

**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 (February 2016). 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**

<b>Product Identity</b>	Evogam®
<b>Alternate Names</b>	Human Normal Immunoglobulin 16% (16g per 100mL) solution for subcutaneous infusion

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

<b>Intended use</b>	See Technical Data Sheet.
<b>Application Method</b>	See Technical Data Sheet.

**1.3. Details of the supplier of the safety data sheet**

<b>Company Name</b>	CSL Behring (Australia) Pty Ltd (ABN 48 160 734 761) 189-209 Camp Road, Broadmeadows, Victoria 3047, Australia
	Telephone +61 03 9246 5200
<b>Emergency</b>	
<b>24 hour Emergency Telephone No.</b>	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.

<b>GHS Classification(s)</b>	None Allocated
<b>Signal Word</b>	No signal word
<b>Pictogram(s)</b>	No Pictogram(s)
<b>Hazard Statement(s)</b>	None Allocated
<b>Prevention statement(s)</b>	None Allocated
<b>Response</b>	None Allocated
<b>Storage</b>	None Allocated
<b>Disposal</b>	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:  
Human Plasma Proteins (16%)  
Other non-hazardous ingredients (up to 100%)

## 4. First aid measures

### 4.1. Description of first aid measures

<b>General</b>	In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye</b>	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
<b>Skin</b>	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
<b>Ingestion</b>	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**

None

## 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.

Store at 2°C to 8°C (Refrigerate. Do not freeze).

Protect from light.

Incompatible materials: No data available.

Store as per Schedule 4 pharmaceutical.

### 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** Not applicable

**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

<b>Appearance</b>	Clear pale-yellow to light-brown solution.
<b>Odor</b>	None
<b>Odor threshold</b>	Not Measured
<b>pH</b>	6.6
<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>	Not Measured
<b>Density</b>	Not Measured
<b>Pallet Packing Density</b>	Not Measured

### 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

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## 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.

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## 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**      04/04/2017

**Reason for Revision**      Update company details  
Update GHS requirements

**Abbreviations**

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

**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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