

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name TACROLIMUS USP MONOHYDRATE
Commercial Name Tacrolimus Monohydrate
Product Use For Prescription Compounding/Rx Only
Restrictions On Use N/A

Product Code 30-4924

Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Acute Toxicity: Oral Toxic To Reproduction Specific Target Organ Toxicity (repeated exposure)
CFR 1910.1200

Signal Word DANGER

Hazard Statement(s) Toxic if swallowed. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention P264: Wash {hands} thoroughly after handling. P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P281: Use personal protective equipment as required. P260: Do not breathe {dust/fume/gas/mist/vapours/spray}
Response P301+310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P330: Rinse mouth. P308+313: IF exposed or concerned: Get medical attention/advice. P314: Get medical attention/advice if you feel unwell.
Storage Not available
Disposal Not available.

Section 3: Composition/Information on Ingredients

Substance/Mixture Sunstance
Components N/A
% By Weight 100%
CAS# 109581-93-3
Molecular Weight 822.02
Chemical Formula C₄₄H₆₉NO₁₂.H₂O
Synonym(s) N/A

Mixtures Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
------------------	------	-------------	---------	-----------

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 4: First-Aid Measures

Inhalation	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention
Skin Contact	Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
Eye Contact	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
Ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel. In any case, seek medical advice and call the nearest poison center.

Symptoms/Effects**Acute** N/A**Delayed** N/A**Immediate Medical Attention**

N/A

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media

A solid water stream may be inefficient.

Products of Combustion

N/A

Firefighters Special Equipment and Precautions

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6: Accidental Release Measures

Protective Precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves) Environmental Precautions: Take steps to avoid release into the environment, if safe to do so. Methods and Material For Containment and Cleaning Up: Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7: Handling and Storage

Precautions To Be Taken in Handling: Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure. Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Not available.
Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
Personal Protection	Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves. Personal Protection in Case of a Large Spill: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Section 9: Physical and Chemical Properties

Appearance	white or off-white Solid.		
Odor	none		
Odor Threshold	N/A		
Melting Point	Not available	pH	N/A
Freezing Point	N/A	Vapor Pressure	N/A
Boiling Point/Range	N/A	Vapor Density	N/A
Decomposition temperature	N/A	Viscosity	N/A
Partition Coefficient: n-octanol/water	N/A	Evaporation Rate	N/A
Flash Point	N/A	Autoignition temperature	N/A
Flammability	N/A	Flammability or Explosive Limits:	
		Lower	N/A
		Upper	N/A
Solubility(ies)	Soluble in methanol, diethyl ether, acetone. Insoluble in cold water, hot water.		
Other	N/A		

Section 10: Stability and Reactivity

Reactivity	N/A
Chemical Stability	Stable under recommended storage conditions.
Hazardous Polymerization	N/A
Conditions to Avoid	N/A
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	Carbon oxides, nitrogen oxides (NOx)

Section 11: Toxicological Information**RTECS** N/A**Acute Toxicity**

Intraperitoneal LD50 (mouse): >200 mg/kg; Intraperitoneal TDLO (rat): 0.5 mg/kg; Oral TDLO (rat): 6 mg/kg; Oral TDLO (human): 0.8 mg/kg; Oral TDLO (woman): 8 mg/kg;

Skin Corrosion/Irritation

N/A

Serious Eye Damage/Irritation

N/A

Respiratory or Skin Sensitization

N/A

Germ Cell Mutagenicity

N/A

Carcinogenicity

N/A

Reproductive Toxicity

N/A

Routes of Entry

N/A

Symptoms Related to Exposure

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Causes damage to organs through prolonged or repeated exposure. Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation or skin absorption. May cause eye, skin, or respiratory system irritation. Suspected of damaging fertility or the unborn child. Toxic if swallowed. To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Potential Health Effects

N/A

Target Organ(s) N/A**Section 12: Ecological Information****Ecotoxicity**

Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

Persistence and Degradability

N/A

Bioaccumulative Potential

N/A

Mobility in Soil

N/A

Other Adverse Effects

N/A

Section 13: Disposal Considerations**Waste Disposal**

Dispose in accordance with local, state, and federal regulations.

Disposal of Container

N/A

Other Considerations

N/A

Section 14: Transport Information**DOT Classification**

DOT Proper Shipping Name: Toxic solid, organic, n.o.s. DOT Hazard Class: 6.1 POISON UN/NA Number: UN2811 Packing Group: III LAND TRANSPORT (European ADR/RID): ADR/RID Shipping Name: Toxic solid, organic, n.o.s. UN Number: 2811 Packing Group: III Hazard Class: 6.1 – POISON AIR TRANSPORT (ICAO/IATA): ICAO/IATA Shipping Name: Toxic solid, organic, n.o.s. UN Number: 2811 Packing Group: III Hazard Class: 6.1 - POISON IATA Classification: 6.1 Additional Transport: Transport in accordance with local, state, and federal regulations. Information: When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

Section 15: Regulatory Information**Regulations**

N/A

Other

N/A

Section 16: Other Information

N/A