

## 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  
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.

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 25C. 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**

#### **Respiratory**

Dust mask

#### **Eyes**

Safety Glasses

#### **Skin**

Impervious gloves.

#### **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

<b>Appearance</b>	Colorless or Pale Yellow Liquid
<b>Odor</b>	None
<b>Odor threshold</b>	Not Measured
<b>pH</b>	4.6-5.2
<b>Melting point / freezing point</b>	Not Measured
<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>	Not Measured
<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>	< 20 mPas
<b>Density</b>	approx. 1.061 g/mL (Hizentra, IgPro20)
<b>Pallet Packing Density</b>	approx. 750 kg/m <sup>3</sup>

**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 and transportation temperatures should not exceed 25C. 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).

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.

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**

	<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 class(es)</b>	<b>DOT Hazard Class:</b> Not Applicable	<b>IMDG:</b> Not Applicable <b>Sub Class:</b> Not Applicable	<b>Air 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**

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**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, Authorization 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.

<b>16. Other information</b>
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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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