

## Material Safety Data Sheet

Date of issue:

17.01.2007

Supersedes edition of:

24.08.2004

### 1. Chemical Product and Company Identification

**Trade name:** Vivaglobin®  
**Common name:** Human normal immunoglobulin  
**Manufacturer:** CSL Behring GmbH  
Emil-von-Behring Straße 76  
35041 Marburg  
Germany  
Tel: +49 (64 21) 39-0

**Emergency telephone No.:** Please contact the regional CSL Behring representation in your country

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### 2. Composition / Information on Ingredients

**Material:** Medicinal product derived from human plasma  
**Active ingredient:** Human normal immunoglobulin  
(non hazardous component)  
**Other components:** Aminoacetic acid ( glycin),sodium chloride ( non Hazard compument)  
**Packaging units:** **EU:** Pack with 5 ml ampoule(s) or 10 ml injection vial(s)  
**US:** Pack with 3,10 or 20 ml injection vial(s)

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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

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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**

General precautions for handling of pharmaceuticals are to be considered

### **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 +8 °C

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
liquid	colourless	None
<b>Molecular weight</b>	about 150 KD	
<b>Melting Point</b>	Not applicable (Decomposition)	
<b>Refraction index</b>	Not applicable	
<b>Water Solubility</b>	Readily soluble	
<b>pH</b>	6.4 – 7.2	

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## 10. Stability and Reactivity

### Conditions to avoid

Storage temperature must not fall below +2°C and not exceed +8°C

### Hazard Decomposition Product

None

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## 11. Toxicological Information

All product components are considered to be non hazardous. The product is intended for subcutaneous or intramuscular application only, therefore no oral, dermal or inhalation toxicity studies have been performed.

### Single dose studies:

Acute toxicity studies were performed in rodents (mice, rats) with single i.m. and s.c. injection. In the i.m. studies mice were administered with a dose up to 8 g/kg and rats with a dose up to 1.6 g/kg b.w.. In the s.c. studies both (mice and rats) were administered with a dose of 600 mg/kg b.w.. No relevant toxic findings were observed in these studies.

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## Local tolerance:

Rabbits were injected with 0.5 mL (80 mg/rabbit) i.m. or s.c.. The substance was regarded as local tolerable after s.c. and i.m. injection.

## **Safety Pharmacology**

Dogs were injected i.m. at a maximal dose of 480 mg/kg (3 mL/kg) b.w.. No relevant adverse effect was observed.

In a further study dogs were injected s.c. at a maximal dose of 400 mg/kg (2.5 mL/kg b.w.). No relevant, adverse effects were caused by the s.c. treatment.

## **Neoantigenicity**

No evidence for the generation of a neoepitope 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.