

## 1. Identification

### 1.1. Product identifier

<b>Product Identity</b>	Intragam® P
<b>Alternate Names</b>	Human Normal Immunoglobulin solution for intravenous injection 37400150 (50mL Aus), 37400160 (200mL Aus), 37400250 (50mL NZ), 37400260 (200mL NZ), 37400450 (50mL Singapore), 37400460 (200mL Singapore), 37400350 (50mL HK), 37400360 (200mL HK), 37400750 (50mL Malaysia), 37401850 (TW)

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

<b>Intended use</b>	Intragam® P is used for patients who need replacement of antibodies which form part of our immune system and can provide protection against some infections. Intragam® P is also used in diseases when the immune system is overactive, these are called autoimmune disorders.
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<b>Application Method</b>	See Technical Data Sheet.
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### 1.3. Details of the supplier of the safety data sheet

<b>Company Name</b>	CSL Behring L.L.C. 1020 First Avenue PO Box 61501 King of Prussia, PA
<b>Emergency</b>	
<b>24 hour Emergency Telephone No.</b>	Emergency Response: (800) 424-9300 Emergency Product Information: (800) 504-5434 (610) 878-4000
<b>Customer Service: CSL Behring L.L.C.</b>	
<b>Supplier Name</b>	CSL Behring (Australia) Pty Ltd (ABN 48 160 734 761). 189-209 Camp Road, Broadmeadows, Victoria 3047, Australia
<b>Emergency</b>	
<b>24 hour Emergency Telephone No.</b>	1800 642 865 (24hr)
<b>Customer Service</b>	+6 03 9246 5200

## 2. Hazard(s) identification

### 2.1. Classification of the substance or mixture

No applicable GHS categories. Not hazardous according to criteria of Australian WHS Regulations

### 2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

**[Prevention]:**

No GHS prevention statements

**[Response]:**

No GHS response statements

**[Storage]:**

No GHS storage statements

**[Disposal]:**

No GHS disposal statements

### 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
<b>Maltose</b> CAS Number: 0000069-79-4	10 - 25	Not Classified	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

\*The full texts of the phrases are shown in Section 16.

**Non-Hazardous Ingredients:**

Human Plasma Proteins (6%)

Maltose (10%)

Other non-hazardous ingredients (up to 100%)

### 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.

**Eyes**

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**

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.

## 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.

### 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

#### Exposure

CAS No.	Ingredient	Source	Value
0000069-79-4	Maltose	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

#### Carcinogen Data

CAS No.	Ingredient	Source	Value
0000069-79-4	Maltose	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

### 8.2. Exposure controls

**Respiratory** Not applicable

**Eyes** Protective safety glasses recommended

**Skin** Protective gloves (e.g. latex or nitrile) recommended.

**Engineering Controls** None under normal conditions

**Other Work Practices** 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.

## 9. Physical and chemical properties

<b>Appearance</b>	Clear, Colorless Liquid
<b>Odor</b>	Slight
<b>Odor threshold</b>	Not Measured
<b>pH</b>	4.25
<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>	Miscible
<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

**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**

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**

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Maltose - (69-79-4)	No data available	No data available	No data available	No data available	No data available

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**

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	ErC50 algae, mg/l
Maltose - (69-79-4)	Not Available	Not Available	Not Available

**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**

Observe all federal, state and local regulations when disposing of this substance.

## 14. Transport information

DOT (Domestic Surface

IMO / IMDG (Ocean

ICAO/IATA

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

**15. Regulatory information**

**Regulatory Overview**    Poisons Schedule Number: **Unscheduled**

**16. Other information**

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The full text of the phrases appearing in section 3 is:

**This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.**

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