


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) 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)	15,19-Epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone, 5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[2-(4-hydroxy-3-methoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetr amethyl-8-(2-propenyl)-, monohydrate, [3S-[3R*, [E(1S*,3S*,4S*)],4S*,5R*,8S*,9E, 12R*,14R*,15S*,16R*,18S*,19S*,26aR*]]-	
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, Reproductive toxicity (Category 1A, 1B)	
Signal Word	Danger	
Hazard Statement(s)	H301 H320 H361 H372	Toxic if swallowed Causes eye irritation Suspected of damaging fertility or the unborn child Causes damage to organs through prolonged or repeated exposure
Pictogram(s)		
Precautionary Statement(s)	P201 P202 P233 P260 P264 P270 P280 P281 P301+P310 P305+P351+P338 P308+P313 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. Use personal protective equipment as required. 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. IF exposed or concerned Get medical advice/attention. 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	See additional ingredient information
Common Name	Tacrolimus
CAS Number	109581-93-3
Additional Ingredient Information	Chemical name: 15,19-Epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone, 5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[2-(4-hydroxy-3-methoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetr amethyl-8-(2-propenyl)-, monohydrate, [3S-[3R*, [E(1S*,3S*,4S*)],4S*,5R*,8S*,9E, 12R*,14R*,15S*,16R*,18S*,19S*,26aR*]]-
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. 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. Call a physician if symptoms develop or persist
In Case of Skin Contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. 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. Do not use mouth-to-mouth method if substance is ingested. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most Important Symptoms and Effects	Immune system depression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. Indication of immediate medical attention and special treatment needed: Indication of immediate medical attention and special treatment needed: Provide general supportive measures and treat symptomatically. Do not induce vomiting. Administer activated charcoal as a slurry. Perform gastric lavage. Protect airways by placement in Trendelenburg and left lateral decubitus position, or by endotracheal intubation. Control any seizures first. Correct magnesium deficits. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, administer phenobarbital or propofol Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For hypertension and tachycardia, administer benzodiazepines. For severe hypertension, nitroprusside is preferred; labetalol, nitroglycerin, and phentolamine are alternatives. Dialysis will not effectively remove this material.

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.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Keep unnecessary personal away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection see section 8.
Methods and Materials Used for Containment	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.
Cleanup Procedures	For waste disposal see section 13. Avoid the generation of dusts during clean-up. Sweep Pick up or vacuum up spillage and collect in suitable container for disposal. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Precautions for Safe Handling	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 as defined on the label. 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	The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits. Exposure limit values: Industrial Use; Material Type Value: Tacrolimus (CAS109581-93-3); TWA: 0.2 micrograms/m ³ ; Biological limit values: 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. Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.
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.
PPE - Body Protection	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. 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	White or almost white crystalline 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	No data available
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	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Stable at normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	Contact with incompatible materials.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions - Carbon oxides, Nitrogen oxides (NOx) In the event of fire: see section 5.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral Mouse 134 mg/kg (male). Toxic if swallowed. Based on information from therapeutic use, this material may cause: Immunosuppression.
Acute Toxicity - Inhalation	Knowledge about health hazard is incomplete.
Acute Toxicity - Dermal	Knowledge about health hazard is incomplete.
Acute Toxicity - Eye	Causes eye irritation.
Skin Corrosion/Irritation	Based on available data, the classification criteria are not met.
Serious Eye Damage/Irritation	Causes eye irritation. Local effects Eye irritation Result: Irritant. Species: Rabbit Skin irritation Result: Negative. Species: Rabbit
Respiratory or Skin Sensitization	Knowledge about health hazard is incomplete.
Germ Cell Mutagenicity	Knowledge about health hazard is incomplete. Ames test Result: Negative. Mutagenicity: In vitro CHO/HGPRT assay Result: Negative. Mutagenicity: In vitro Chinese hamster lung-derived cells assay Result: Negative. Mutagenicity: In vivo clastogenicity assay Result: Negative. Species: Mouse
Carcinogenicity IARC	Not listed
Carcinogenicity ACGIH	No data available. Knowledge about carcinogenicity is incomplete. Studies in animals have yielded mixed results. 1.1 - 111 mg/kg/day Carcinogenicity: Dermal Result: Incidence of skin tumors was minimal. Species: Mouse Test Duration: 104 weeks 3 mg/kg Carcinogenicity Result: Negative. Species: Mouse Test Duration: 80 weeks 3.5 mg/kg Carcinogenicity: Dermal Result: Lymphomas were noted (0.1% tacrolimus ointment). Species: Mouse 5 mg/kg Carcinogenicity Result: Negative. Species: Rat Test Duration: 104 weeks
Carcinogenicity NTP	Not listed
Carcinogenicity OSHA	Not regulated.
Reproductive Toxicity	Suspected of damaging fertility or the unborn child. Reproductivity 0.32 - 1 mg/kg Reproductivity Result: Maternal toxicity observed; increased incidence of abortions. Species: Rabbit 1 - 3.2 mg/kg Reproductivity Result: Reduced pup weights. Species: Rat 3.2 mg/kg Reproductivity Result: Maternal toxicity observed; increase in late resorptions; decreased number of live births; decreased pup weight and viability. Species: Rat
Specific Target Organ Toxicity - Single Exposure	Knowledge about health hazard is incomplete.
Specific Target Organ Toxicity - Repeated Exposure	Causes damage to organs (Immune system) through prolonged or repeated exposure.
Aspiration Hazard	Based on available data, the classification criteria are not met. Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

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	No data available
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. 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 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	2811
UN Proper Shipping Name	TOXIC SOLID, ORGANIC, N.O.S. (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
Prepared By	Scarlotte Smith
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Disclaimer

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