Material Safety Data Sheet

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

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 compoment)
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)

3. Potential Hazards

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

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

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

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

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

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

### 9. Physical and Chemical Properties

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<thead>
<tr>
<th>Physical state</th>
<th>Colour</th>
<th>Smell</th>
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</thead>
<tbody>
<tr>
<td>liquid</td>
<td>colourless</td>
<td>None</td>
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**Molecular weight**
about 150 KD

**Melting Point**
Not applicable (Decomposition)

**Refraction index**
Not applicable

**Water Solubility**
Readily soluble

**pH**
6.4 – 7.2

### 10. Stability and Reactivity

**Conditions to avoid**
Storage temperature must not fall below +2°C and not exceed +8°C

**Hazard Decomposition Product**
None

### 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.
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.

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

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)

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.

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
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.