1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
Product Identity
Beriate 250/500/1000
Alternate Names
Beriate 250/500/1000

1.2. Relevant identified uses of the substance or mixture and uses advised against
Intended use
See Technical Data Sheet.
Application Method
See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet
Company Name
CSL Behring L.L.C.
1020 First Avenue
PO Box 61501
King of Prussia, PA

Emergency
24 hour Emergency Telephone No.
Emergency Response: (800) 424-9300
Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring L.L.C.
(610) 878-4000

2. Hazard identification of the product

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008
No applicable CLP categories.
Classification according to 67/548/EEC or 1999/45/EC.

No applicable DPD categories.

2.2. Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.
According to Regulation (EC) No 1272/2008
[Prevention]:
No CLP prevention statements
[Response]:
No CLP response statements
[Storage]:
No CLP storage statements
[Disposal]:
No CLP disposal statements
See Technical Data Sheet.

2.3. Other hazards
This product contains no PBT/vPvB chemicals.

### 3. Composition/information on ingredients

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Non-Hazardous Ingredients:
- Material: Medicinal product derived from human plasma
- Active ingredient: Human Coagulation Factor VIII (non-hazardous component)
- Other components: Glycine, Sodium Chloride, Sucrose (non-hazardous components)

Packaging units: 1 vial with 90-134 mg/250 IU package, 179-268 mg/500 IU package or 359-536 mg/1000 IU package dried substance
- 1 vial with 2.5, 5 or 10 ml water for injections
- 1 transfer device

### 4. First aid measures

#### 4.1. Description of first aid measures

**General**
In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

**Inhalation**
Remove to fresh air.

**Eye**
Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

**Skin**
Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

**Ingestion**
Drink water. Obtain medical attention if feeling ill.

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

**Overview**
No specific symptom data available.
See section 2 for further details.

### 5. Fire-fighting measures

#### 5.1. Extinguishing media

As suitable for surrounding fire.

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

Hazardous decomposition: No hazardous decomposition data available.

#### 5.3. Advice for fire-fighters

None

ERG Guide No. ----

### 6. Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures
Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions
Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up
Collect/absorb spilled material and dispose of properly.

7. Handling and storage

7.1. Precautions for safe handling
General precautions for handling of pharmaceuticals are to be considered. Protect from light when handling.

7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage.
Storage and transportation temperatures should not fall below 2°C and not exceed 8°C.
Incompatible materials: No data available.
Keep container closed tightly.
Store locked up or accessible to authorized persons or their representatives only.

7.3. Specific end use(s)
No data available.

8. Exposure controls and personal protection

8.1. Control parameters
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

8.2. Exposure controls
Respiratory: Not Applicable
Eyes: Not Applicable
Skin: Not Applicable

Engineering Controls: Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

Other Work Practices: Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>White Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>None</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not Measured</td>
</tr>
<tr>
<td>pH</td>
<td>6.5-7.5 (reconstituted product)</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not Measured</td>
</tr>
</tbody>
</table>
10. Stability and reactivity

10.1. Reactivity
Hazardous Polymerization will not occur.

10.2. Chemical stability
Stable under normal circumstances.

10.3. Possibility of hazardous reactions
No data available.

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

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No hazardous decomposition data available.

11. Toxicological information

Acute toxicity

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

Single dose toxicity studies:
Acute toxicity studies were performed in rodents (mice, rats) with single i.v injection. Mice were administered with a dose up to 1250 IU/kg and rats with a dose up to 500 IU/kg b.w.. No relevant toxic findings were observed in these studies.

Local tolerance:
Rabbits were injected with 0.5 mL (50 IU/mL) i.v. or i.a. and with 0.1 mL (50 IU/mL) p.v., respectively. In another study rabbits were administered with 0.5 mL (100 IU/mL). The substance was regarded as local tolerable after i.v., i.a. and p.v. injection.

Safety Pharmacology:
Dogs were injected i.v. with 3 consecutive doses of 25, 50 and 100 IU/kg (total of 175 IU/kg) b.w.. No relevant adverse effect was observed.

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product’s ATE (Acute Toxicity Estimate).

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

12. Ecological information

12.1. Toxicity
No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

12.2. Persistence and degradability
There is no data available on the preparation itself.

12.3. Bioaccumulative potential
Not Measured

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects
No data available.

## 13. Disposal considerations

13.1. Waste treatment methods
Observe all federal, state and local regulations when disposing of this substance.

## 14. Transport information

<table>
<thead>
<tr>
<th>DOT (Domestic Surface Transportation)</th>
<th>IMO / IMDG (Ocean Transportation)</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
<tr>
<td>14.1. UN number</td>
<td>14.2. UN proper shipping name</td>
<td>14.3. Transport hazard classes</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>DOT Hazard Class: Not Applicable</td>
</tr>
<tr>
<td>14.4. Packing group</td>
<td>IMDG: Not Applicable</td>
<td>Sub Class: Not Applicable</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IMDG Marine Pollutant: No</td>
<td>14.5. Environmental hazards</td>
<td></td>
</tr>
<tr>
<td>14.6. Special precautions for user</td>
<td>IMDG: Not Applicable</td>
<td>Air class: Not Applicable</td>
</tr>
<tr>
<td>No further information</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

## 15. Regulatory information

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

**EU Legislation**


**National Legislation**

None noted.

## 16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein.
We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

Not Applicable

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

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End of Document