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

1.1. Product identifier

Product Identity          Hizentra
Alternate Names           Immunoglobulin G, Hizentra, IgPro10

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
Customer Service: CSL Behring L.L.C. Emergency Product Information: (800) 504-5434
                          (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**

**Trade names:**

Hizentra

**Chemical characterization of the substance / preparation:**

Hizentra, IgPro20: 20% Proteins IVIG, amino acid L-proline / Polysorbat 80 / liquid

Hizentra, IgPro10: 10% Proteins IVIG, amino acid L-proline / Polysorbat 80 / liquid

### 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 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

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.
Storage and transportation temperatures should not exceed 25°C. Keep away 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

<table>
<thead>
<tr>
<th>Respiratory</th>
<th>Dust mask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eyes</td>
<td>Safety Glasses</td>
</tr>
<tr>
<td>Skin</td>
<td>Impervious gloves</td>
</tr>
</tbody>
</table>

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.

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><strong>Appearance</strong></td>
<td>Colorless or Pale Yellow Liquid</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>4.6-5.2</td>
</tr>
<tr>
<td><strong>Melting point / freezing point</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Evaporation rate (Ether = 1)</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Upper/lower flammability or explosive limits</strong></td>
<td><strong>Lower Explosive Limit</strong>: Not Measured</td>
</tr>
<tr>
<td></td>
<td><strong>Upper Explosive Limit</strong>: Not Measured</td>
</tr>
<tr>
<td><strong>Vapor pressure (Pa)</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Vapor Density</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Solubility in Water</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Partition coefficient n-octanol/water (Log Kow)</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Viscosity (cSt)</strong></td>
<td>&lt; 20 mPas</td>
</tr>
<tr>
<td><strong>Density</strong></td>
<td>approx. 1.061 g/mL (Hizentra, IgPro20)</td>
</tr>
<tr>
<td><strong>Pallet Packing Density</strong></td>
<td>approx. 750 kg/m^3</td>
</tr>
<tr>
<td><strong>9.2. Other information</strong></td>
<td>No other relevant information.</td>
</tr>
</tbody>
</table>

### 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 and transportation temperatures should not exceed 25°C. Keep away from light. 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

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

14.1. UN number
DOT (Domestic Surface Transportation) Not Applicable
IMO / IMDG (Ocean Transportation) Not Regulated
ICAO/IATA Not Regulated

14.2. UN proper shipping name
Not Regulated

14.3. Transport hazard class(es)
DOT Hazard Class: Not Applicable
IMDG: 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

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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