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

1.1. Product identifier
- **Product Identity**: Berirab® P
- **Alternate Names**: Human rabies immunoglobulin

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 rabies immunoglobulin (non hazardous component).

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

**Packaging units:** Pack with 1 ampoule of 2 or 5 or 10 ml or pack with 1 pre-filled syringe of 2 or 5 ml solution (ready-for-use) for intramuscular administration.

4. First aid measures

4.1. Description of first aid measures

**General**
- Take off and remove dirty clothes.

**Inhalation**
- Remove to fresh air.

**Eye**
- Flush thoroughly with copious amounts of water. In case of enduring disorders seek medical advice.

**Skin**
- Wash off 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.

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
Respiratory Not Required
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 Colorless to Pale-Yellow Up to Light Brown Liquid
Odor None
Odor threshold 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 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).

<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>
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<tr>
<td>STOT-repeated exposure</td>
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<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>14.1. UN number</td>
<td>Not Applicable</td>
<td>Not Regulated</td>
</tr>
<tr>
<td>14.2. UN proper shipping name</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
<tr>
<td>14.3. Transport hazard class(es)</td>
<td>DOT Hazard Class: Not Applicable</td>
<td>IMDG: Not Applicable</td>
</tr>
<tr>
<td></td>
<td>IMDG: Not Applicable</td>
<td>Sub Class: Not Applicable</td>
</tr>
<tr>
<td>14.4. Packing group</td>
<td>Not Applicable</td>
<td>Air class: Not Applicable</td>
</tr>
<tr>
<td>14.5. Environmental hazards</td>
<td>IMDG Marine Pollutant: No</td>
<td></td>
</tr>
</tbody>
</table>

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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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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