Safety Data Sheet

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

Section 1: Identification

Product Name MYCOPHENOLATE MOFETIL USP
Commercial Name N/A
Product Use IMMUNOSUPPRESSANT
Restrictions On Use N/A

Product Code 30-5125

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

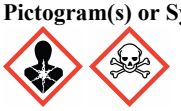
Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 N/A

Signal Word DANGER

Hazard Statement(s) Toxic if swallwed. May damage the ubnorn child. Causes damage to organs (Immune system) through prolonged or repeated exposure if swallowed.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Obtain special instructions before use. Wash hands thoroughly after handling. Use personal protective equipment as required.

Response IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. IF exposed or concerned: Get medical advice/ attention.

Storage N/A

Disposal Dispose of contents/ container to an approved waste disposal plant.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Mycophenolate Mofetil
% By Weight 98-102%
CAS# 128794-94-5
Molecular Weight 433.49
Chemical Formula C23H31NO7
Synonym(s) 4-Hexenoic acid, 6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofurany l)-4-methyl-,2-(4-morpholonyl)ethyl ester,(E);2-Morpholinoethyl (E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-5-phthalanyl) -4-methyl-4- hexenoate;2-(Morpholin-4-yl)ethyl (4E)-6-(4-hydroxy-6-methoxy-7-methyl-3- -oxo-1,3-dihydroisobenzofur an-5-yl)-4-methylhex-4-enoate.

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Mycophenolate Mofetil	12879-94-5	98-102	N/A	N/A

Section 4: First-Aid Measures

Inhalation Leave contaminated area. Supply fresh air. If required, provide artificial respiration. Seek immediate medical advice.

Skin Contact Remove contaminated clothing, jewelry, and shoes at once. Immediately wash with water and rinse thoroughly. Seek immediate medical advice

Eye Contact Rinse opened eye for several minutes under running water. Then consult a doctor.

Ingestion Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek immediate medical advice.

Symptoms/Effects

Acute N/A

Delayed N/A

Immediate Medical Attention

N/A

Section 5: Fire-Fighting Measures

Suitable Extinguishing Media

Extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Unsuitable Extinguishing Media

N/A

Products of Combustion

Carbon dioxides

Firefighters Special Equipment and Precautions

Wear self contained breathing apparatus (SCBA).Wear fully protective impervious suit.

Section 6: Accidental Release Measures

Personal Precautions and Protective Equipment:Do not inhale vapor or gas Wear protective equipment. Cordon off the spill area. Keep unprotected persons away. Ensure adequate ventilation. Environmental Precautions:Do not allow material to be released to the environment without proper governmental permits. Dispose of absorbed material in accordance with the local regulations. Cleaning up Methods: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7: Handling and Storage

Handling: Wear appropriate gloves, lab coat, nylon coveralls or disposable Tyvek suit, safety glass safety shoes, and disposable boots. Use dood manufacturing practices(i.e., cGMPs). Protective garment (coveralls, Tyvek, lab coat) is not to be worn outside th e work area. Clear/ dirty/ decontamination areas are to be established.Negative/ positive air pressure relationships and buffer zones required (i.e., anteroom / degowning room / airlock). Area access is to be restricted.High energy operations such as milling, particle sizing, spraying or fluidizing should only be done within an approved emission control or containment system. Develop cleaning procedures and techniques that limit potential exposure.Emphasis is to be placed material trans fer systems and process containment, with no open handling of powders. Use enclosures and containment measures to reduce potential exposures. Use a powered, air purifying respirator (PAPR) with HEPA cartridges or a supplied air respirator (SAR) until pr ocesses have been monitored to show that respirator protection is not required. Storage: Stored at or below 27

Section 8: Exposure Controls/Personal Protection

Exposure Limits TWA:0.01 mg/m3

Engineering Controls Handle substances in a closed system. Use stable and firm barricades to separates workers from the hazardous substances.The closed system can only allow for controlled and restricted opening. In other words, it can only be opened for a few minutes to handle a small quantity of substance, for example, for QC sampling.A closed system should be designed for better and easier maintenance.Try to operate the equipment at negative pressure to avoid leaks.Exhaust the air to places away from doors, windows and air inlets. Make sure the exhaust air does not affect the surrounding residents.Provide a sewage tank or a separate draining system to avoid leaks or pollutants.

Personal Protection	Breathing Equipment Use: NIOSH/MSHA approved respirator when high concentrations are present. Protection of Hands: Chemical resistant rubber gloves . Check protective gloves pri or to each use for their proper condition. Eye Protection: Safety glasses Body Protection Protective: impervious clothing. Hygienic Measure: The usual precautionary measures for handling chemicals should be followed. Keep away from foodstuffs, beverages and feed. Remove all soiled and contaminated clothing immediately. Wash hands before br eaks and at the end of work. Avoid contact with the eyes and skin.

PCCA

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Section 9: Physical and Chemical Properties

Appearance	White to almost white crystalline powder
Odor	N/A
Odor Threshold	N/A

Melting Point	N/A	**pH**	N/A
Freezing Point	N/A	**Vapor Pressure**	N/A
Boiling Point/Range	637.6C at 760mmHg	**Vapor Density**	N/A
Decomposition temperature	N/A	**Viscosity**	N/A
Partition Coefficient: n-octanol/water	N/A	**Evaporation Rate**	N/A
Flash Point	339.4C	**Autoignition temperature**	N/A
Flammability	N/A	**Flammability or Explosive Limits:**	
		Lower	N/A
		Upper	N/A

Solubility(ies)	N/A
Other	N/A

Section 10: Stability and Reactivity

Reactivity	Decomposition will not occur if used and stored according to specifications
Chemical Stability	N/A
Hazardous Polymerization	N/A
Conditions to Avoid	N/A
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	N/A

Section 11: Toxicological Information

RTECS N/A

Acute Toxicity

Anxious Toxicity: Organism, Test Type, Route Reported Dose (Normalized Dose) ,Source ,Category of GHS Rat,LD50,Oral,250~500 mg/kg,Mycophenolate Mofetil, SDS, Version #: 02 Revision date: 11-17-2014, U. S. Pharmacopeia,Category_3?Toxic ifswallowed. ? Mouse: LD50, Oral,> 4000 mg/kg Mycophenolate Mofetil, SDS,NIL Chronic Toxicity or Long termToxicity:The FDA assigned pregnancy categories Category_D There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.Toxic to reproduction Category_1A/BMay damage fertility or the unborn child.

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
Oral

Symptoms Related to Exposure
N/A

Potential Health Effects
N/A

Target Organ(s) N/A

Section 12: Ecological Information

Ecotoxicity
Organism: (Crustacea) Daphniamagna TestType: EC50 Route: Ecolo gical Reported Dose (Normalized Dose):> 100 mg/l, 48 hours Source:Mycophenolate Mofetil, SDS, Version #: 02 Revision date: 11-17-2014, U. S. Pharmacopeia,. Category of GHS: NIL

Persistance 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 the waste in accordance with all applicable Federal, State and local laws. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Disposal of Container
N/A

Other Considerations
N/A

Section 14: Transport Information

DOT Classification
DOT(US): UN Number 2811 UN Proper Shipping Name: Toxic solids, organic, n.o.s.Mycophenolate Mofetil Hazards Classification:6.1 Packing Group:III Marine pollutant:No Poison Inhalation Hazard:No IMDG UN Number:2811 UN Proper Shipping Name:Toxic solids, organic, n.o.s. Mycophenolate Mofetil Hazards Classification:6.1 Packing Group:? EMS No: S A, F A Marine pollutant:No IATA UN Number: 2811 UN Proper Shipping Name: Toxic solids, organic, n.o.s. Mycophenolate Mofetil Hazards Classification:6.1 Packing Group:?

Section 15: Regulatory Information

Regulations
This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

Other
N/A

Section 16: Other Information

N/A