


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>TACROLIMUS, USP (Monohydrate)</b>
<b>PRODUCT CODE</b>	<b>2698</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 3) Toxic to Reproduction (Category 2) (Effects on or via lactation) Eye Irritation (Category 2B) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (Immune system) Carcinogenicity (Category 1A)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT(S)</b>	Toxic if swallowed. May cause cancer. May cause harm to breast-fed children. Suspected of damaging fertility or the unborn child. Causes eye irritation. Causes damage to organs through prolonged or repeated exposure (immune system).
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.

**PRECAUTIONARY STATEMENT(S)**

<b>Prevention</b>	Wash hands thoroughly after handling. Do not touch eyes. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy and while nursing. Do not breathe dust/fume/gas/mist/ vapors/spray. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection.
<b>Response</b>	IF SWALLOWED: Immediately call a poison center. Get emergency medical help immediately. Rinse mouth. IF EXPOSED OR CONCERNED: Get medical advice. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help. Get medical help if you feel unwell.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.

**HMIS CLASSIFICATION**

<b>Health Hazard</b>	3	<b>Flammability</b>	0
<b>Reactivity</b>	0	<b>Personal Protection</b>	H

**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-methoxycyclohexyl)-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propenyl)-, monohydrate, [3S-[3R\*,E(1S\*,3S\*,4S\*)],4S\*,5R\*,8S\*,9E,12R\*,14R\*,15S\*,16R\*,18S\*,19S\*,26aR\*)]-

**BOTANICAL NAME**

Not applicable

**SYNONYM**

Not applicable

**CHEMICAL FORMULA**

C<sub>44</sub>H<sub>69</sub>NO<sub>12</sub> · H<sub>2</sub>O

**CHEMICAL FAMILY**

Macrolide

**CAS NUMBER**

109581-93-3

**ALTERNATE CAS NUMBER**

Not applicable

**MOLECULAR WEIGHT**

822.0389

**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
TACROLIMUS (monohydrate)	109581-93-3	634-559-2	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**SECTION 4: FIRST-AID MEASURES**
**IN CASE OF EYE CONTACT**

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

**IN CASE OF SKIN CONTACT**

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

**IF SWALLOWED**

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

**IF INHALED**

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

**MEDICAL ATTENTION AND SPECIAL TREATMENT**

Get emergency medical help.

## SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING MEASURES

## SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

## FLAMMABLE PROPERTIES

May be combustible at high temperature

## HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

## SUITABLE &amp; UNSUITABLE EXTINGUISHING MEDIA

**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

## PROTECTIVE EQUIPMENT AND 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

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

## METHODS &amp; MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

## CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

## SECTION 7: HANDLING AND STORAGE

## PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

## CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

## STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**
**Chemical Name: TACROLIMUS (monohydrate) CAS #: 109581-93-3**

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	84:92 skin and mucous membrane agents, miscellaneous; 92:44 immunosuppressive agents	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>
**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

**NOTES**

 USP: ELV: Industrial use: TWA: 0.2 micrograms/m<sup>3</sup>
**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White to off-white powder.

**SOLUBILITY**

Insoluble in water; soluble in acetone, chloroform and ethyl acetate.

**ODOR**

Not available.

**FLAMMABILITY**

May be combustible at high temperature

**AUTO-IGNITION TEMPERATURE**

Not available

**BOILING POINT**

Not available

**DECOMPOSITION TEMPERATURE**

Not available

<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	Not available	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(127 - 133)°C, (260.6-271.4)°F
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	Not available
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	Not available	<b>VISCOSITY</b>	Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidants
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): 134 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Based on available data, the classification criteria are not met. Local effects:Irritancy test:Result: Non-Irritant; Species: Rabbit; Organ: Skin.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Causes eye irritation. Local effects:Irritancy test:Result: Irritant; Species: Rabbit; Organ: Eye.
<b>RESPIRATORY SENSITIZATION</b>	Due to lack of data the classification is not possible.
<b>SKIN SENSITIZATION</b>	Due to lack of data the classification is not possible.
<b>GERM CELL MUTAGENICITY</b>	Based on available data, the classification criteria are not met.
<b>CARCINOGENICITY</b>	<b>OSHA</b> TACROLIMUS is not listed. <b>NTP</b> TACROLIMUS is not listed. <b>IARC</b> TACROLIMUS is listed in group 1 (carcinogenic to humans).

<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	<p><b>California Proposition 65</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p> <p>The systemic use of tacrolimus increases the risk of malignancy. Carcinogenicity studies in animals have also reported an increase in the incidence of malignancies associated with the topical tacrolimus. As of December 2004 the FDA had received reports of 19 cases of lymphoma or cutaneous tumours associated with topical tacrolimus, of which 4 cases were a recurrence or aggravation of a pre-existing malignancy, and 3 other cases were confounded by other possible risk factors. In general, longterm data are still needed to determine the carcinogenic risk, if there is any, from topical tacrolimus.</p> <p>Mouse: 1.1 - 111 mg/kg/day Carcinogenicity: Dermal; Test Duration: 104 weeks; Result: Incidence of skin tumors was minimal.          Mouse: 3 mg/kg Carcinogenicity; Test Duration: 80 weeks; Result: Negative.          Mouse: 3.5 mg/kg Carcinogenicity: Dermal; Result: Lymphomas were noted (0.1% tacrolimus ointment).          Rat: 5 mg/kg Carcinogenicity; Test Duration: 104 weeks; Result: Negative.</p>
<b>REPRODUCTIVE TOXICITY</b>	<p>Suspected of damaging fertility or the unborn child. Tacrolimus is distributed into breast milk. Tacrolimus concentrations were measured in milk from a liver transplant recipient on a dose of 100 micrograms/kg daily. The authors estimated that the infant would ingest only 0.06% (0.06 micrograms/kg daily) of the mother's weight-adjusted dose. No adverse effects were noted in the infant at 2.5 months of age.</p> <p>Rabbit: 0.32 - 1 mg/kg Reproductivity; Result: Maternal toxicity observed; increased incidence of abortions.          Rat: 1 - 3.2 mg/kg Reproductivity; Result: Reduced pup weights.          Rat: 3.2 mg/kg Reproductivity; Result: Maternal toxicity observed; increase in late resorptions; decreased number of live births; decreased pup weight and viability.</p> <p>Due to lack of data, the classification is not possible.</p>
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Causes damage to organs (Immune system) through prolonged or repeated exposure.
<b>ASPIRATION HAZARDS</b>	Based on available data, the classification criteria are not met.
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	<p><b>ROUTES OF EXPOSURE:</b>          Oral, Dermal, Inhalation, Eye contact</p> <p><b>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:</b>          Not available</p> <p><b>DELAYED HEALTH EFFECT FROM EXPOSURE:</b>          Not available</p> <p>May produce neprotoxicity and neurotoxicity, tremor, headache, paraesthesias, nausea, diarrhoea, hypertension, leucocytosis, impaired renal function, anaemia, lucopenia, hyperkalaemia, mood changes, sleep disturbances, confusion, tinnitus, visual disturbances, convulsions, constipation, gastrointestinal haemorrhage, skin rash, cramps, peripheral oedema liver dysfunction and coagulation disorders.</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics:          Hypertension. Kidney damage. Infection. Gastrointestinal disturbances. Headache. Tremor. Hyperglycemia. Seizures.</p>
<b>POTENTIAL HEALTH EFFECTS</b>	<p><b>Inhalation</b> May be harmful if inhaled. May cause respiratory tract irritation.</p> <p><b>Ingestion</b> Toxic if swallowed.</p> <p><b>Skin</b> May be harmful if absorbed through skin. May cause skin irritation</p> <p><b>Eyes</b> Causes eye irritation.</p>
<b>NOTES</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects

## SECTION 12: ECOLOGICAL INFORMATION

<b>ECOTOXICITY</b>	<p>EC50: 48 Hr: Crustacea: (mg/L): Not available          LC50: 96 Hr: Fish: (mg/L): Not available          EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p>
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<b>PERSISTENCE AND DEGRADABILITY</b>	Not available
<b>BIOACCUMULATIVE POTENTIAL</b>	Not available
<b>MOBILITY IN SOIL</b>	Insoluble in water
<b>OTHER ADVERSE EFFECTS</b>	Not available
	This product is not intended to be released into the environment

### SECTION 13: DISPOSAL CONSIDERATIONS

<b>DISPOSAL METHODS</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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### SECTION 14: TRANSPORT INFORMATION

<b>UN PROPER SHIPPING NAME</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>UN NUMBER</b>	2811
<b>CLASS</b>	6.1
<b>PACKING GROUP</b>	III

<b>AUSTRALIA</b>	
<b>HAZCHEM</b>	2X

<b>EU</b>	
<b>TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not Listed

<b>ENVIRONMENTAL HAZARDS</b>	Not available
<b>SPECIAL SHIPPING INFORMATION</b>	Not applicable

### SECTION 15: REGULATORY INFORMATION

#### UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
TACROLIMUS 109581-93-3	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

#### AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
TACROLIMUS 109581-93-3	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

**EU REGULATIONS**

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
TACROLIMUS 109581-93-3	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

**SECTION 16: OTHER INFORMATION**
**REFERENCES**
**ABBREVIATIONS AND ACRONYMS**

Available upon request

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMIS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

**LAST REVISION**

05/2025

**SUPERSEDES**

04/2024

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.