

## Kit SDS Cover Sheet

### HMM™ SingleQuotes®

Version 2.0

Revision Date 30.06.2021

Print Date 26.04.2024

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#### Product Information

Commercial : Clonetics®  
Product Name  
Product name : HMM™ SingleQuotes®  
Material number : CC-4192

#### Components

Dexamethasone solution	SDS attached
GA-1000	SDS attached
Recombinant human insulin 0.5%	SDS attached

## SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

### GA-1000

Version 2.0

Revision Date 30.06.2021

Print Date 26.04.2024

## 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, 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 : Scientific research and development

## 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 protection.

### Response:

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

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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

No information available.

### 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 immediately.  
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.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
If eye irritation persists, consult a specialist.
- If swallowed : Immediately give plenty of water (if possible charcoal slurry).  
Do not induce vomiting without medical advice.  
Never give anything by mouth to an unconscious person.  
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : Allergic appearance  
sensitising effects
- Notes to physician : Treat symptomatically.

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### SECTION 5. FIREFIGHTING MEASURES

- |   |   |   |
|---|---|---|
| Suitable extinguishing media                  | : | Not combustible.<br>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Hazardous combustion products                 | : | No hazardous combustion products are known  |
| 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.<br>Refer to protective measures listed in sections 7 and 8.  |
| 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). |

### SECTION 7. HANDLING AND STORAGE

- |   |   |   |
|---|---|---|
| Advice on protection against fire and explosion | : | Stable under normal conditions.   |
| Advice on safe handling                         | : | In case of insufficient ventilation, wear suitable respiratory equipment.<br>Avoid exposure - obtain special instructions before use.<br>Use only in area provided with appropriate exhaust ventilation.<br>Avoid contact with skin and eyes. |
| Hygiene measures                                | : | DANGER!<br>Avoid contact with the skin and the eyes.<br>Avoid breathing dust or spray mist.<br>Wash hands before breaks and immediately after handling the product.   |
| Conditions for safe storage                     | : | Keep frozen or refrigerated.  |

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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#### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

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

#### Personal protective equipment

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

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Eye protection : Safety glasses  
Safety goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.  
Complete suit protecting against chemicals

## 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

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Relative density	:	no data available
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

## 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	:	None known.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored normally.

## SECTION 11. TOXICOLOGICAL INFORMATION

### Further information

Remarks: No data is available on the product itself.

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Toxicity to fish	:	Remarks: no data available
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### Persistence and degradability

Biodegradability	:	Result: no data available
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### Bioaccumulative potential

Bioaccumulation	:	Remarks: no data available
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### Mobility in soil

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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.

Contaminated packaging : Dispose of as unused product.

## 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  
 Environmental hazards : no

#### IMDG

Not dangerous goods

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

**Standard for the Uniform Scheduling of Medicines and Poisons**

Not applicable

## SECTION 16. OTHER INFORMATION

Revision Date : 30.06.2021

### 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) 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



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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  
Date format : dd.mm.yyyy

**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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### Dexamethasone solution

Version 2.0

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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 : Scientific research and development

#### 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.

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.

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#### 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.  
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

- 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.

#### 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).

#### 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.

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

##### Components with workplace control parameters

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

Evaporation rate : no data available

Flammability (solid, gas) : no data available

Flammability (liquids) : no data available

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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

**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.

**SECTION 11. TOXICOLOGICAL INFORMATION****Further information**

Remarks: No data is available on the product itself.

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#### The following toxicological data refer to:

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

#### Acute toxicity

Acute oral toxicity : LD50 (Rat): > 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  
  
LC50 (Rat): 117 - 125 mg/l  
Exposure time: 4 h

Acute dermal toxicity : Remarks: no data available

#### Skin corrosion/irritation

Species: Rabbit  
Method: OECD Test Guideline 404  
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

#### Reproductive toxicity

Effects on fertility : Remarks: no data available

Species: Mouse  
Application Route: Oral  
Method: OECD Test Guideline 416

#### Repeated dose toxicity

Species: Rat, male and female

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NOAEL: 1 730 mg/kg  
LOAEL: 3 200 mg/kg  
Application Route: Oral  
Exposure time: 14 Weeks

## 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

### Components:

#### Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0,3

### Mobility in soil

Distribution among environmental compartments : Remarks: no data available

### Other adverse effects

Additional ecological information : Information refers to the main component.

## 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.



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#### SECTION 14. TRANSPORT INFORMATION

##### IATA

UN number	: 1170
Proper shipping name	: Ethanol solution
Transport hazard class	: 3
Packing group	: II
Labels	: 3
Environmental hazards	: no

##### IMDG

UN number	: 1170
Proper shipping name	: Ethanol solution
Transport hazard class	: 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	: 3
Packing group	: II
Classification Code	: F1
Hazard Identification Number	: 33
Labels	: 3
Environmental hazards	: no

##### RID

UN number	: 1170
Proper shipping name	: ETHANOL SOLUTION
Transport hazard class	: 3
Packing group	: II
Classification Code	: F1
Hazard Identification Number	: 33
Labels	: 3
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**

**Standard for the Uniform Scheduling of Medicines and Poisons**

Not applicable

## SECTION 16. OTHER INFORMATION

Revision Date : 30.06.2021

### Full text of other abbreviations

ACGIH : US. ACGIH Threshold Limit Values  
 AU NOEL : Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A), as amended  
 ACGIH / STEL : Short term exposure limit  
 AU NOEL / TWA : Time weighted average

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) 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  
 Date format : dd.mm.yyyy

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**Recombinant human insulin 0.5%**

Version 2.0

Revision Date 30.06.2021

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Recombinant human insulin 0.5%

**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 : Scientific research and development

**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 : No special precautions required.

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.

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- 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.

## SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Dry powder  
Foam
- Hazardous combustion products : No hazardous combustion products are known
- 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 personal protective equipment.
- Environmental precautions : No special environmental precautions required.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Dispose of in accordance with local regulations.

## SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special precautions required.
- Advice on safe handling : No special precautions required.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
- Conditions for safe storage : No special storage conditions required.

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## 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.

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 : Aqueous solution

Colour : colourless

Odour : odourless

Odour Threshold : no data available

pH : 2 - 4

Melting point/freezing point : no data available

Initial boiling point and 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 : 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 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

## 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.

## SECTION 11. TOXICOLOGICAL INFORMATION

### Acute toxicity

Acute oral toxicity : Remarks: no data available

Acute inhalation toxicity : Remarks: no data available

Acute dermal toxicity : Remarks: no data available

### Skin corrosion/irritation

Assessment: No skin irritation

### Serious eye damage/eye irritation

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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

#### 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.

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.

## 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 : no data available



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#### SECTION 13. DISPOSAL CONSIDERATIONS

##### Disposal methods

Waste from residues : Contact waste disposal services.  
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  
Environmental hazards : no

##### IMDG

Not dangerous goods

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

**Standard for the Uniform Scheduling of Medicines and Poisons**

Not applicable

## SECTION 16. OTHER INFORMATION

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### Full text of other abbreviations

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 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

Date format : dd.mm.yyyy

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