

**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

### 1.1. Product identifier

**Product Identity**

RiaSTAP

**Alternate Names**

Fibrinogen Concentrate, Human

### 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

Telephone  
+61 03 9246 5200

**Emergency**

**24 hour Emergency Telephone No.**

1800 642 865 (24hr)

## 2. Hazard(s) identification

**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.**

**Material:** Medicinal product derived from human plasma.

**Active ingredient:** Fibrinogen concentrate, human (non hazardous component).

**Other components:** Human Albumin, sodium chloride, arginine hydrochloride, sodium citrate (non hazardous components).

**Packaging units:** Vial of powder for injection with 1 g active ingredient.

## 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.  
See section 2 for further details.

## 5. Fire-fighting measures

### 5.1. Extinguishing media

Water or any medium suitable for extinguishing.

### 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

Avoid the formation of dust. General precautions for handling of pharmaceuticals are to be considered. Collect/absorb spilled material and dispose properly.

## 7. Handling and storage

### 7.1. Precautions for safe handling

General precautions for handling of pharmaceuticals are to be considered.

See section 2 for further details. - [Prevention]:

### 7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

Store and transport at 2-8 degrees C (36-46 degrees F).

Incompatible materials: No data available.

Keep container closed tightly. Refrigerate. Do not freeze. Protect from light. Store locked up or accessible for authorized persons or their representatives only.

See section 2 for further details. - [Storage]:

### 7.3. Specific end use(s)

No data available.

## 8. Exposure controls and personal protection

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

<b>Respiratory</b>	Not Required
<b>Eyes</b>	Not Applicable
<b>Skin</b>	Not Applicable
<b>Engineering Controls</b>	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>	White Solid
<b>Odor</b>	None
<b>Odor threshold</b>	Not Measured
<b>pH</b>	6.5-7.5
<b>Melting point / freezing point</b>	Not Applicable (Decomposition)
<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>	Readily Soluble
<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>Molecular Weight</b>	340 KD

### 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 temperature must not fall below +2C and not exceed +8C.

**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.

**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**

<b>14.1. UN number</b>	Not Applicable
<b>14.2. UN proper shipping name</b>	Not Regulated
<b>14.3. Transport hazard class(es)</b>	Not Applicable
<b>14.4. Packing group</b>	Not Applicable
<b>14.5. Environmental hazards</b>	Marine pollutant: No
<b>14.6. Special precautions for user</b>	No further information

## 15. Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Poisons Schedule Number (SUSMP)**      **Unscheduled**

## 16. Other information

<b>Last Revised</b>	04/04/2017
<b>Reason for Revision</b>	Periodic Update Change to the SWA SDS Code of Practice

**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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