

## SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

### ProCHO5 w/Pluronic w/o L-Gln or HT, 1L

Version 3.0

Revision Date 16.04.2024

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#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : ProCHO5 w/Pluronic w/o L-Gln or HT, 1L

Material number : BELN12-766Q

##### 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 : Suitable for GMP manufacturing.

Restrictions on use : Not for 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

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**SECTION 4. FIRST AID MEASURES**

|   |   |  |
|---|---|--|
| If inhaled  | : | No special precautions required.   |
| In case of skin contact                                     | : | Wash with water and soap as a precaution.<br>If skin irritation persists, call a physician.  |
| In case of eye contact                                      | : | Immediately flush eye(s) with plenty of water.<br>If eye irritation persists, consult a specialist.  |
| If swallowed  | : | Immediately give large quantities of water to drink.<br>Do not induce vomiting without medical advice.<br>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                  | : | Water spray<br>Dry powder<br>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. |

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**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). |

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**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 |

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practice.  
Conditions for safe storage : Store in cool place.

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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** : 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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Aqueous solution

Colour : light yellow

Odour : No data available

Odour Threshold : No data available

pH : 6,8 - 7,4

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

Upper explosion limit / Upper flammability limit : No data available

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|  |   |   |
|--|---|---|
| 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  | : | 1,01 g/cm <sup>3</sup><br>No data available |
| Water solubility                                 | : | No data available                           |
| Partition coefficient: n-octanol/water           | : | No data available                           |
| Auto-ignition temperature                        | : | No data available                           |
| Decomposition temperature                        | : | No data available                           |
| Viscosity, dynamic                               | : | No data available                           |
| Viscosity, kinematic                             | : | No data available                           |

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**SECTION 10. STABILITY AND REACTIVITY**

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

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

|                           |   |                            |
|---------------------------|---|----------------------------|
| Acute oral toxicity       | : | Remarks: No data available |
| Acute inhalation toxicity | : | Remarks: No data available |
| Acute dermal toxicity     | : | Remarks: No data available |

**Skin corrosion/irritation**

|         |   |                   |
|---------|---|-------------------|
| Remarks | : | No data available |
|---------|---|-------------------|

**Serious eye damage/eye irritation**

|         |   |                   |
|---------|---|-------------------|
| Remarks | : | No data available |
|---------|---|-------------------|

**Respiratory or skin sensitisation**

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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.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**

Toxicity to fish :  
Remarks: No data available

**Persistence and degradability**

Biodegradability : Result: no data available

**Bioaccumulative potential**

Bioaccumulation : Remarks: No data available

**Mobility in soil**

Distribution among environmental compartments : Remarks: No data available

**Other adverse effects**

Additional ecological information : No data available

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

Waste from residues : Dispose of contents/container in accordance with local regulation.  
Contact waste disposal services.

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**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

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**SECTION 16. OTHER INFORMATION**

Revision Date : 16.04.2024

Date format : dd.mm.yyyy

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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); EC<sub>x</sub> - Concentration associated with x% response; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - 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; IC<sub>50</sub> - 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; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - 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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