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

1.1. Product identifier

Product Identity
Privigen

Alternate Names
Immune Globulin Intravenous (Human), 10% Liquid for intravenous administration

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 disposal 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

Trade names: Privigen

Chemical characterization of the substance / preparation:
Privigen, IgPro10: 10% Proteins IVIG, amino acid L-proline

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.

5. Fire-fighting measures

5.1. Extinguishing media
As appropriate 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
Special advice in case of fire:
Cool container and metallic parts with a water spray.

Hazardous products of combustion: Nitrogen oxide
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
Collect/absorb spilled material and dispose of properly.
After spillage, leakage, large amounts:
Must not be released into sewers, drains or wells.
After spillage, leakage, small amounts:
Wash away remnants with plenty of water and detergents.

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.
Max. storage temperature: When stored at room temperature (up to 25°C [77°F]), Privigen is stable for up to 36 months, as indicated by the expiration date printed on the outer carton and vial label (storage temperature for product quality reasons).

Protective measures, storage and handling: Store protected 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 Dust mask
Eyes Safety Glasses
Skin Impervious gloves.
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>Colorless or Pale Yellow Liquid</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>4.6-5.0 (20C)</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>
</tbody>
</table>
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: Not Measured
Partition coefficient n-octanol/water (Log Kow): Not Measured
Auto-ignition temperature: Not Measured
Decomposition temperature: Not Measured
Viscosity (cSt): < 20 mPas (20C)
Density: approx. 1.033 g/mL (Privigen, IgPro10)
Pallet Packing Density: approx. 750 kg/m^3

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
None

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>
<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.

**Biological degradation:**
Based on results of similar compounds good biodegradation can be expected.

Further ecological data:
No ecological problems are to be expected when the product is handled and used with due care and attention.

**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
Product:
Incineration in controlled furnaces.

Packaging:
Must be disposed of in compliance with country-specific regulations.

### 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></td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
</tbody>
</table>

14.1. UN number
Not Applicable

14.2. UN proper shipping name
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

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


National Legislation
None noted.

### 16. Other information

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The full text of the phrases appearing in section 3 is:
Not Applicable

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