

IMPORTANT NOTICE: This Safety Data Sheet (SDS) is prepared by CSL Behring in accordance with Safe Work Australia National Code of Practice for the Preparation of Safety Data Sheets (June 2023). The information contained herein must not be altered or deleted. Additional information may be appended to the SDS, but it must be marked clearly to indicate that it is not part of the original.

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

1.1. Product Identifier

Product Identity	Privigen®
Alternate Names	(Human normal immunoglobulin) – Solution for intravenous infusion

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 (Australia) Pty Ltd (ABN 48 160 734 761) 189-209 Camp Road, Broadmeadows, Victoria 3047, Australia
Emergency	Telephone +61 03 9246 5200
24 hour Emergency Telephone No.	1800 642 865 (24hr)

2. Hazard identification of the product

Not classified as hazardous according to the WHS Regulations

All blood products should be treated as potentially infectious. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

GHS Classification(s)	None Allocated
Signal Word	No signal word
Pictogram(s)	No Pictogram(s)
Hazard Statement(s)	None Allocated
Prevention statement(s)	None Allocated
Response	None Allocated
Storage	None Allocated
Disposal	None Allocated

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 characterisation of the substance / preparation:
Privigen® is a 10% solution containing 100 mg/mL of total human plasma protein with a purity of at least 98% immunoglobulin G (IgG).

The product contains 250 mmol/L of L-proline as a stabiliser which is a physiological non-essential amino acid.

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

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), 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:

In accordance with state land and waste management authority.

Incineration in controlled furnaces.

Packaging:

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

14. Transport information

Not classified as a dangerous good by the criteria of the ADG Code

14.1. UN number	Not Applicable
14.2. UN proper shipping name	Not Regulated
14.3. Transport hazard class(es)	Not Applicable
14.4. Packing group	Not Applicable
14.5. Environmental hazards	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

Poisons Schedule Number (SUSMP) Schedule 4 (S4) – Prescription only medicine

16. Other information

Last Revised 3/10/2016

Reason for Revision Periodic Update

Abbreviations

SWA GHS WHS ACGIH ADG Code UN Number DG Class CAS Number	Safe Work Australia Globally Harmonised System Work, Health and Safety American Conference of Governmental Industrial Hygienists Australian Dangerous Goods Code United Nations Number Dangerous Goods Class Chemical Abstract Service Number
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Contact Point

Company Contact: 1800 642 865 (24hr)

Australian Poisons Information Centre, 24 hour service: 13 11 26

Australian Police, Fire Brigade or Ambulance: 000

New Zealand Poisons Information Centre, 24 hour service: 0800 764 766

New Zealand Police, Fire Brigade or Ambulance: 111

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