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 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

Appearance	Colorless or Pale Yellow Liquid
Odor	None
Odor threshold	Not Measured
pH	4.6-5.0 (20C)
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured

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).

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

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

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.

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

Revision History
11-4-2019 Review, no changes.

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