


Section 1: Identification

Common Name/Trade Name	TACROLIMUS USP	
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)
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)	N/A	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 3), Serious eye damage/eye irritation (Category 2B), Specific target organ toxicity, repeated exposure (Category 1) Immune system	
Signal Word	Danger	
Hazard Statement(s)	H301 H320 H372	Toxic if swallowed Causes eye irritation Causes damage to organs through prolonged or repeated exposure
Pictogram(s)		
Precautionary Statement(s)	P201 P202 P233 P260 P264 P270 P280 P301+P310 P305+P351+P338 P314 P330 P337+P313 P405 P501	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Keep container tightly closed. Do not breathe dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. Get Medical advice/attention if you feel unwell. Rinse mouth. If eye irritation persists Get medical advice/attention. Store locked up. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	The toxicological properties of this compound have not been fully investigated. Exercise appropriate precautions to prevent opportunities for inhalation and to prevent direct contact with skin and eyes. All uncharacterized chemicals should be treated as suspected toxins.	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	N/A
Common Name	Tacrolimus
CAS Number	109581-93-3
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Have the product container, label or Safety Data Sheet with you when calling the Biocon Emergency Number, a poison control center or physician, or going for treatment
If Inhaled	If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration
In Case of Skin Contact	Flush with copious amounts of water; remove contaminated clothing and shoes; Use soap; call a physician
In Case of Eye Contact	Check for and remove contact lenses and flush with copious amounts of water for 15 minutes; assure adequate flushing by separating the eyelids with fingers; call a physician

If Swallowed	If swallowed, DO NOT INDUCE VOMITING, wash out mouth with copious amounts of water; call a physician.
Most Important Symptoms and Effects	For information on potential signs and symptoms of exposure see Section 2. Hazards Identification and/or Section 11. Toxicological Information
Section 5: Fire Fighting Measures	
Suitable Extinguishing Media	Suitable Extinguishing Media Foam, carbon dioxide, dry chemical powder or water
Special Hazards Arising From the Substance/Mixture	No unusual fire or explosion hazards noted. Formation of toxic gases possible during heating or fire
Special PPE and/or Precautions for Firefighters	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves
Methods and Materials Used for Containment	Take steps to avoid release into environment
Cleanup Procedures	Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pick up is complete. Avoid generating dust. Additional Advice Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7: Handling and Storage	
Precautions for Safe Handling	Avoid inhalation and contact with skin and eyes. Provide appropriate exhaust ventilation at places where dust is formed. Do not breathe vapor, avoid contact with skin and eyes. Normal measures for preventive fire protection
Conditions for Safe Storage	Store in original containers. Keep containers securely sealed. Store in cool, dry area protected from heat/direct sunlight The material should be handled and stored as per label instructions on container/packaging to ensure product quality and integrity.

Section 8: Exposure Controls/Personal Protection	
Components with Workplace Control Parameters	Components: Tacrolimus, Exposure Limits: 1.05 ug/m ³ , Type of Exposure Limit: TWA, Source of OEL data: Manufacturer. OEB 4 (control exposure to < 1ug/m ³)
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the containment at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glove box, or other effective containment.
PPE - Eye/Face Protection	Chemical safety goggles.
PPE - Skin Protection	Chemical-resistant rubber gloves. Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific workplace.
PPE - Body Protection	Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific workplace.
PPE - Respiratory Protection	NIOSH/MSHA-approved respirator protecting mask (Filter P3). Where risk assessment shows air-purifying respirators are appropriate use (EN 143) respirator cartridges as a backup to engineering controls.

Section 9: Physical and Chemical Properties

Appearance	Solid. A white to off white powder.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	No data available
Solubility	Insoluble in water
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	No data available
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	Not available
Chemical Stability	Stable at normal conditions.
Possibility of Hazardous Reactions	No data available
Conditions to Avoid	Protect from light and heat.
Incompatible Materials	Avoid storing with strong oxidizing agents.
Hazardous Decomposition Products	Thermal decomposition may product COx, NOx gases.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral (mouse) > 134 mg/kg
Acute Toxicity - Inhalation	Classification not possible.
Acute Toxicity - Dermal	Classification not possible.
Acute Toxicity - Eye	Causes eye irritation.
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	Causes eye irritation
Respiratory or Skin Sensitization	Classification not possible.
Germ Cell Mutagenicity	No data available.
Carcinogenicity IARC	No data available
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	No data available
Carcinogenicity OSHA	No data available
Reproductive Toxicity	No data available.
Specific Target Organ Toxicity - Single Exposure	Classification not possible.
Specific Target Organ Toxicity - Repeated Exposure	Causes damage to organs (Immune system) through prolonged or repeated exposure.
Aspiration Hazard	Classification not possible.

Section 12: Ecological Information

Toxicity	Avoid release into the environment. Do not release into sewer or waterways. Run off from fire control or dilution water may cause pollution. No other ecotoxicity data is available.
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	To be disposed as directed on the packaging. Material and packaging should be disposed of in accordance with Federal, State and local environmental control regulations. Contact a licensed professional waste disposal service to dispose of this material.
Waste Treatment Methods Packaging	Material and packaging should be disposed of in accordance with Federal, State and local environmental control regulations. Contact a licensed professional waste disposal service to dispose of this material.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	2811
UN Proper Shipping Name	TOXIC SOLID, ORGANIC, N.O.S. (contains tacrolimus)
Transport Hazard Class(es)	6.1
Packaging Group	III
Environmental Hazards	No data available

Section 15: Regulatory Information

No further data available.

Section 16: Other Information

Additional Information	N/A
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