

Kit SDS Cover Sheet**KGM® Gold SingleQuots®**

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

Product Information

Commercial Product Name : Clonetics®
Product name : KGM® Gold SingleQuots®
Material number : 00192152

Components

Hydrocortisone solution	SDS attached
Transferrin	SDS attached
Epinephrine	SDS attached
GA-1000	SDS attached
BPE Low Protein - non specific	SDS attached
hEGF	SDS attached
Recombinant human insulin 0.5%	SDS attached

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Hydrocortisone solution

Manufacturer or supplier's detailsCompany : 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 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.

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 : Prevent product from entering drains.

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.

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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 ³	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 °C
Information refers to the main component.

Flash point : 12 °C
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 ³ (20 °C)
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	:	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**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

ACGIHConfirmed 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): > 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/irritationSpecies : 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

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 is available on the product itself.

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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.

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

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
Special precautions for user	: none
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	: 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 : 30.04.2024

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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GA-1000

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : GA-1000

Manufacturer or supplier's detailsCompany : 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

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.

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

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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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

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 : 30.04.2024

Date format : dd.mm.yyyy

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 -

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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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SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Transferrin

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Transferrin

Manufacturer or supplier's detailsCompany : 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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according to Work Health and Safety Regulations 2011

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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.

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	:	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).

SECTION 7. HANDLING AND STORAGE

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 practice.

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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 : > 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 : 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

Flammability (liquids) : No data available

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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

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

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according to Work Health and Safety Regulations 2011

Transferrin

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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.

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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Version 3.0

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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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Print Date 26.05.2024

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 : 30.04.2024

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) 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

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Transferrin

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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SAFETY DATA SHEET

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Epinephrine

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Epinephrine

Manufacturer or supplier's detailsCompany : 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.

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	:	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).

SECTION 7. HANDLING AND STORAGE

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 practice.

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Epinephrine

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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 : > 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 : 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

Flammability (liquids) : No data available

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according to Work Health and Safety Regulations 2011

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Revision Date 30.04.2024

Print Date 26.05.2024

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

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

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Acute dermal toxicity

: Remarks: No data available

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Epinephrine

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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.

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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according to Work Health and Safety Regulations 2011

Epinephrine

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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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according to Work Health and Safety Regulations 2011

Epinephrine

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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 : 30.04.2024

Date format : dd.mm.yyyy

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

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Epinephrine

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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SAFETY DATA SHEET

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BPE Low Protein - non specific

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : BPE Low Protein - non specific

Manufacturer or supplier's detailsCompany : 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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BPE Low Protein - non specific

Version 3.0

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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.

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	:	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).

SECTION 7. HANDLING AND STORAGE

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 practice.

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BPE Low Protein - non specific

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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 : > 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 : 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

Flammability (liquids) : No data available

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according to Work Health and Safety Regulations 2011

BPE Low Protein - non specific

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Revision Date 30.04.2024

Print Date 26.05.2024

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

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

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according to Work Health and Safety Regulations 2011

BPE Low Protein - non specific

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Acute dermal toxicity

: Remarks: No data available

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according to Work Health and Safety Regulations 2011

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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.

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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BPE Low Protein - non specific

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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

Revision Date : 30.04.2024

Date format : dd.mm.yyyy

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

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according to Work Health and Safety Regulations 2011

BPE Low Protein - non specific

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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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SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

hEGF

Version 3.0

Revision Date 30.04.2024

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : hEGF

Manufacturer or supplier's detailsCompany : 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.

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	:	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).

SECTION 7. HANDLING AND STORAGE

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 practice.

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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 : > 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 : 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

Flammability (liquids) : No data available

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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

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

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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.

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

Revision Date : 30.04.2024

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) 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

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according to Work Health and Safety Regulations 2011

hEGF

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant human insulin 0.5%

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Recombinant human insulin 0.5%

Manufacturer or supplier's detailsCompany : 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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Recombinant human insulin 0.5%

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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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Recombinant human insulin 0.5%

Version 3.0

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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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Recombinant human insulin 0.5%

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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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Recombinant human insulin 0.5%

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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.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

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

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Recombinant human insulin 0.5%

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Acute dermal toxicity

: Remarks: No data available

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Recombinant human insulin 0.5%

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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 informationRemarks : 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

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

Biodegradability : Remarks: No data available

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according to Work Health and Safety Regulations 2011

Recombinant human insulin 0.5%

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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

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant human insulin 0.5%

Version 3.0

Revision Date 30.04.2024

Print Date 26.05.2024

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

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 : 30.04.2024

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)

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

Recombinant human insulin 0.5%

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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

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