</b>	
Remarks	No data available.
<b>Acute inhalational toxicity</b>	
Remarks	No data available.
<b>Skin corrosion/irritation</b>	
Remarks	No data available.
<b>Serious eye damage/irritation</b>	
Remarks	No data available.
<b>Respiratory or skin sensitisation</b>	
No data available	
<b>Germ cell mutagenicity</b>	
Type of examination	In vivo mammalian germ cells - chromosome effects
Source	HSDB
Remarks	No experimental indications on genotoxicity in vivo found.
<b>Reproduction toxicity</b>	
No data available	
<b>Carcinogenicity</b>	
No data available	
<b>STOT-single exposure</b>	
No data available	
<b>STOT-repeated exposure</b>	
No data available	
<b>Aspiration hazard</b>	
No data available	
<b>Other information</b>	
Our data are not sufficient for a complete toxicological judgement. Follow the usual hygienic directives for handling with chemicals. Take the precautions customary when handling chemicals.	

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## SECTION 12: Ecological information

### 12.1 Toxicity

<b>Fish toxicity</b>
No data available
<b>Daphnia toxicity</b>
No data available
<b>Algae toxicity</b>
No data available
<b>Bacteria toxicity</b>
No data available

### 12.2 Persistence and degradability

No data available.

### 12.3 Bioaccumulative potential

No data available.

### 12.4 Mobility in soil

No data available.

### 12.5 Results of PBT and vPvB assessment

No data available.

### 12.6 Other adverse effects

No data available.

### 12.7 Other information

<b>Other information</b>
Ecological data are not available.
Do not discharge product unmonitored into the environment.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

#### 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

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

## SECTION 14: Transport information

### 14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

### 14.2 Transport IMDG

The product is not subject to IMDG regulations.

### 14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

### 14.4 Other information

No data available.

### 14.6 Special precautions for user

No data available.

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU regulations

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

Remarks

Annex I: not listed.

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## 15.2 Chemical safety assessment

No data available.

## SECTION 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.

### 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), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EC

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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