

## Material Safety Data Sheet

Date of issue:

23.09.2009

Supersedes edition of:

05.09.2007

### 1. Chemical Product and Company Identification

**Trade name:** Berinert®  
**Common name:** C1 esterase inhibitor, human  
**Manufacturer:** CSL Behring GmbH  
Emil-von-Behring Straße 76  
35041 Marburg  
Germany  
Tel: +49 (64 21) 39-0

**U.S. Telephone Number:** (610) 878-4000

**Emergency Telephone Number:** (800) 504-5434

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### 2. Composition / Information on Ingredients

**Material:** Medicinal product derived from human plasma  
**Active ingredient:** C1 esterase inhibitor, human (C1-INH)  
(non hazardous component)  
**Other components:** Aminoacetic acid, sodium chloride, sodium citrate  
(non hazardous components)  
**Content:** 500 U per vial  
**Packaging units:** Pack with 1 vial with dried drug substance and 1 ampoule with 10 ml for injections (solvent)

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### 3. Potential Hazards

No hazardous product according to guideline 67/548/EWG.

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### 4. First Aid Measures

#### General

Take off and remove dirty clothes

#### Inhalation

Not applicable

#### Skin Contact

Wash off with water

## **Eye Contact**

Flush thoroughly with copious amounts of water. In case of enduring disorders seek medical advice.

## **Ingestion**

Drink water

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## **5. Fire Fighting Measures**

### **Extinguishing Media**

Water or any medium suitable for extinguishing

### **Special hazards caused by the product, by its combustion products or by developing gases**

Not applicable

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## **6. Accidental Release Measures**

### **Personal Measures**

Avoid the formation of dust.

### **Environmental Measures**

No environmental hazard known

### **Purification / Absorption**

Collect/adsorb spilled material and dispose properly

Dispose the absorbent material

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## **7. Handling and Storage**

### **General**

General precautions for handling of pharmaceuticals are to be considered.

### **Storage Information**

Keep container closed tightly

Store and transport at +2 to +25 °C (+36 to +77 °F)

Do not freeze

Store locked up or accessible for authorized persons or their representatives only

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## **8. Exposure Controls / Personal Protection**

## Respiratory Protection

Not required

## Hand Protection

Not applicable

## Eye Protection

Not applicable

## Hygienic Measures

Do not drink and eat at work

Take off dirty clothes

Wash hands immediately after work

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## 9. Physical and Chemical Properties

Physical state	Colour	Smell
solid	white	none
<b>Molecular weight</b>	<b>105 KD</b>	
<b>Melting Point</b>	Not applicable	
<b>Refraction index</b>	Not applicable	
<b>Water Solubility</b>	Readily soluble	
<b>pH</b>	6.5 – 7.5	

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## 10. Stability and Reactivity

### Conditions to avoid

Storage temperature must not fall below +2°C and not exceed +25°C (+36 °F and not exceed +77 °F)

### Hazard Decomposition Product

None

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## 11. Toxicological Information

### Single dose studies:

Acute toxicity studies were performed in rodents (mice, rats) with single i.v. injection. Up to doses of 6000 U/kg (mice) and 3000 U/kg (rats), no toxic findings were observed.

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## Local tolerance:

Rabbits were injected with 5 mL (1500 U/rabbit) i.v. The substance was regarded as local tolerable after i.v. injection.

### **1.1.1 Safety Pharmacology**

Dogs were injected i.v. at a maximal dose of 3500 U/kg b.w.. No relevant adverse effects were observed.

### **1.1.2 Neoantigenicity**

No evidence for the generation of a neoepitope in the C1 esterase inhibitor molecule was detected in a rabbit/guinea pig study.

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## **12. Ecological Information**

The nature as human plasma protein does not provide any risk for the environment (water, soil, air).

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## **13. Disposal Consideration**

This material should be disposed off in accordance with local, state and / federal regulations. Not classified as Hazardous waste.

EWC-Code: 180109 (070599)

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## **14. Transport Information**

**Proper shipping name:** Not regulated

**Hazard class:** Not required

This material is not regulated by US-DOT and European Transport regulations. A copy of this Material Safety Data Sheet should accompany shipments of this material.

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## **15. Regulatory Information**

No hazardous product according to guideline 67/548/EWG.

The product has been licensed as Drug in several countries worldwide since 1992

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## **16. Other Information**

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the users responsibility to determine the suitability of this information for the adaptation of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.