

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.
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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 2C and not exceed 8C.

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

Appearance	White Liquid
Odor	None
Odor threshold	Not Measured
pH	6.5-7.5 (reconstituted product)
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
Molecular Weight	about 265 KD

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 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).

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

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
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

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.

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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