

## 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

<b>Appearance</b>	White Solid
<b>Odor</b>	None
<b>Odor threshold</b>	Not Measured
<b>pH</b>	Not Measured

<b>Melting point / freezing point</b>	Not Measured
<b>Initial boiling point and boiling range</b>	Not Measured
<b>Flash Point</b>	Not Measured
<b>Evaporation rate (Ether = 1)</b>	Not Measured
<b>Flammability (solid, gas)</b>	Not Applicable
<b>Upper/lower flammability or explosive limits</b>	<b>Lower Explosive Limit:</b> Not Measured <b>Upper Explosive Limit:</b> Not Measured
<b>Vapor pressure (Pa)</b>	Not Measured
<b>Vapor Density</b>	Not Measured
<b>Specific Gravity</b>	Not Measured
<b>Solubility in Water</b>	Readily Soluble
<b>Partition coefficient n-octanol/water (Log Kow)</b>	Not Measured
<b>Auto-ignition temperature</b>	Not Measured
<b>Decomposition temperature</b>	Not Measured
<b>Viscosity (cSt)</b>	Not Measured
<b>9.2. Other information</b>	
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 25C. 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).

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

## 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

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

## 15. Regulatory information

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

#### EU Legislation

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

#### National Legislation

None noted.

<b>16. Other information</b>
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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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