

**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 (July 2020). 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**

|                                    |  |
|------------------------------------|--|
| <b>Product Identity</b>            | Albumex® 20 (Human Albumin 20%)  |
| <b>Alternate Names</b>             | Human Albumin, solution for intravenous injection  |
| <b>Manufacturer’s Product Code</b> | Australia: 34700110, 34700155; NZ: 34700255, 34700210; Hong Kong: 34700350; Singapore: 34700450; Indonesia (Albapure® 20): 347B1350, 347B1355; Malaysia Toll: 34700755; Malaysia Commercial (Albapure® 20): 347L1355; Taiwan: 34701850, 34701855 |

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

|                           |   |
|---------------------------|---|
| <b>Intended use</b>       | Albumex® 20 may be used when the quantity of protein in the blood is low (hypoproteinaemia) in the acutely ill patient, for resuscitation in shock due to acute loss of blood or plasma, in extensive burns, adult respiratory distress syndrome, blood purification (haemodialysis) and plasma exchange.<br><br>Albumex® 20 is given as an infusion by a doctor and can only be obtained on a doctor’s prescription. |
| <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)<br>189-209 Camp Road<br>Broadmeadows, Victoria, 3047<br>Australia |
| <b>Customer Service</b>    | +61 03 9246 5200   |
| <b>Emergency Telephone</b> | 1800 642 865 (24hr)  |

## 2. Hazard(s) identification

### 2.1. Classification of the substance or mixture

**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 Albumin (20% w/v)

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.<br>Never give anything by mouth to an unconscious person. |
| <b>Inhalation</b> | Remove to fresh air.   |
| <b>Eyes</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.                          |

**Ingestion** Wash out mouth thoroughly with water, if irritation or discomfort persists seek medical attention.

**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**

Non-Combustible. Not considered a significant fire risk.

**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**

Minor Spills: Soak up spills with absorbent material i.e. paper towels or vermiculite.

Place spilled material in clean, dry, sealed container for disposal.

Decontaminate area with 1% sodium hypochlorite in water.

Major Spills: Contain and absorb spills using earth, sand or inert absorbent.

Prevent material entering open drains and waterways.

Collect residues and seal in labelled drums for disposal.

Decontaminate area with 1% sodium hypochlorite in water.

**7. Handling and storage**

**7.1. Precautions for safe handling**

Limit all unnecessary personal contact. Always wash hands with soap and water after handling.

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 at < 30°C. Protect from light.

Incompatible materials: No data available.

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.

**8.1 Exposure Standards**

No exposure limits set by SWA or ACGIH

**8.2. Exposure controls**

|                             |   |
|-----------------------------|---|
| <b>Respiratory</b>          | Not required  |
| <b>Eyes</b>                 | Protective safety glasses recommended.  |
| <b>Skin</b>                 | Protective gloves (e.g. latex or nitrile) recommended.  |
| <b>Engineering Controls</b> | None under normal conditions  |
| <b>Other Work Practices</b> | The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser. 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, almost Colourless Yellow, Amber or Green Liquid                                   |
| <b>Odor</b>   | Slight   |
| <b>Odor threshold</b>                               | Not Measured   |
| <b>pH</b>   | Approximately 7.0  |
| <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<br><b>Upper Explosive Limit:</b> Not Measured |

|   |              |
|---|--------------|
| Vapor pressure (Pa)                             | Not Measured |
| Vapor Density                                   | Not Measured |
| Specific Gravity                                | Not Measured |
| Solubility in Water                             | Miscible     |
| Partition coefficient n-octanol/water (Log Kow) | Not Measured |
| Auto-ignition temperature                       | Not Measured |
| Decomposition temperature                       | Not Measured |
| Viscosity (cSt)                                 | Not Measured |
| 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

No data available.

### 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

**Poisons Schedule Number (SUSMP)**      Unscheduled

## 16. Other information

|  |   |
|--|---|
| <b>Last Revised</b>                                      | 17 <sup>th</sup> November 2016  |
| <b>Reason for Revision</b>                               | Update to Code of Practice version<br>General review and update to Poisons Scheduling |
| <b>Abbreviations</b>                                     |   |
| 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  |
| <b>Contact Point</b>                                     |   |
| 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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