

# Kit SDS Cover Sheet

## PGM™ 2 SingleQuots®

Version 3.1

Revision Date 14.05.2024

Print Date 13.06.2024

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### Product Information

Commercial Product Name : Poietics®  
Product name : PGM™ 2 SingleQuots®  
Material number : PT-9502

### Components

GA-1000	SDS attached
Dexamethasone solution	SDS attached
Indomethacin for PGM-2	SDS attached
IBMX	SDS attached
Recombinant human insulin 0.1%	SDS attached
Fetal Bovine Serum	SDS attached
L-GLUTAMINE	SDS attached

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : GA-1000

**Manufacturer or supplier's details**Company : Capsugel Australia Pty Ltd.  
Suite 610, 12 Century Circuit,  
Norwest NSW 2153, AustraliaLonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

**Recommended use of the chemical and restrictions on use**

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.Precautionary statements : **Prevention:**  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves.  
P285 In case of inadequate ventilation wear respiratory

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protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

P363 Wash contaminated clothing before reuse.

#### Disposal:

P501 Dispose of contents/ container to a local hazardous waste disposal facility.

#### Other hazards which do not result in classification

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Gentamicin, sulfate (salt)	1405-41-0	>= 3 - < 5

### SECTION 4. FIRST AID MEASURES

General advice : When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : Move to fresh air.  
Call a physician or poison control centre immediately.  
If unconscious, place in recovery position and seek medical advice.  
Keep respiratory tract clear.  
If breathing is irregular or stopped, administer artificial respiration.

In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.  
Wash clothing before reuse.  
Get medical attention if irritation develops and persists.

After contact with skin, wash immediately with plenty of soap and water.  
If on clothes, remove clothes.  
In the case of skin irritation or allergic reactions see a physician.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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- If eye irritation persists, consult a specialist.
- Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Keep eye wide open while rinsing.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : Allergic appearance  
sensitising effects  
No information available.
- Notes to physician : Treat symptomatically.  
  
Treat symptomatically.

## SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Not combustible.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
  
Water spray
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during firefighting : Heating or fire can release toxic gas.
- Hazardous combustion products : No hazardous combustion products are known
- Specific extinguishing methods : Use a water spray to cool fully closed containers.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use respirator when performing operations involving potential exposure to vapour of the product.  
Refer to protective measures listed in sections 7 and 8.  
Use personal protective equipment.  
Ensure adequate ventilation.  
Use respirator when performing operations involving potential exposure to vapour of the product.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.

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Methods and materials for containment and cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : Stable under normal conditions.

Normal measures for preventive fire protection.

Advice on safe handling : Avoid formation of aerosol.  
Avoid exposure - obtain special instructions before use.  
Do not breathe vapours/dust.  
Avoid contact with skin and eyes.  
Smoking, eating and drinking should be prohibited in the application area.  
For personal protection see section 8.  
Provide sufficient air exchange and/or exhaust in work rooms.  
Dispose of rinse water in accordance with local and national regulations.

Hygiene measures : Wash hands before breaks and at the end of workday.  
Avoid contact with skin, eyes and clothing.

Conditions for safe storage : Keep frozen or refrigerated.  
  
Observe label precautions.  
Keep container tightly closed.  
Keep in a well-ventilated place.  
To maintain product quality, do not store in heat or direct sunlight.

Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

**Engineering measures** : Use only in area provided with appropriate exhaust ventilation.

**Personal protective equipment**

Respiratory protection : In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.

Respirator with a vapour filter (EN 141)

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## Hand protection

- Material : Nitrile rubber
- Remarks : Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact). Impervious gloves Break through time : > 480 min
- Eye protection : Safety glasses
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place. Impervious clothing

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : Aqueous solution
- Colour : light yellow
- Odour : odourless
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : 0 °C
- Initial boiling point and boiling range : No data available
- Flash point : Does not sustain combustion.
- Evaporation rate : No data available
- Flammability (solid, gas) : No data available
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : No data available
- Relative vapour density : No data available
- Relative density : No data available
- Density : No data available

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Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	No decomposition if stored and applied as directed.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	Heat
Incompatible materials	:	Oxidizing agents Strong acids and strong bases
Hazardous decomposition products	:	No decomposition if used as directed.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Acute oral toxicity	:	Acute toxicity estimate: Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available

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Acute dermal toxicity

: Remarks: No data available



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**Skin corrosion/irritation**

Remarks : No data available

**Serious eye damage/eye irritation**

Remarks : No data available

**Respiratory or skin sensitisation**

Remarks : No data available

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

**Carcinogenicity**

Remarks : No data available

**ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**Reproductive toxicity**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

**STOT - single exposure**

Remarks : No data available

**STOT - repeated exposure**

Remarks : No data available

**Repeated dose toxicity**

Remarks : No data available

**Aspiration toxicity**

No aspiration toxicity classification

**Further information**

Remarks : No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**Toxicity to fish :  
Remarks: No data available

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#### Persistence and degradability

Biodegradability : Remarks: No data available

#### Bioaccumulative potential

Bioaccumulation : Remarks: No data available

#### Mobility in soil

Distribution among environmental compartments : Remarks: No data available

#### Other adverse effects

Additional ecological information : No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Dispose of contents/container in accordance with local regulation.  
Contact waste disposal services.  
Do not dispose of waste into sewer.

Contaminated packaging : Dispose of as unused product.  
Do not re-use empty containers.

### SECTION 14. TRANSPORT INFORMATION

**IATA** Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable

**IMDG** Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class(es)** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : Marine pollutant: no

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<b>ADR</b>	:	Not dangerous goods
<b>UN number</b>	:	Not applicable
<b>Proper shipping name</b>	:	Not applicable
<b>Transport hazard class</b>	:	Not applicable
<b>Packing group</b>	:	Not applicable
<b>Environmental hazards</b>	:	no
<b>RID</b>	:	Not dangerous goods
<b>UN number</b>	:	Not applicable
<b>Proper shipping name</b>	:	Not applicable
<b>Transport hazard class</b>	:	Not applicable
<b>Packing group</b>	:	Not applicable
<b>Environmental hazards</b>	:	no
<b>Special precautions for user</b>	:	none
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	:	Not applicable

## SECTION 15. REGULATORY INFORMATION

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

**Therapeutic Goods (Poisons Standard) Instrument**

Not applicable

## SECTION 16. OTHER INFORMATION

Revision Date : 14.05.2024

Date format : dd.mm.yyyy

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL -

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Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

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#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone solution

##### Manufacturer or supplier's details

Company : Capsugel Australia Pty Ltd.  
Suite 610, 12 Century Circuit,  
Norwest NSW 2153, Australia

Lonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

##### Recommended use of the chemical and restrictions on use

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

#### SECTION 2. HAZARDS IDENTIFICATION

##### GHS Classification

Flammable liquids : Category 2

Serious eye damage/eye irritation : Category 2A

##### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P233 Keep container tightly closed.  
P240 Ground and bond container and receiving equipment.  
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.

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P242 Use non-sparking tools.  
 P243 Take action to prevent static discharges.  
 P264 Wash skin thoroughly after handling.  
 P280 Wear protective gloves/ eye protection/ face protection.

#### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P337 + P313 If eye irritation persists: Get medical advice/ attention.  
 P370 + P378 In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.

#### Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

#### Disposal:

P501 Dispose of contents/ container to a local hazardous waste disposal facility.

#### Other hazards which do not result in classification

No information available.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Ethanol	64-17-5	>= 90 - <= 100

### SECTION 4. FIRST AID MEASURES

If inhaled : Remove to fresh air.  
 If breathing is irregular or stopped, administer artificial respiration.

In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.  
 Consult a physician.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
 Call a physician immediately.

If swallowed : If accidentally swallowed obtain immediate medical attention.  
 Clean mouth with water and drink afterwards plenty of water.  
 Do not induce vomiting without medical advice.

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Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : None known.

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**SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Dry powder  
Water spray  
Foam

Hazardous combustion products : Carbon oxides (COx)

Specific extinguishing methods : Use water spray to cool unopened containers.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures : Use respirator when performing operations involving potential exposure to vapour of the product.

Environmental precautions : No special environmental precautions required.

Methods and materials for containment and cleaning up : Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according to local / national regulations (see section 13).

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**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : Highly flammable.  
Keep away from sources of ignition - No smoking.  
Take precautionary measures against static discharges.

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.  
Avoid contact with skin and eyes.

Hygiene measures : Avoid contact with skin, eyes and clothing.  
Wash hands before breaks and immediately after handling the product.

Conditions for safe storage : Keep away from sources of ignition - No smoking.  
Keep containers tightly closed in a cool, well-ventilated place.

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## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1 000 ppm 1 880 mg/m <sup>3</sup>	AU OEL
		STEL	1 000 ppm	ACGIH

**Engineering measures** : Provide sufficient air exchange and/or exhaust in work rooms.

### Personal protective equipment

Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

Hand protection

Material : Nitrile rubber  
Rate of permeability : > 480 min

Eye protection : Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.  
No special protective equipment required.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless

Odour : alcohol-like

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : -114,5 - -114 °C  
Information refers to the main component.

Initial boiling point and boiling range : 78,3 °C  
Information refers to the main component.

Flash point : 12 °C

Method: closed cup  
Information refers to the main component.



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Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	15,0 %(V) Information refers to the main component.
Lower explosion limit / Lower flammability limit	:	3,5 %(V) Information refers to the main component.
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	0,79 g/cm <sup>3</sup> (20 °C)
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, dynamic	:	1,17 - 1,2 mPa.s ( 20 °C)
Viscosity, kinematic	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Stable under recommended storage conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Stable under normal conditions.
Conditions to avoid	:	Keep away from heat and sources of ignition.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored normally.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Acute oral toxicity : Remarks: No data available

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Acute inhalation toxicity : Method: No information available.

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Acute dermal toxicity

: Remarks: No data available

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**Skin corrosion/irritation**

Remarks : No data available

**Serious eye damage/eye irritation**

Remarks : No data available

**Respiratory or skin sensitisation**

Remarks : No data available

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

**Carcinogenicity**

Remarks : No data available

**ACGIH**Confirmed animal carcinogen with unknown relevance to  
humans  
Ethanol

64-17-5

**Reproductive toxicity**

Effects on fertility : Remarks: No data available

**STOT - single exposure**

Remarks : No data available

**STOT - repeated exposure**

Remarks : No data available

**Further information**

Remarks : No data is available on the product itself.

**The following toxicological data refer to:**

Ethanol(CAS-No.: 64-17-5)

**Acute toxicity**

Acute oral toxicity : LD50 (Rat): &gt; 5 000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 124,7 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: OECD Test Guideline 403

Acute dermal toxicity : Remarks: No data available

**Skin corrosion/irritation**

Species : Rabbit

Method : OECD Test Guideline 404

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Result : No skin irritation

#### Serious eye damage/eye irritation

Species : Rabbit  
 Result : Moderate eye irritation  
 Assessment : Mild eye irritation

#### Respiratory or skin sensitisation

Exposure routes : Dermal  
 Species : Mouse  
 Result : not sensitizing

#### Germ cell mutagenicity

Genotoxicity in vitro : Test Type: Ames test  
 Result: negative  
 : Test Type: gene mutation test  
 Species: mouse lymphoma cells  
 Result: negative

#### Repeated dose toxicity

Species : Rat, male and female  
 NOAEL : 1 730 mg/kg  
 LOAEL : 3 200 mg/kg  
 Application Route : Oral

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## SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

Toxicity to fish :  
 Remarks: No data available

#### Persistence and degradability

Biodegradability : Result: no data available

#### Bioaccumulative potential

Bioaccumulation : Remarks: No data available

#### Mobility in soil

Distribution among environmental compartments : Remarks: No data available

#### Other adverse effects

Additional ecological information : Information refers to the main component.

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

- Waste from residues : Dispose of in accordance with local regulations.
- Contaminated packaging : Dispose of as unused product.  
Do not burn, or use a cutting torch on, the empty drum.

**SECTION 14. TRANSPORT INFORMATION****IATA**

- UN number** : 1170  
**Proper shipping name** : ETHANOL SOLUTION  
**Transport hazard class(es)** : 3  
**Packing group** : II  
Labels : 3  
**Environmental hazards** : no

**IMDG**

- UN number** : 1170  
**Proper shipping name** : ETHANOL SOLUTION  
**Transport hazard class(es)** : 3  
**Packing group** : II  
Labels : 3  
EmS Number 1 : F-E  
EmS Number 2 : S-D  
**Environmental hazards** : Marine pollutant: no

**ADR**

- UN number** : 1170  
**Proper shipping name** : ETHANOL SOLUTION  
**Transport hazard class(es)** : 3  
**Packing group** : II  
Classification Code : F1  
Hazard Identification Number : 33  
Labels : 3  
**Environmental hazards** : no

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**RID**

<b>UN number</b>	: 1170
<b>Proper shipping name</b>	: ETHANOL SOLUTION
<b>Transport hazard class(es)</b>	: 3
<b>Packing group</b>	: II
Classification Code	: F1
Hazard Identification Number	: 33
Labels	: 3
<b>Environmental hazards</b>	: no
<b>Special precautions for user</b>	: none
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	: Not applicable

**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****Therapeutic Goods (Poisons Standard) Instrument**

Not applicable

**SECTION 16. OTHER INFORMATION**

Revision Date : 14.05.2024

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / STEL : Short-term exposure limit  
AU OEL / TWA : Exposure standard - time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose

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to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

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**Indomethacin for PGM-2**

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Indomethacin for PGM-2

**Manufacturer or supplier's details**Company : Capsugel Australia Pty Ltd.  
Suite 610, 12 Century Circuit,  
Norwest NSW 2153, AustraliaLonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

**Recommended use of the chemical and restrictions on use**

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Flammable liquids : Category 4

Acute toxicity (Oral) : Category 4

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H227 Combustible liquid.  
H302 Harmful if swallowed.Precautionary statements : **Prevention:**  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ eye protection/ face protection.

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#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
P370 + P378 In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.

#### Disposal:

P501 Dispose of contents/ container to a local hazardous waste disposal facility.

#### Other hazards which do not result in classification

No information available.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Dimethyl sulfoxide	67-68-5	>= 90 - <= 100
Indometacin	53-86-1	>= 0,5 - < 1

### SECTION 4. FIRST AID MEASURES

- If inhaled : Remove to fresh air.  
If breathing is irregular or stopped, administer artificial respiration.
- In case of skin contact : In the case of skin irritation or allergic reactions see a physician.  
After contact with skin, wash immediately with plenty of soap and water.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Call a physician immediately.
- If swallowed : Call a physician immediately.  
Clean mouth with water and drink afterwards plenty of water.  
Do not induce vomiting without medical advice.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : None known.

### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

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- Dry powder  
Foam
- Hazardous combustion products : Carbon oxides (COx)  
Sulphur oxides (SOx)
- Specific extinguishing methods : Use water spray to cool unopened containers.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use respirator when performing operations involving potential exposure to vapour of the product.
- Environmental precautions : Prevent product from entering drains.
- Methods and materials for containment and cleaning up : Do not flush into surface water or sanitary sewer system. Sweep up or vacuum up spillage and collect in suitable container for disposal.

#### SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Highly flammable.  
Keep away from sources of ignition - No smoking.  
Take precautionary measures against static discharges.
- Advice on safe handling : Avoid contact with skin and eyes.  
Provide sufficient air exchange and/or exhaust in work rooms.
- Hygiene measures : Wash hands before breaks and immediately after handling the product.  
Avoid contact with skin, eyes and clothing.
- Conditions for safe storage : Keep container tightly closed.  
To maintain product quality, do not store in heat or direct sunlight.  
Keep in a dry, cool and well-ventilated place.
- Recommended storage temperature : -20 °C

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

##### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis

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Dimethyl sulfoxide	67-68-5	TWA	250 ppm	US WEEL
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**Engineering measures** : Provide sufficient air exchange and/or exhaust in work rooms.

#### Personal protective equipment

Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Eye protection : Tightly fitting safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: colourless
Odour	: characteristic
Odour Threshold	: No data available
pH	: Not applicable
Melting point/freezing point	: 18,4 °C Solvent
Initial boiling point and boiling range	: 189 °C Solvent
Flash point	: 89 °C  Method: closed cup Solvent
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: 42 %(V) Solvent
Lower explosion limit / Lower	: No data available

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flammability limit	
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Water solubility	: completely miscible
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, dynamic	: No data available
Viscosity, kinematic	: not determined
Explosive properties	: Not explosive

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Stable under recommended storage conditions.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: None known.
Conditions to avoid	: Temperature 89 °C Keep away from heat and sources of ignition.
Incompatible materials	: Strong oxidizing agents Strong reducing agents Halogens Copper
Hazardous decomposition products	: No decomposition if stored normally.

#### SECTION 11. TOXICOLOGICAL INFORMATION

##### Acute toxicity

Acute oral toxicity	: Acute toxicity estimate: 1 500 mg/kg Method: Calculation method
Acute inhalation toxicity	: Remarks: No data available

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Acute dermal toxicity

: Remarks: No data available

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**Skin corrosion/irritation**

Remarks : No data available

**Serious eye damage/eye irritation**

Remarks : No data available

**Respiratory or skin sensitisation**

Remarks : No data available

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

**Carcinogenicity**

Remarks : No data available

**ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**Reproductive toxicity**

Effects on fertility : Remarks: No data available

**STOT - single exposure**

Remarks : No data available

**STOT - repeated exposure**

Remarks : No data available

**Further information**

Remarks : No data is available on the product itself.

**The following toxicological data refer to:**

Indometacin(CAS-No.: 53-86-1)

**Acute toxicity**

Acute oral toxicity : LD50 (Rat): 2,42 mg/kg

**The following toxicological data refer to:**

Dimethyl sulfoxide(CAS-No.: 67-68-5)

**Acute toxicity**

Acute oral toxicity : LD50 (Rat): 14 500 mg/kg

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- Acute inhalation toxicity : LC50 (Rat): 40250 ppm  
 Exposure time: 4 h  
 Test atmosphere: dust/mist
- LC50 (Rat): 5 330 mg/l  
 Exposure time: 4 h  
 Test atmosphere: vapour  
 Method: OECD Test Guideline 403
- Acute dermal toxicity : LD50 (Rat, male and female): 40 000 mg/kg

#### Skin corrosion/irritation

- Species : Rabbit  
 Exposure time : 4 h  
 Assessment : No skin irritation  
 Method : OECD Test Guideline 404  
 Result : Mild skin irritation  
 GLP : yes

#### Serious eye damage/eye irritation

- Species : Rabbit  
 Result : Mild eye irritation  
 Exposure time : 24 h  
 Assessment : No eye irritation  
 Method : OECD Test Guideline 405

#### Respiratory or skin sensitisation

- Test Type : Maximisation Test  
 Species : Guinea pig  
 Assessment : Did not cause sensitisation on laboratory animals.  
 Method : OECD Test Guideline 406  
 Result : not sensitizing

#### Germ cell mutagenicity

- Genotoxicity in vitro : Test Type: Ames test  
 Species: Salmonella  
 Metabolic activation: with and without metabolic activation  
 Method: OECD Test Guideline 471  
 Result: negative
- : Test Type: Chromosome aberration test in vitro  
 Species: Chinese hamster ovary cells  
 Metabolic activation: yes  
 Result: negative
- Genotoxicity in vivo : Test Type: In vivo micronucleus test  
 Species: Rat  
 Application Route: ip  
 Dose: 200, 1000 and 5000 mg/kg/d  
 Method: OECD Test Guideline 474  
 Result: negative  
 GLP: yes



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#### Carcinogenicity

Remarks : No data available

#### Reproductive toxicity

Effects on fertility : Species: Rat  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 1 000 mg/kg body weight  
General Toxicity F1: NOAEL: 1 000 mg/kg body weight  
Early Embryonic Development: NOAEL: 1 000 mg/kg body weight

Effects on foetal development : Species: Rat  
Application Route: Oral  
Method: OECD Test Guideline 414  
Result: No adverse effects

#### STOT - single exposure

Remarks : No data available

Exposure routes : inhalation (vapour)  
Target Organs : Respiratory system

#### STOT - repeated exposure

Remarks : No data available

#### Repeated dose toxicity

Species : Rat  
NOAEC : 47,5 mg/m<sup>3</sup>  
Application Route : Inhalation  
Target Organs : Liver, Lungs

#### Further information

Remarks : Can be absorbed through skin.

## SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

Toxicity to fish :  
Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates :  
Remarks: No data available

Toxicity to algae/aquatic plants :  
Remarks: No data available

Toxicity to microorganisms :  
Remarks: No data available

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#### Persistence and degradability

Biodegradability : Result: no data available

#### Bioaccumulative potential

Bioaccumulation : Remarks: No data available

#### Mobility in soil

Distribution among environmental compartments : Remarks: No data available

#### Other adverse effects

Additional ecological information : No data is available on the product itself.

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Dispose of in accordance with local regulations. Contact waste disposal services.

Contaminated packaging : Dispose of as unused product. Do not burn, or use a cutting torch on, the empty drum.

### SECTION 14. TRANSPORT INFORMATION

**IATA** Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable

**IMDG** Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class(es)** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : Marine pollutant: no

**ADR** Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : no

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<b>RID</b>	:	Not dangerous goods
<b>UN number</b>	:	Not applicable
<b>Proper shipping name</b>	:	Not applicable
<b>Transport hazard class</b>	:	Not applicable
<b>Packing group</b>	:	Not applicable
<b>Environmental hazards</b>	:	no
<b>Special precautions for user</b>	:	none
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	:	Not applicable

## SECTION 15. REGULATORY INFORMATION

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

**Therapeutic Goods (Poisons Standard) Instrument**

Not applicable

## SECTION 16. OTHER INFORMATION

Revision Date : 14.05.2024

Date format : dd.mm.yyyy

### Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development;

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OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

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**IBMX**

Version 3.1

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : IBMX

**Manufacturer or supplier's details**Company : Capsugel Australia Pty Ltd.  
Suite 610, 12 Century Circuit,  
Norwest NSW 2153, AustraliaLonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

**Recommended use of the chemical and restrictions on use**

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Flammable liquids : Category 4

**GHS label elements**

Hazard pictograms : None

Signal word : Warning

Hazard statements : H227 Combustible liquid.

Precautionary statements :

**Prevention:**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P280 Wear protective gloves/ eye protection/ face protection.

**Response:**

P370 + P378 In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.

**Other hazards which do not result in classification**

No information available.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Dimethyl sulfoxide	67-68-5	>= 90 - <= 100
3,7-Dihydro-3-isobutyl-1-methyl-1H-purine-2,6-dione	28822-58-4	>= 5 - < 10

### SECTION 4. FIRST AID MEASURES

- If inhaled : Remove person to fresh air. If signs/symptoms continue, get medical attention.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.  
Get medical attention if irritation develops and persists.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- If swallowed : Do not induce vomiting without medical advice.  
Immediately give large quantities of water to drink.  
Call a physician immediately.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : No information available.

### SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Dry powder  
Water spray  
Foam
- Hazardous combustion products : Nitrogen oxides (NO<sub>x</sub>)  
Carbon oxides (CO<sub>x</sub>)  
Sulphur oxides (SO<sub>x</sub>)
- Specific extinguishing methods : Use water spray to cool unopened containers.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

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#### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use respirator when performing operations involving potential exposure to vapour of the product.
- Environmental precautions : No special environmental precautions required.
- Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Do not flush into surface water or sanitary sewer system.

#### SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Take precautionary measures against static discharges. Keep away from open flames, hot surfaces and sources of ignition.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Hygiene measures : Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.
- Conditions for safe storage : Keep container tightly closed. To maintain product quality, do not store in heat or direct sunlight. Keep in a dry, cool and well-ventilated place.
- Recommended storage temperature : -20 °C

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

##### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dimethyl sulfoxide	67-68-5	TWA	250 ppm	US WEEL

- Engineering measures** : Use only in area provided with appropriate exhaust ventilation.

##### Personal protective equipment

- Respiratory protection : In the case of vapour formation use a respirator with an approved filter.
- Hand protection : Nitrile rubber
- Material : Nitrile rubber
- Rate of permeability : > 480 min

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Remarks	:	Wear suitable gloves.
Eye protection	:	Tightly fitting safety goggles
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear, colourless
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	Not applicable
Melting point/freezing point	:	18,4 °C
Initial boiling point and boiling range	:	189 °C
Flash point	:	89 °C
		Method: closed cup Solvent
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	42 %(V) Solvent
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Water solubility	:	completely miscible
Partition coefficient: n-octanol/water	:	No data available



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Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Stable under recommended storage conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	Temperature 89 °C Keep away from heat and sources of ignition.
Incompatible materials	:	Strong oxidizing agents Strong reducing agents Halogens Copper
Hazardous decomposition products	:	No decomposition if stored normally.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Acute oral toxicity	:	Acute toxicity estimate: > 2 000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Remarks: No data available

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Acute dermal toxicity

: Remarks: No data available

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**Skin corrosion/irritation**

Remarks : No data available

**Serious eye damage/eye irritation**

Remarks : No data available

**Respiratory or skin sensitisation**

Remarks : No data available

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

**Carcinogenicity**

Remarks : No data available

**ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**Reproductive toxicity**

Effects on fertility : Remarks: No data available

**STOT - single exposure**

Remarks : No data available

**STOT - repeated exposure**

Remarks : No data available

**Further information**

Remarks : No data is available on the product itself.

**The following toxicological data refer to:**

Dimethyl sulfoxide(CAS-No.: 67-68-5)

**Acute toxicity**

Acute oral toxicity : LD50 (Rat): 14 500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 40250 ppm  
Exposure time: 4 h  
Test atmosphere: dust/mistLC50 (Rat): 5 330 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rat, male and female): 40 000 mg/kg

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#### Skin corrosion/irritation

Species : Rabbit  
 Exposure time : 4 h  
 Assessment : No skin irritation  
 Method : OECD Test Guideline 404  
 Result : Mild skin irritation  
 GLP : yes

#### Serious eye damage/eye irritation

Species : Rabbit  
 Result : Mild eye irritation  
 Exposure time : 24 h  
 Assessment : No eye irritation  
 Method : OECD Test Guideline 405

#### Respiratory or skin sensitisation

Test Type : Maximisation Test  
 Species : Guinea pig  
 Assessment : Did not cause sensitisation on laboratory animals.  
 Method : OECD Test Guideline 406  
 Result : not sensitizing

#### Germ cell mutagenicity

Genotoxicity in vitro : Test Type: Ames test  
 Species: Salmonella  
 Metabolic activation: with and without metabolic activation  
 Method: OECD Test Guideline 471  
 Result: negative

: Test Type: Chromosome aberration test in vitro  
 Species: Chinese hamster ovary cells  
 Metabolic activation: yes  
 Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
 Species: Rat  
 Application Route: ip  
 Dose: 200, 1000 and 5000 mg/kg/d  
 Method: OECD Test Guideline 474  
 Result: negative  
 GLP: yes

#### Carcinogenicity

Remarks : No data available

#### Reproductive toxicity

Effects on fertility : Species: Rat  
 Application Route: Oral  
 General Toxicity - Parent: NOAEL: 1 000 mg/kg body weight  
 General Toxicity F1: NOAEL: 1 000 mg/kg body weight  
 Early Embryonic Development: NOAEL: 1 000 mg/kg body weight

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Effects on foetal development : Species: Rat  
 Application Route: Oral  
 Method: OECD Test Guideline 414  
 Result: No adverse effects

#### STOT - single exposure

Remarks : No data available

Exposure routes : inhalation (vapour)  
 Target Organs : Respiratory system

#### STOT - repeated exposure

Remarks : No data available

#### Repeated dose toxicity

Species : Rat  
 NOAEC : 47,5 mg/m<sup>3</sup>  
 Application Route : Inhalation  
 Target Organs : Liver, Lungs

#### Further information

Remarks : Can be absorbed through skin.

## SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

#### Persistence and degradability

Biodegradability : Result: no data available

#### Bioaccumulative potential

Bioaccumulation : Remarks: No data available

#### Mobility in soil

Distribution among environmental : Remarks: No data available

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compartments

**Other adverse effects**

Additional ecological information : No data is available on the product itself.

---

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**Waste from residues : Dispose of in accordance with local regulations.  
Contact waste disposal services.Contaminated packaging : Dispose of as unused product.  
Do not burn, or use a cutting torch on, the empty drum.

---

**SECTION 14. TRANSPORT INFORMATION****IATA**

Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable**IMDG**

Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class(es)** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : Marine pollutant: no**ADR**

: Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : no

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<b>RID</b>	:	Not dangerous goods
<b>UN number</b>	:	Not applicable
<b>Proper shipping name</b>	:	Not applicable
<b>Transport hazard class</b>	:	Not applicable
<b>Packing group</b>	:	Not applicable
<b>Environmental hazards</b>	:	no
<b>Special precautions for user</b>	:	none
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	:	Not applicable

## SECTION 15. REGULATORY INFORMATION

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

**Therapeutic Goods (Poisons Standard) Instrument**

Not applicable

## SECTION 16. OTHER INFORMATION

Revision Date : 14.05.2024

Date format : dd.mm.yyyy

### Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development;

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OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

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**Recombinant human insulin 0.1%**

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Recombinant human insulin 0.1%

**Manufacturer or supplier's details**Company : Capsugel Australia Pty Ltd.  
Suite 610, 12 Century Circuit,  
Norwest NSW 2153, AustraliaLonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

**Recommended use of the chemical and restrictions on use**

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards which do not result in classification**

Insulin: may cause hypoglycaemia.

Insulin is inactivated in the gastro-intestinal tract when ingested.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

No hazardous ingredients

**SECTION 4. FIRST AID MEASURES**

If inhaled : Move to fresh air.

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		If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	Wash with water and soap as a precaution. If on clothes, remove clothes. In the case of skin irritation or allergic reactions see a physician.
In case of eye contact	:	Flush eyes with water as a precaution. Remove contact lenses. Keep eye wide open while rinsing. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	Treat symptomatically.

#### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during firefighting	:	Heating or fire can release toxic gas.
Hazardous combustion products	:	No hazardous combustion products are known
Specific extinguishing methods	:	Use a water spray to cool fully closed containers.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment.
Environmental precautions	:	No special environmental precautions required. Try to prevent the material from entering drains or water courses.
Methods and materials for containment and cleaning up	:	Wipe up with absorbent material (e.g. cloth, fleece). Dispose of in accordance with local regulations.  Use neutralizing agents.

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Neutralize with chalk, alkali solution or ammonia.  
Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

## SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special precautions required.
- Normal measures for preventive fire protection.
- Advice on safe handling : No special precautions required.  
For personal protection see section 8.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
- Conditions for safe storage : Keep container tightly closed.  
Keep in a well-ventilated place.  
To maintain product quality, do not store in heat or direct sunlight.
- Materials to avoid : No special restrictions on storage with other products.
- Further information on storage stability : No decomposition if stored and applied as directed.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

- Engineering measures** : Use only in area provided with appropriate exhaust ventilation.

### Personal protective equipment

- Respiratory protection : No personal respiratory protective equipment normally required.  
In the case of vapour formation use a respirator with an approved filter.

Hand protection

- Remarks : Wear protective gloves. Break through time : > 480 min

- Eye protection : Safety glasses

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Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.  
Lightweight protective clothing

---

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Aqueous solution

Colour : colourless

Odour : odourless

Odour Threshold : No data available

pH : 2 - 4

Melting point/freezing point : No data available

Boiling point/boiling range : No data available

Flash point : Water

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Water solubility : completely soluble

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	No decomposition if stored and applied as directed.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	Heat
Incompatible materials	:	Oxidizing agents Strong acids and strong bases
Hazardous decomposition products	:	No decomposition if used as directed.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available

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Acute dermal toxicity

: Remarks: No data available

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**Skin corrosion/irritation**

Assessment : No skin irritation

**Serious eye damage/eye irritation**

Assessment : No eye irritation

**Respiratory or skin sensitisation**

Remarks : No data available

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

**Carcinogenicity**

Remarks : No data available

**ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**Reproductive toxicity**

Effects on fertility : Remarks: No data available

**STOT - single exposure**

Remarks : No data available

**STOT - repeated exposure**

Remarks : No data available

**Aspiration toxicity**

No aspiration toxicity classification

**Further information**Remarks : Insulin: may cause hypoglycaemia.  
Insulin is inactivated in the gastro-intestinal tract when ingested.  
May cause central nervous system depression.  
May induce sweating, pallor or visual disturbances.

Remarks : No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**Toxicity to fish :  
Remarks: No data available**Persistence and degradability**

Biodegradability : Remarks: No data available

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#### Bioaccumulative potential

Bioaccumulation : Remarks: No data available

#### Mobility in soil

Distribution among environmental compartments : Remarks: No data available

#### Other adverse effects

Additional ecological information : No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Solutions with low pH-value must be neutralized before discharge.  
Dispose of contents/container in accordance with local regulation.  
Contact waste disposal services.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

### SECTION 14. TRANSPORT INFORMATION

**IATA** Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable

**IMDG** Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class(es)** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : Marine pollutant: no

**ADR** : Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : no



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<b>RID</b>	:	Not dangerous goods
<b>UN number</b>	:	Not applicable
<b>Proper shipping name</b>	:	Not applicable
<b>Transport hazard class</b>	:	Not applicable
<b>Packing group</b>	:	Not applicable
<b>Environmental hazards</b>	:	no
<b>Special precautions for user</b>	:	none
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	:	Not applicable

## SECTION 15. REGULATORY INFORMATION

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

**Therapeutic Goods (Poisons Standard) Instrument**

Not applicable

## SECTION 16. OTHER INFORMATION

Revision Date : 14.05.2024

Date format : dd.mm.yyyy

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative)

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Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

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**Fetal Bovine Serum**

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Fetal Bovine Serum

**Manufacturer or supplier's details**Company : Capsugel Australia Pty Ltd.  
Suite 610, 12 Century Circuit,  
Norwest NSW 2153, AustraliaLonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

**Recommended use of the chemical and restrictions on use**

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards which do not result in classification**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

No hazardous ingredients

**SECTION 4. FIRST AID MEASURES**If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical

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		advice. If symptoms persist, call a physician.
In case of skin contact	:	Wash with water and soap as a precaution. If on clothes, remove clothes. In the case of skin irritation or allergic reactions see a physician.
In case of eye contact	:	Flush eyes with water as a precaution. Remove contact lenses. Keep eye wide open while rinsing. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	Treat symptomatically.

#### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during firefighting	:	Heating or fire can release toxic gas.
Hazardous combustion products	:	No hazardous combustion products are known
Specific extinguishing methods	:	Use a water spray to cool fully closed containers.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

#### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment.
Environmental precautions	:	Try to prevent the material from entering drains or water courses.
Methods and materials for containment and cleaning up	:	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

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**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : No special precautions required.  
Normal measures for preventive fire protection.
- Advice on safe handling : No special precautions required.  
For personal protection see section 8.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
- Conditions for safe storage : Keep container tightly closed.  
Keep in a well-ventilated place.  
To maintain product quality, do not store in heat or direct sunlight.
- Materials to avoid : No special restrictions on storage with other products.
- Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

- Engineering measures** : Use only in area provided with appropriate exhaust ventilation.

**Personal protective equipment**

- Respiratory protection : No personal respiratory protective equipment normally required.  
In the case of vapour formation use a respirator with an approved filter.

Hand protection

- Remarks : Wear protective gloves. Break through time : > 480 min

- Eye protection : Safety glasses

- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.  
Lightweight protective clothing

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	Aqueous solution
Colour	:	brown
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	6,8 - 8,3
Melting point/freezing point	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available

**SECTION 10. STABILITY AND REACTIVITY**

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Reactivity	:	No decomposition if stored and applied as directed.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	Heat
Incompatible materials	:	Oxidizing agents Strong acids and strong bases
Hazardous decomposition products	:	No decomposition if used as directed.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

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Acute dermal toxicity

: Remarks: No data available



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**Skin corrosion/irritation**

Remarks : No data available

**Serious eye damage/eye irritation**

Remarks : No data available

**Respiratory or skin sensitisation**

Remarks : No data available

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

**Carcinogenicity**

Remarks : No data available

**ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**Reproductive toxicity**

Effects on fertility : Remarks: No data available

**STOT - single exposure**

Remarks : No data available

**STOT - repeated exposure**

Remarks : No data available

**Aspiration toxicity**

No aspiration toxicity classification

**Further information**

Remarks : No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**Toxicity to fish :  
Remarks: No data available**Persistence and degradability**

Biodegradability : Remarks: No data available

**Bioaccumulative potential**

Bioaccumulation : Remarks: No data available

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**Mobility in soil**

Distribution among environmental compartments : Remarks: No data available

**Other adverse effects**

Additional ecological information : No data available

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

**SECTION 14. TRANSPORT INFORMATION****IATA**

Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable

**IMDG**

Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class(es)** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : Marine pollutant: no

**ADR**

Not dangerous goods

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Transport hazard class** : Not applicable  
**Packing group** : Not applicable  
**Environmental hazards** : no

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<b>RID</b>	:	Not dangerous goods
<b>UN number</b>	:	Not applicable
<b>Proper shipping name</b>	:	Not applicable
<b>Transport hazard class</b>	:	Not applicable
<b>Packing group</b>	:	Not applicable
<b>Environmental hazards</b>	:	no
<b>Special precautions for user</b>	:	none
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	:	Not applicable

## SECTION 15. REGULATORY INFORMATION

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

**Therapeutic Goods (Poisons Standard) Instrument**

Not applicable

## SECTION 16. OTHER INFORMATION

Revision Date : 14.05.2024

Date format : dd.mm.yyyy

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative)

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Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

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**L-GLUTAMINE**

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : L-GLUTAMINE

**Manufacturer or supplier's details**Company : Capsugel Australia Pty Ltd.  
Suite 610, 12 Century Circuit,  
Norwest NSW 2153, AustraliaLonza Ltd  
Muenchensteinerstrasse 38  
CH-4002 Basel, Switzerland

Telephone : Tel +61 3 9550 0883

Telefax : Tel +61 3 9550 0890

E-mail address : sds@lonza.com

Emergency telephone number : +41 61 313 94 94 (24h)

**Recommended use of the chemical and restrictions on use**

Recommended use : For research use only.

Restrictions on use : NOT FOR USE IN GMP MANUFACTURING, NOR HUMAN OR ANIMAL IN VIVO OR DIAGNOSTIC USE.

**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards which do not result in classification**

No information available.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

No hazardous ingredients

**SECTION 4. FIRST AID MEASURES**

If inhaled : No special precautions required.

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In case of skin contact	:	Wash with water and soap as a precaution. If skin irritation persists, call a physician.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.
If swallowed	:	Immediately give large quantities of water to drink. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	No information available.

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**SECTION 5. FIREFIGHTING MEASURES**

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Suitable extinguishing media	:	Water spray Dry powder Foam
Hazardous combustion products	:	Nitrogen oxides (NO <sub>x</sub> ) Carbon oxides (CO <sub>x</sub> )
Specific extinguishing methods	:	Use water spray to cool unopened containers.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

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Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment.
Environmental precautions	:	Prevent product from entering drains.
Methods and materials for containment and cleaning up	:	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

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**SECTION 7. HANDLING AND STORAGE**

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Advice on protection against fire and explosion	:	Take precautionary measures against static discharges.
Advice on safe handling	:	No special precautions required.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety

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practice.

Conditions for safe storage : No special storage conditions required.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

**Engineering measures** : Avoid splashes.**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Nitrile rubber

Rate of permeability : &gt; 480 min

Eye protection : Safety glasses

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.  
No special protective equipment required.**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Aqueous solution

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

No data available

Evaporation rate : No data available

Flammability (solid, gas) : No data available

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Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	:	Stable under recommended storage conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Stable under normal conditions.
Conditions to avoid	:	No data available
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored normally.

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Acute oral toxicity	:	Remarks: No data available
Acute inhalation toxicity	:	Remarks: No data available



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Acute dermal toxicity

: Remarks: No data available

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**Skin corrosion/irritation**

Remarks : No data available

**Serious eye damage/eye irritation**

Remarks : No data available

**Respiratory or skin sensitisation**

Remarks : No data available

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

**Carcinogenicity**

Remarks : No data available

**ACGIH**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**Reproductive toxicity**

Effects on fertility : Remarks: No data available

**STOT - single exposure**

Remarks : No data available

**STOT - repeated exposure**

Remarks : No data available

**Further information**

Remarks : No data is available on the product itself.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**Toxicity to fish :  
Remarks: No data available**Persistence and degradability**

Biodegradability : Result: no data available

**Bioaccumulative potential**

Bioaccumulation : Remarks: No data available

**Mobility in soil**

Distribution among environmental compartments : Remarks: No data available

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#### Other adverse effects

Additional ecological information : No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

### SECTION 14. TRANSPORT INFORMATION

#### IATA

Not dangerous goods

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Transport hazard class : Not applicable  
 Packing group : Not applicable

#### IMDG

Not dangerous goods

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Transport hazard class(es) : Not applicable  
 Packing group : Not applicable  
 Environmental hazards : Marine pollutant: no

#### ADR

Not dangerous goods

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Transport hazard class : Not applicable  
 Packing group : Not applicable  
 Environmental hazards : no

#### RID

Not dangerous goods

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Transport hazard class : Not applicable  
 Packing group : Not applicable  
 Environmental hazards : no

Special precautions for user : none

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not applicable

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture****Therapeutic Goods (Poisons Standard) Instrument**

Not applicable

**SECTION 16. OTHER INFORMATION**

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