

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

(STD) ProCHO5 Powder

Version 3.0

Revision Date 16.04.2024

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : (STD) ProCHO5 Powder

Material number : WPW-045D

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

Skin sensitisation : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

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.

Response:

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P302 + P352 IF ON SKIN: Wash with plenty of water.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
 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

May form combustible dust concentrations in air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Sodium pyruvate	113-24-6	>= 1 - < 3

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
 In the case of inhalation of aerosol/mist consult a physician if necessary.

In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
 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 : If swallowed, do not induce vomiting - seek medical advice.
 Immediately give large quantities of water to drink.
 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 : Nitrogen oxides (NOx)
 Sodium oxides
 Potassium oxides
 Carbon oxides (COx)
 Hydrogen chloride (HCl)
 Sulphur oxides (SOx)

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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. Avoid dust formation.
Environmental precautions	:	Prevent product from entering drains.
Methods and materials for containment and cleaning up	:	Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are re-leased into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Non-sparking tools should be used.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Avoid dust formation. During processing, dust may form explosive mixture in air.
Advice on safe handling	:	Minimize dust generation and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.
Conditions for safe storage	:	No special storage conditions required. Store in cool place.
Further information on storage conditions	:	Dark and Dry

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures	:	It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust-handling systems (such as exhaust ducts,
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dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Personal protective equipment

Respiratory protection	:	Dust safety masks are recommended when the dust concentration is more than 10 mg/m ³ .
Hand protection	:	
Material	:	Nitrile rubber
Rate of permeability	:	> 480 min
Eye protection	:	Safety glasses with side-shields
Skin and body protection	:	No special protective equipment required.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	powder
Colour	:	colourless
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	Not applicable
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapour pressure	:	No data available
Relative vapour density	:	Not applicable
Relative density	:	No data available

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Density	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	No data available
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

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

Skin corrosion/irritation

Remarks	:	No data available
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Serious eye damage/eye irritation

Remarks	:	No data available
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Respiratory or skin sensitisation

Remarks	:	No data available
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Germ cell mutagenicity

Genotoxicity in vitro	:	Remarks: No data available
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Carcinogenicity

Remarks	:	No data available
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Reproductive toxicity

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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:

Sodium pyruvate(CAS-No.: 113-24-6)

Acute toxicity

Acute oral toxicity : LD50 (Rat): > 5 600 mg/kg

Respiratory or skin sensitisation

Method : OECD Test Guideline 429
Result : May cause sensitisation by skin contact.
GLP : yes

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

SECTION 13. DISPOSAL CONSIDERATIONS

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Disposal methods

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

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

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

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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