

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)
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-m 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	
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)	P264 P270 P305+P351+P338 P314 P330 P337+P313 P405 P501	Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. 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	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

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-m monohydrate,
Common Name	Tacrolimus
CAS Number	109581-93-3
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. 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 cautiously with water for several minutes. Get medical attention if irritations develops and persists.
If Swallowed	Call a physician or poison control center immediately. Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into lungs. Do not use mouth to mouth method if victim ingested the substance.
Most Important Symptoms and Effects	Irritation of eyes and mucous membranes. Prolonged exposure may cause chronic effects. Provide general supportive measures and treat symptomatically. Do not induce vomiting. Administer activated charcoal as a slurry. Perform gastric lavage. For protection of airways, place 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 occur, give phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For hypertension and tachycardia, administer with benzodiazepines. For severe hypertension, nitroprusside is preferred; labetalol, nitroglycerin, and phentolamine are alternatives. Dialysis will not effectively remove this material. (Meditext) (USP DI).

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Special Hazards Arising From the Substance/Mixture	No unusual fire 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. Cool containers exposed to flames with water until well after the fire is out.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	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	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of SDS. Wash spill site.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

Section 7: Handling and Storage

Precautions for Safe Handling	As a general rule, when handling chemicals, 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. Use a designated area is recommended for handling or potent materials.
Conditions for Safe Storage	Store in tight container as defined in the USP-NF. 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	Material Tacrolimus (CAS 109581-93-3) Type: TWA Value 0.2 micrograms/m3
Appropriate Engineering Controls	Airborne exposures 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 contaminant 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, glovebox, or other effective containment.
PPE - Eye/Face Protection	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection is preferred. Maintain eyewash facilities in the work area.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
PPE - Body Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment. For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
PPE - Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place.

Section 9: Physical and Chemical Properties

Appearance	Form: Powder Physical state: Solid Colour: 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	260.6 - 271.4 °F (127 - 133 °C)
Solubility	Solubility in water: Soluble
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	No reactivity hazards known.
Chemical Stability	Stable at normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	None under normal conditions.
Incompatible Materials	Strong 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	LD50 Oral Mouse 134 mg/kg (male)
Acute Toxicity - Inhalation	Due to lack of data the classification is not possible.
Acute Toxicity - Dermal	Due to lack of data the classification is not possible.
Acute Toxicity - Eye	Causes eye irritation.
Skin Corrosion/Irritation	Due to lack of data the classification is not possible.
Serious Eye Damage/Irritation	Causes eye irritation
Respiratory or Skin Sensitization	Due to lack of data the classification is not possible.
Germ Cell Mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity IARC	This product is not considered to be a carcinogen by IARC.
Carcinogenicity ACGIH	This product is not considered to be carcinogen by ACGIH.
Carcinogenicity NTP	This product is not considered to be carcinogen by NTP.
Carcinogenicity OSHA	This product in not considered to be carcinogen by OSHA.
Reproductive Toxicity	Based on available data, the classification criteria are not met. 0.32 - 1 mg/kg Reproductively test Result: Maternal toxicity observed; increased incidence of abortions. Species: Rabbit 1 - 3.2 mg/kg Reproductively test Result: Reduced pup weights. Species: Rat 3.2 mg/kg Reproductively test 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	Due to lack of data the classification is not possible.
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.

Section 12: Ecological Information

Toxicity	No ecotoxicity data noted for the ingredients.
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	This product, in its present state, when discarded or disposed of, its not a hazardous waste according to Federal regulations (40 CFR 261.4 (b) 94). Under RCRA, its it the responsibility of the user or the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
Waste Treatment Methods Packaging	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).
Special Precautions Landfill or Incinerations	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.
Other Information	No data available

Section 14: Transport Information

UN Number	
UN Proper Shipping Name	
Transport Hazard Class(es)	
Packaging Group	
Environmental Hazards	No

Section 15: Regulatory Information

CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S EPA TSCA Inventory List. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazard substance: No SARA 311/312 Hazardous chemical: No Other federal regulations: Safe Drinking Water Act (SDWA) Not regulated Food and Drug Administration (FDA) US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. Issue Date 01/21/2008 Revision Date 12/07/2012.

Section 16: Other Information

Additional Information	N/A
Prepared By	Lisa Russell
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