

SAFETY DATA SHEET

according to Work Health and Safety Regulations 2011

STD POWERCHO-2W/OPEG,InsProIpCit

Version 4.0

Revision Date 16.04.2024

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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : STD POWERCHO-2W/OPEG,InsProIpCit

Material number : WPW-088F

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

Serious eye damage/eye irritation : Category 2A

Skin sensitisation : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out

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of the workplace.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

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

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

P337 + P313 If eye irritation persists: 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
Tyrosine disodium salt dihydrate	122666-87-9	>= 1 - < 3

SECTION 4. FIRST AID MEASURES

- If inhaled : Remove to fresh air.
If breathing is irregular or stopped, administer artificial respiration.
If symptoms persist, call a physician.
- 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 : Call a physician immediately.
Clean mouth with water and drink afterwards plenty of water.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : None known.

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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Dry powder
Water spray
Foam
- Hazardous combustion products : Nitrogen oxides (NO_x)
Sodium oxides
Potassium oxides
Carbon oxides (CO_x)
Hydrogen chloride (HCl)
Sulphur oxides (SO_x)
- 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 : Avoid dust formation.
Use personal protective equipment.
- Environmental precautions : Prevent product from entering drains.
- Methods and materials for containment and cleaning up : Do not flush into surface water or sanitary sewer system.
Non-sparking tools should be used.
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Contain spillage, pick up with an electrically protected vacuum cleaner or by wet-brushing and transfer to a container for disposal according to local regulations (see section 13).
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SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Avoid dust formation.
Take precautionary measures against static discharges.
During processing, dust may form explosive mixture in air.
- Advice on safe handling : Avoid formation of respirable particles.
Provide sufficient air exchange and/or exhaust in work rooms.
Avoid contact with skin and eyes.
- 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.

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| Hygiene measures | : | Wash hands before breaks and immediately after handling the product.
Avoid contact with skin, eyes and clothing. |
| Conditions for safe storage | : | No special storage conditions required. |
| Further information on storage conditions | : | Dark and Dry |
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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

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| 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, 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. |
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Personal protective equipment

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|--------------------------|---|---|
| Respiratory protection | : | In the case of dust or aerosol formation use respirator with an approved filter. |
| Hand protection | : | |
| Material | : | Nitrile rubber |
| Rate of permeability | : | > 480 min |
| Eye protection | : | Safety glasses with side-shields |
| 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

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|------------------------------|---|-------------------|
| Appearance | : | powder |
| Colour | : | white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | 6,3 - 6,9 |
| Melting point/freezing point | : | No data available |

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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
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

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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

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.

The following toxicological data refer to:

Tyrosine disodium salt dihydrate(CAS-No.: 122666-87-9)

Acute toxicity

Acute oral toxicity : LD50 (Rat, female): > 2 000 mg/kg
Method: OECD Test Guideline 420

Serious eye damage/eye irritation

Species : Bovine cornea
Result : Causes serious eye damage.
Exposure time : 4 h
Method : OECD Test Guideline 437
Test substance : Information given is based on data obtained from similar substances.

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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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

Contaminated packaging : Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

IATA

Not dangerous goods

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

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

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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 Ob-

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servable 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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