

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

### 1.1. Product identifier

**Product Identity** Berinin® P  
**Alternate Names** Human Coagulation Factor IX

### 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.

**Material:** Medicinal product derived from human plasma.

**Active ingredient:** Human Coagulation Factor IX (non hazardous component).

**Other components:** Aminoacetic acid, sodium citrate, Sodium chloride (non hazardous components).

**Packaging units:** Pack with 1 bottle of dried substance (300, 600 or 1200 IU) and one vial with 2.5, 5 or 10 ml water for injections.

## 4. First aid measures

### 4.1. Description of first aid measures

<b>General</b>	Take off and remove dirty clothes.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye</b>	Flush thoroughly with copious amounts of water. In case of enduring disorders seek medical advice.
<b>Skin</b>	Wash off with water.
<b>Ingestion</b>	Drink water. Obtain medical attention if feeling ill.

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

<b>Overview</b>	No specific symptom data available.
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## 5. Fire-fighting measures

### 5.1. Extinguishing media

Water or any medium suitable for extinguishing.

### 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

Do not allow spills to enter drains or waterways.

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**

Avoid the formation of dust. General precautions for handling of pharmaceuticals are to be considered. Collect/absorb spilled material and dispose properly.

**7. Handling and storage**

**7.1. Precautions for safe handling**

General precautions for handling of pharmaceuticals are to be considered.

**7.2. Conditions for safe storage, including any incompatibilities**

Handle containers carefully to prevent damage and spillage.

Store and transport at +2 to +8 °C.

Incompatible materials: No data available.

Keep container closed tightly. Do not freeze. Store locked up or accessible for authorized persons or their representatives only.

**7.3. Specific end use(s)**

No data available.

**8. Exposure controls and personal protection**

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**

<b>Respiratory</b>	Not Required
<b>Eyes</b>	Not Applicable
<b>Skin</b>	Not Applicable
<b>Engineering Controls</b>	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.
<b>Other Work Practices</b>	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**

<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 Applicable (Decomposition)
<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>Molecular Weight</b>	about 57 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**

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</b>	<b>DOT Hazard Class:</b> Not	<b>IMDG:</b> Not Applicable	<b>Air class:</b> Not Applicable

<b>class(es)</b>	Applicable	<b>Sub 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, Authorisation 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

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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