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

1.1. Product identifier

Product Identity  Beriplex P/N 250/500
Alternate Names  Beriplex P/N 250/500

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: Concentrate of human Coagulation Factors II, VII, IX, X, Protein C and Protein S (non hazardous component)

Other components: Human Albumin, Antithrombin III and Heparin (non-hazardous components)

Packaging units: 1 vacuum vial with dried substance and one vial with 10 or 20 ml water for injections

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
Beriplex is made from human plasma. Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. There is also the possibility that unknown infectious agents may be present in such products. The risk that such products could transmit viruses has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and removing certain viruses during manufacture. Despite these measures, such products may still potentially transmit disease. 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.
Avoid formation of dust.

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 exceed 25C. Keep away from light. Do not freeze.
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 Avoid formation of dust.
Eyes Not Applicable
Skin Not Applicable
Engineering Controls Provide adequate ventilation.
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.

See section 2 for further details. - [Prevention]:

9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>White Solid</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>Not Measured</td>
</tr>
</tbody>
</table>
Melting point / freezing point  Not Measured
Initial boiling point and boiling range Not Measured
Flash Point Not Measured
Evaporation rate (Ether = 1) Not Measured
Flammability (solid, gas) Not Applicable
Upper/lower flammability or explosive limits Lower Explosive Limit: Not Measured
Upper Explosive Limit: Not Measured
Vapor pressure (Pa) Not Measured
Vapor Density Not Measured
Specific Gravity Not Measured
Solubility in Water Readily Soluble
Partition coefficient n-octanol/water (Log Kow) Not Measured
Auto-ignition temperature Not Measured
Decomposition temperature Not Measured
Viscosity (cSt) Not Measured
9.2. Other information
No other relevant information.

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 and transportation temperatures should not exceed 25°C. Keep away from light. Do not freeze.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No hazardous decomposition data available.

11. Toxicological information

Acute toxicity
The active ingredients of Beriplex® P consists the coagulation factors of the prothrombin complex (FII, FVII, FIX and FX) and protein C and protein S in enriched formulation which has been derived from human plasma. Standard measures to prevent infections resulting from the use of the medicinal product include selection of donors, screening of individual donations and plasma pool for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses.

All product components are considered to be non hazardous. The product is intended for intravenous application, therefore oral, dermal or inhalation toxicity studies are not relevant.
Single dose studies:
Acute toxicity studies were performed in rodents (mice, rats) with single i.v. injection. Mice were administered with a dose of 20, 60 and 200 U/kg b.w. and rats with a dose of 20, 50, and 100 U/kg body weight respectively. In mice, a dose of 60 U/kg was tolerated, 200 U/kg induced mild signs of toxicity. In rats, acute lethal i.v. dose demonstrated to be greater than 100 U/kg.

Local tolerance:
Rabbits were injected with 5 mL/rabbit (43.5 U/kg) i.v. or i.a. and with 0.1 mL/rabbit (0.9 U/kg) p.v. respectively. The substance was regarded as moderately tolerable after i.v., i.a. and p.v. injection. In another study rabbits were injected with 5 mL/rabbit (50 U/kg) i.v.. In this study the substance was regarded as local tolerable after i.v. injection.

Safety Pharmacology:
Dogs were injected i.v. at a maximal total dose of 350 U/kg body weight. No relevant adverse effect was observed.

Neoantigenicity:
No evidence for the generation of a neoepitope was detected in a rabbit study.
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>DOT Hazard Class: Not Applicable</td>
<td>IMDG: Not Applicable</td>
<td>Air class: Not Applicable</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>Sub Class: Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

14.5. Environmental hazards

IMDG Marine Pollutant: No

14.6. Special precautions for user
No further information

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

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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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