1. Identification

1.1. Product identifier

Product Identity: Berinert
Alternate Names: Berinert

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.
Address: 1020 First Avenue, PO Box 61501, King of Prussia, PA
Emergency: Emergency Response: (800) 424-9300
Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring L.L.C. (610) 878-4000

2. Hazard(s) identification

2.1. Classification of the substance or mixture

No applicable GHS categories.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

[Prevention]:
No GHS prevention statements

[Response]:
No GHS response statements

[Storage]:
No GHS storage statements

[Disposal]:
No GHS disposal statements

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: C1 esterase inhibitor, human (C1-INH) (non hazardous component)
Other components: Aminoacetic acid, sodium chloride, sodium citrate (non hazardous components)
Content: 500 U per vial
Packaging units: Pack with 1 vial with dried drug substance and 1 ampoule with 10 ml for injections (solvent)

4. First aid measures

4.1. Description of first aid measures
General: Take off and remove dirty clothes
Inhalation: Not applicable
Eyes: Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
Skin: Wash with water
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
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
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.
Store and transport at 2C to 25C. 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 Not Applicable
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>6.5-7.5</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>
<tr>
<td>Flash Point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Evaporation rate (Ether = 1)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>Lower Explosive Limit: Not Measured</td>
</tr>
<tr>
<td></td>
<td>Upper Explosive Limit: Not Measured</td>
</tr>
</tbody>
</table>
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  105 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
Store and transport at 2°C to 25°C. 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

Single dose studies:
Acute toxicity studies were performed in rodents (mice, rats) with single i.v. injection. Up to doses of 6000 U/kg (mice) and 3000 U/kg (rats), no toxic findings were observed.

Local tolerance:
Rabbits were injected with 5 mL (1500 U/rabbit) i.v. The substance was regarded as local tolerable after i.v. injection.

Safety Pharmacology:
Dogs were injected i.v. at a maximal dose of 3500 U/kg b.w.. No relevant adverse effects were observed.

Neoantigenicity:
No evidence for the generation of a neoepitope in the C1 esterase inhibitor molecule was detected in a rabbit/guinea pig 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
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>Not Applicable</td>
</tr>
<tr>
<td>IMDG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marine Pollutant: No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

14.6. Special precautions for user
No further information

15. Regulatory information

Regulatory Overview
The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Toxic Substance Control Act (TSCA)
All components of this material are either listed or exempt from listing on the TSCA Inventory.

WHMIS Classification
Not Regulated

US EPA Tier II Hazards
Fire: No
Sudden Release of Pressure: No
Reactive: No
Immediate (Acute): No
Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.
Proposition 65 - Developmental Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Pennsylvania RTK Substances (>1%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

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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