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SAFETY DATA SHEET

SECTION 1. CHEMICAL IDENTIFICATION

CATALOG #: 38049

NAME: Tacrolimus monohydrate

SYNONYMS: FK 506 monohydrate

24 HOUR EMERGENCY TELEPHONE: (800) 535-5053(USA)
352-323-3500 (INTERNATIONAL)

TO REQUEST AN MSDS: (800) 869-9290

CUSTOMER SERVICE: (630) 766-2112

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

GHS CLASSIFICATION IN ACCORDANCE WITH 29 CFR 1910 (OSHA HCS)
ACUTE TOXICITY, ORAL (CATEGORY 3), H301

FOR THE FULL TEXT OF THE H-STATEMENTS MENTIONED IN THIS SECTION, SEE SECTION 16.

GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS
PICTOGRAM



SIGNAL WORD DANGER

HAZARD STATEMENT(S)

H301 TOXIC IF SWALLOWED.

PRECAUTIONARY STATEMENT(S)

P264 WASH SKIN THOROUGHLY AFTER HANDLING.
P270 DO NOT EAT, DRINK OR SMOKE WHEN USING THIS PRODUCT.
P301 + P310 IF SWALLOWED: IMMEDIATELY CALL A POISON CENTER/DOCTOR.
P321 SPECIFIC TREATMENT (SEE SUPPLEMENTAL FIRST AID INSTRUCTIONS ON THIS LABEL).
P330 RINSE MOUTH.
P405 STORE LOCKED UP.
P501 DISPOSE OF CONTENTS/ CONTAINER TO AN APPROVED WASTE DISPOSAL PLANT.

HAZARDS NOT OTHERWISE CLASSIFIED (HNO) OR NOT COVERED BY GHS NONE

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

MF: $C_{44}H_{69}NO_{12} \cdot H_2O$
MW: 822.05
CAS-NO. 109581-93-3
PURITY: $\geq 80\%$ (HPLC)

COMPONENT	CLASSIFICATION	CONCENTRATION
Tacrolimus monohydrate	ACUTE TOX. 3; H301	$\leq 100\%$

FOR THE FULL TEXT OF THE H-STATEMENTS MENTIONED IN THIS SECTION, SEE SECTION 16.

SECTION 4. FIRST-AID MEASURES

DESCRIPTION OF FIRST AID MEASURES

GENERAL ADVICE CONSULT A PHYSICIAN. SHOW THIS SAFETY DATA SHEET TO THE DOCTOR IN ATTENDANCE. MOVE OUT OF DANGEROUS AREA.

IF INHALED IF BREATHED IN, MOVE PERSON INTO FRESH AIR. IF NOT BREATHING, GIVE ARTIFICIAL RESPIRATION. CONSULT A

	PHYSICIAN.
IN CASE OF SKIN CONTACT	WASH OFF WITH SOAP AND PLENTY OF WATER. TAKE VICTIM IMMEDIATELY TO HOSPITAL. CONSULT A PHYSICIAN.
IN CASE OF EYE CONTACT	FLUSH EYES WITH WATER AS A PRECAUTION.
IF SWALLOWED	NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. RINSE MOUTH WITH WATER. CONSULT A PHYSICIAN.
MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED	THE MOST IMPORTANT KNOWN SYMPTOMS AND EFFECTS ARE DESCRIBED IN THE LABELLING (SEE SECTION 2.2) AND/OR IN SECTION 11
INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED	NO DATA AVAILABLE

SECTION 5. FIRE AND EXPLOSION DATA

EXTINGUISHING MEDIA	
SUITABLE EXTINGUISHING MEDIA	USE WATER SPRAY, ALCOHOL-RESISTANT FOAM, DRY CHEMICAL OR CARBON DIOXIDE.
SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE	CARBON OXIDES, NITROGEN OXIDES (NOX),
ADVICE FOR FIREFIGHTERS	WEAR SELF-CONTAINED BREATHING APPARATUS FOR FIREFIGHTING IF NECESSARY.
FURTHER INFORMATION	NO DATA AVAILABLE

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES	WEAR RESPIRATORY PROTECTION. AVOID DUST FORMATION. AVOID BREATHING VAPOURS, MIST OR GAS. ENSURE ADEQUATE VENTILATION. EVACUATE PERSONNEL TO SAFE AREAS. AVOID BREATHING DUST. FOR PERSONAL PROTECTION SEE SECTION 8.
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ENVIRONMENTAL PRECAUTIONS	PREVENT FURTHER LEAKAGE OR SPILLAGE IF SAFE TO DO SO. DO NOT LET PRODUCT ENTER DRAINS.
METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP	PICK UP AND ARRANGE DISPOSAL WITHOUT CREATING DUST. SWEEP UP AND SHOVEL. KEEP IN SUITABLE, CLOSED CONTAINERS FOR DISPOSAL.
REFERENCE TO OTHER SECTIONS	FOR DISPOSAL SEE SECTION 13.

SECTION 7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING	AVOID CONTACT WITH SKIN AND EYES. AVOID FORMATION OF DUST AND AEROSOLS. PROVIDE APPROPRIATE EXHAUST VENTILATION AT PLACES WHERE DUST IS FORMED. FOR PRECAUTIONS SEE SECTION 2.2.
CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES	KEEP CONTAINER TIGHTLY CLOSED IN A DRY AND WELL-VENTILATED PLACE. KEEP IN A DRY PLACE. Store at < 0 °C
SPECIFIC END USE(S)	APART FROM THE USES MENTIONED IN SECTION 1.2 NO OTHER SPECIFIC USES ARE STIPULATED.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

CONTROL PARAMETERS

COMPONENTS WITH WORKPLACE CONTROL PARAMETERS	CONTAINS NO SUBSTANCES WITH OCCUPATIONAL EXPOSURE LIMIT VALUES.
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EXPOSURE CONTROLS

APPROPRIATE ENGINEERING CONTROLS	AVOID CONTACT WITH SKIN, EYES AND CLOTHING. WASH HANDS BEFORE BREAKS AND IMMEDIATELY AFTER HANDLING THE PRODUCT.
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PERSONAL PROTECTIVE EQUIPMENT

EYE/FACE PROTECTION	FACE SHIELD AND SAFETY GLASSES USE EQUIPMENT FOR EYE PROTECTION TESTED AND APPROVED UNDER APPROPRIATE GOVERNMENT STANDARDS SUCH AS NIOSH (US) OR EN 166(EU).
SKIN PROTECTION	<p>HANDLE WITH GLOVES. GLOVES MUST BE INSPECTED PRIOR TO USE. USE PROPER GLOVE REMOVAL TECHNIQUE (WITHOUT TOUCHING GLOVE'S OUTER SURFACE) TO AVOID SKIN CONTACT WITH THIS PRODUCT. DISPOSE OF CONTAMINATED GLOVES AFTER USE IN ACCORDANCE WITH APPLICABLE LAWS AND GOOD LABORATORY PRACTICES. WASH AND DRY HANDS.</p> <p>FULL CONTACT MATERIAL: NITRILE RUBBER MINIMUM LAYER THICKNESS: 0.11 MM BREAK THROUGH TIME: 480 MIN MATERIAL TESTED:DERMATRIL (KCL 740, SIZE M)</p> <p>SPLASH CONTACT MATERIAL: NITRILE RUBBER MINIMUM LAYER THICKNESS: 0.11 MM BREAK THROUGH TIME: 480 MIN MATERIAL TESTED:DERMATRIL (KCL 740, SIZE M)</p> <p>IF USED IN SOLUTION, OR MIXED WITH OTHER SUBSTANCES, AND UNDER CONDITIONS WHICH DIFFER FROM EN 374, CONTACT THE SUPPLIER OF THE CE APPROVED GLOVES. THIS RECOMMENDATION IS ADVISORY ONLY AND MUST BE EVALUATED BY AN INDUSTRIAL HYGIENIST AND SAFETY OFFICER FAMILIAR WITH THE SPECIFIC SITUATION OF ANTICIPATED USE BY OUR CUSTOMERS. IT SHOULD NOT BE CONSTRUED AS OFFERING AN APPROVAL FOR ANY SPECIFIC USE SCENARIO.</p>
BODY PROTECTION	COMPLETE SUIT PROTECTING AGAINST CHEMICALS, THE TYPE OF PROTECTIVE EQUIPMENT MUST BE SELECTED ACCORDING TO THE CONCENTRATION AND AMOUNT OF THE DANGEROUS SUBSTANCE AT THE SPECIFIC WORKPLACE.
RESPIRATORY PROTECTION	WHERE RISK ASSESSMENT SHOWS AIR-PURIFYING RESPIRATORS ARE APPROPRIATE USE A FULLFACE PARTICLE RESPIRATOR TYPE N99 (US) OR TYPE P2 (EN 143) RESPIRATOR CARTRIDGES AS A BACKUP TO ENGINEERING CONTROLS. IF THE RESPIRATOR IS THE SOLE MEANS OF PROTECTION, USE A FULL-FACE SUPPLIED AIR RESPIRATOR. USE RESPIRATORS AND COMPONENTS TESTED AND APPROVED UNDER APPROPRIATE GOVERNMENT STANDARDS SUCH AS NIOSH (US) OR CEN (EU).

CONTROL OF ENVIRONMENTAL EXPOSURE

PREVENT FURTHER LEAKAGE OR SPILLAGE IF SAFE TO DO SO. DO NOT LET PRODUCT ENTER DRAINS.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE	White to almost white powder to crystal
ODOUR	NO DATA AVAILABLE
ODOUR THRESHOLD	NO DATA AVAILABLE
PH	NO DATA AVAILABLE
MELTING POINT/FREEZING POINT	125 - 129 °C
INITIAL BOILING POINT AND BOILING RANGE	
FLASH POINT	
EVAPORATION RATE	NO DATA AVAILABLE
FLAMMABILITY (SOLID, GAS)	NO DATA AVAILABLE
UPPER/LOWER FLAMMABILITY OR EXPLOSIVE LIMITS	NO DATA AVAILABLE
VAPOUR PRESSURE	NO DATA AVAILABLE
VAPOUR DENSITY	NO DATA AVAILABLE
RELATIVE DENSITY	
WATER SOLUBILITY	NO DATA AVAILABLE
PARTITION COEFFICIENT: N- OCTANOL/WATER	NO DATA AVAILABLE
AUTO-IGNITION TEMPERATURE	NO DATA AVAILABLE
DECOMPOSITION TEMPERATURE	NO DATA AVAILABLE
VISCOSITY	NO DATA AVAILABLE
EXPLOSIVE PROPERTIES	NO DATA AVAILABLE
OXIDIZING PROPERTIES	NO DATA AVAILABLE

OTHER SAFETY INFORMATION NO DATA AVAILABLE

SECTION 10. STABILITY AND REACTIVITY

REACTIVITY	NO DATA AVAILABLE
CHEMICAL STABILITY	STABLE UNDER RECOMMENDED STORAGE CONDITIONS.
POSSIBILITY OF HAZARDOUS REACTIONS	NO DATA AVAILABLE

CONDITIONS TO AVOID	NO DATA AVAILABLE
INCOMPATIBLE MATERIALS	STRONG OXIDIZING AGENTS
HAZARDOUS DECOMPOSITION PRODUCTS	HAZARDOUS DECOMPOSITION PRODUCTS FORMED UNDER FIRE CONDITIONS. - CARBON OXIDES, NITROGEN OXIDES (NOX) OTHER DECOMPOSITION PRODUCTS - NO DATA AVAILABLE IN THE EVENT OF FIRE: SEE SECTION 5

SECTION 11. TOXICOLOGICAL INFORMATION

INFORMATION ON TOXICOLOGICAL EFFECTS

ACUTE TOXICITY	LD50 ORAL - RAT - 134 MG/KG INHALATION: NO DATA AVAILABLE DERMAL: NO DATA AVAILABLE NO DATA AVAILABLE
SKIN CORROSION/IRRITATION	NO DATA AVAILABLE
SERIOUS EYE DAMAGE/EYE IRRITATION	NO DATA AVAILABLE
RESPIRATORY OR SKIN SENSITISATION	NO DATA AVAILABLE
GERM CELL MUTAGENICITY	NO DATA AVAILABLE
CARCINOGENICITY	
IARC:	NO COMPONENT OF THIS PRODUCT PRESENT AT LEVELS GREATER THAN OR EQUAL TO 0.1% IS IDENTIFIED AS PROBABLE, POSSIBLE OR CONFIRMED HUMAN CARCINOGEN BY IARC.
ACGIH:	NO COMPONENT OF THIS PRODUCT PRESENT AT LEVELS GREATER THAN OR EQUAL TO 0.1% IS IDENTIFIED AS A CARCINOGEN OR POTENTIAL CARCINOGEN BY ACGIH.
NTP:	NO COMPONENT OF THIS PRODUCT PRESENT AT LEVELS GREATER THAN OR EQUAL TO 0.1% IS IDENTIFIED AS A KNOWN OR ANTICIPATED CARCINOGEN BY NTP.

OSHA:	NO COMPONENT OF THIS PRODUCT PRESENT AT LEVELS GREATER THAN OR EQUAL TO 0.1% IS ON OSHA S LIST OF REGULATED CARCINOGENS.
REPRODUCTIVE TOXICITY	NO DATA AVAILABLE
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	NO DATA AVAILABLE
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	NO DATA AVAILABLE
ASPIRATION HAZARD	NO DATA AVAILABLE
ADDITIONAL INFORMATION	RTECS: KD4201200 TO THE BEST OF OUR KNOWLEDGE, THE CHEMICAL, PHYSICAL, AND TOXICOLOGICAL PROPERTIES HAVE NOT BEEN THOROUGHLY INVESTIGATED. STOMACH - IRREGULARITIES - BASED ON HUMAN EVIDENCE

SECTION 12. ECOLOGICAL INFORMATION

TOXICITY	NO DATA AVAILABLE
PERSISTENCE AND DEGRADABILITY	NO DATA AVAILABLE
BIOACCUMULATIVE POTENTIAL	NO DATA AVAILABLE
MOBILITY IN SOIL	NO DATA AVAILABLE
RESULTS OF PBT AND VPVB ASSESSMENT	PBT/VPVB ASSESSMENT NOT AVAILABLE AS CHEMICAL SAFETY ASSESSMENT NOT REQUIRED/NOT CONDUCTED
OTHER ADVERSE EFFECTS	NO DATA AVAILABLE

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

PRODUCT OFFER SURPLUS AND NON-RECYCLABLE SOLUTIONS TO A LICENSED DISPOSAL COMPANY. CONTACT A LICENSED PROFESSIONAL WASTE DISPOSAL SERVICE TO DISPOSE OF THIS MATERIAL. DISSOLVE OR MIX THE MATERIAL WITH A COMBUSTIBLE SOLVENT AND BURN IN A CHEMICAL INCINERATOR EQUIPPED WITH AN AFTERBURNER AND SCRUBBER.

CONTAMINATED PACKAGING DISPOSE OF AS UNUSED PRODUCT.

SECTION 14. TRANSPORT INFORMATION

DOT (US)

PROPER SHIPPING NAME: TOXIC SOLIDS, ORGANIC, N.O.S. (Tacrolimus monohydrate)
UN NUMBER: 2811
CLASS: 6.1
PACKING GROUP: III
REPORTABLE QUANTITY (RQ):
POISON INHALATION HAZARD: NO

IMDG

PROPER SHIPPING NAME: TOXIC SOLIDS, ORGANIC, N.O.S. (Tacrolimus monohydrate)
UN NUMBER: 2811
CLASS: 6.1
PACKING GROUP: III
EMS-NO: F-A, S-A

IATA

PROPER SHIPPING NAME: TOXIC SOLIDS, ORGANIC, N.O.S. (Tacrolimus monohydrate)
UN NUMBER: 2811
CLASS: 6.1
PACKING GROUP: III

SECTION 15. REGULATORY INFORMATION

SARA 302 COMPONENTS NO CHEMICALS IN THIS MATERIAL ARE SUBJECT TO THE REPORTING REQUIREMENTS OF SARA TITLE III, SECTION 302.

SARA 313 COMPONENTS THIS MATERIAL DOES NOT CONTAIN ANY CHEMICAL COMPONENTS WITH KNOWN CAS NUMBERS THAT EXCEED THE THRESHOLD (DE MINIMIS) REPORTING LEVELS ESTABLISHED BY SARA TITLE III, SECTION 313.

SARA 311/312 HAZARDS ACUTE HEALTH HAZARD, CHRONIC HEALTH HAZARD

MASSACHUSETTS RIGHT TO KNOW COMPONENTS NO COMPONENTS ARE SUBJECT TO THE MASSACHUSETTS RIGHT TO KNOW ACT.

PENNSYLVANIA RIGHT TO KNOW COMPONENTS

	CAS-NO.	REVISION DATE
Tacrolimus monohydrate	109581-93-3	

NEW JERSEY RIGHT TO KNOW COMPONENTS

	CAS-NO.	REVISION DATE
Tacrolimus monohydrate	109581-93-3	

CALIFORNIA PROP. 65 COMPONENTS

THIS PRODUCT DOES NOT CONTAIN ANY CHEMICALS KNOWN TO STATE OF CALIFORNIA TO CAUSE CANCER, BIRTH DEFECTS, OR ANY OTHER REPRODUCTIVE HARM.

SECTION 16. OTHER INFORMATION

FULL TEXT OF H-STATEMENTS REFERRED TO UNDER SECTIONS 2 AND 3.
H301 TOXIC IF SWALLOWED.

MSDS LEGEND

MW: MOLECULAR WEIGHT
MF: MOLECULAR FORMULA
VOC: VOLATILE ORGANIC COMPOUNDS
ACGIH: AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGINISTS
CAS: CHEMICAL ABSTRACTS SERIVE REGISTRY NUMBER
OSHA: OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
PEL: PERMISSIBLE EXPOSURE LIMIT (OSHA)
TLV: THRESHOLD LIMIT VALUE (ACGIH)

IMPORTANT:

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