


Section 1: Identification

Common Name/Trade Name	CYCLOSPORINE	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours) NSW Poisons Information Centre: 131 126 (24 hours)
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	Ciclosporin	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4), Carcinogenicity (Category 1A), Specific target organ toxicity, repeated (Category 1) (immune system, kidney)	
Signal Word	Danger	
Hazard Statement(s)	H302 H350 H372	Harmful if swallowed May cause cancer Causes damage to organs through prolonged or repeated exposure
Pictogram(s)		
Precautionary Statement(s)	P201 P202 P260 P264 P280 P301+P312+P330 P308+P313 P314 P405 P501	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. IF exposed or concerned Get medical advice/attention. Get Medical advice/attention if you feel unwell. Store locked up. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	None known	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	Cyclosporine
Common Name	Cyclosporine
CAS Number	59865-13-3
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
If Inhaled	Move to fresh air. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
In Case of Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
If Swallowed	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
Most Important Symptoms and Effects	Immunosuppression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. Treat symptomatically. Overdose treatment should be symptomatic and supportive and may include the following: Support respiratory and cardiovascular function. Induced vomiting is not recommended. Consider activated charcoal or gastric lavage after a potentially toxic ingestion. Control seizures with a benzodiazepine; if seizures persist or recur, administer phenobarbital. Correct magnesium deficits. Calcium channel blockers may be the preferred agent for treatment of cyclosporine-induced hypertension, as they may prevent nephrotoxicity. Low-dose dopamine is effective for treatment of nephrotoxicity. Azithromycin or metronidazole has been used to treat gingival hyperplasia. Monitor cyclosporine plasma levels, kidney and liver function, and serum electrolytes. Hemodialysis does not appear to be effective in increasing clearance of cyclosporine. [Poisindex 2005; Poisoning & Toxicity 2005]

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Water. Foam. Dry chemical or CO ₂ . Use fire-extinguishing media appropriate for surrounding materials.
Special Hazards Arising From the Substance/Mixture	No unusual fire or explosion hazards noted.
Special PPE and/or Precautions for Firefighters	Wear suitable protective equipment. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Specific methods Use standard firefighting procedures and consider the hazards of other involved materials. General fire hazards No unusual fire or explosion hazards noted.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	For personal protection, see section 8 of the SDS. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and Materials Used for Containment	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Cleanup Procedures	Avoid discharge into drains, water courses or onto the ground

Section 7: Handling and Storage

Precautions for Safe Handling	As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential
Conditions for Safe Storage	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No exposure limits noted for ingredient(s). No biological exposure limits noted for the ingredient(s).
Appropriate Engineering Controls	No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
PPE - Eye/Face Protection	Wear safety glasses with side shields, chemical splash goggles, or full-face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available
PPE - Skin Protection	Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
PPE - Body Protection	Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Thermal hazards Wear appropriate thermal protective clothing, when necessary
PPE - Respiratory Protection	Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls

Section 9: Physical and Chemical Properties

Appearance	Form: Solid Color: White
Upper/Lower Flammability or Explosive Limits	Not available.
Odor	Not available
Vapor Pressure	< 0.0000001 kPa at 25°C
Odor Threshold	Not available
Vapor Density	No data available
pH	No data available
Relative Density	Not available
Melting Point/Freezing Point	298.4 - 303.8°F (148 – 151°C)
Solubility	Solubility (water) Practically insoluble. Solubility (other) Acetone: Soluble. Alcohol: Soluble. Chloroform: Soluble. Ether: Soluble.
Initial Boiling Point and Boiling Range	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability (Solid, Gas)	Not available
Partition Coefficient	(n-octanol/water) 2.92
Auto-Ignition Temperature	Not available
Decomposition Temperature	Not available
Viscosity	Not available

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Contact with incompatible materials.
Incompatible Materials	Oxidizing agents.
Hazardous Decomposition Products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Harmful if swallowed.
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	Knowledge about health hazard is incomplete
Serious Eye Damage/Irritation	Knowledge about health hazard is incomplete
Respiratory or Skin Sensitization	Knowledge about health hazard is incomplete
Germ Cell Mutagenicity	Based on available data, the classification criteria are not met. Mutagenicity Ames test (Salmonella typhimurium) Result: Negative. Dominant lethal test Result: Negative. Species: Mouse In vitro sister chromatid exchange (human lymphocytes) Result: Positive. Mutagenicity, Chromosomal aberrations in bone marrow of Chinese hamsters Result: Negative. Mutagenicity, Gene mutations in Chinese hamster cells Result: Negative.
Carcinogenicity IARC	1 Carcinogenic to humans.
Carcinogenicity ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen or potential carcinogen by ACGIH.
Carcinogenicity NTP	Known To Be Human Carcinogen.
Carcinogenicity OSHA	Not regulated.
Reproductive Toxicity	Knowledge about health hazard is incomplete. 100 mg/kg/day Reproductivity. Increased prenatal and postnatal mortality and reduced fetal weight. Result: Positive. Species: Rabbit 30 mg/kg Reproductivity. No increase in malformations was found at maternally toxic doses, but fetal death and growth retardation occurred. Result: Negative. Species: Rat < 17 mg/kg/day Reproductivity, No embryo-lethal or teratogenic effects. Result: Positive. Species: Rat
Specific Target Organ Toxicity - Single Exposure	Knowledge about health hazard is incomplete.
Specific Target Organ Toxicity - Repeated Exposure	Causes damages to organs (immune system kidney) through prolonged or repeated exposure.
Aspiration Hazard	Based on available data, the classification criteria are not met

Section 12: Ecological Information

Toxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and Degradability	No data is available on the degradability of this product.
Bio-accumulative Potential	Bio-accumulative potential Octanol/water partition coefficient log Kow 2.92
Mobility in Soil	No data available
Other Adverse Effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Section 13: Disposal Considerations

Waste Treatment Methods Product	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Waste Treatment Methods Packaging	Dispose in accordance with all applicable regulations. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not regulated. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance Not listed SARA 311/312 Hazardous chemical Yes SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water Act (SDWA) Not regulated. US state regulations US - California Proposition 65 - CRT: Listed date/Carcinogenic substance Cyclosporine (CAS 59865-13-3) Listed: January 1, 1992 International Inventories Country(s) or region Inventory name On inventory (yes/no)* Australia Australian Inventory of Chemical Substances (AICS) No Canada Domestic Substances List (DSL) Yes Canada Non-Domestic Substances List (NDSL) No China Inventory of Existing Chemical Substances in China (IECSC) Yes Europe European Inventory of Existing Commercial Chemical Substances (EINECS) No Europe European List of Notified Chemical Substances (ELINCS) No Japan Inventory of Existing and New Chemical Substances (ENCS) No Korea Existing Chemicals List (ECL) No New Zealand New Zealand Inventory Yes Philippines Philippine Inventory of Chemicals and Chemical Substances (PICCS) No United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No *A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s)

Section 16: Other Information

Additional Information	N/A
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