Mycophenolate sodium



PRODUCT NAME

Mycophenolate sodium

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.



SUPPLIER

Santa Cruz Biotechnology, Inc. 2145 Delaware Avenue Santa Cruz, California 95060 800.457.3801 or 831.457.3800 **EMERGENCY** ChemWatch Within the US & Canada: 877-715-9305 Outside the US & Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C17-H19-O6.Na, "mycophenolic acid, sodium salt", "mycophenolic acid monosodium salt, trans-salt", Myfortic, "4-hexenoic acid, ", "6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-5-phthalanyl)-4-methyl-, (E)-", ", sodium salt", 4-methyl-5-methoxy-7-hydroxy-6-(5-carboxy-3-methylpent-2-en-1-, "yl)phthalide sodium salt", immunosuppressant, "psoriasis treatment", "antibiotic/ antineoplastic/ cytotoxic"

Section 2 - HAZARDS IDENTIFICATION **CHEMWATCH HAZARD RATINGS** Min Max Flammability: 1 Toxicity: 2 Min/Nil=0 2 Body Contact: Low=1 Moderate=2 Reactivity: 1 High=3 Chronic: 3 Extreme=4

CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW RISK

Harmful if swallowed. May cause harm to the unborn child. Possible risk of irreversible effects. Harmful: danger of serious damage to health by prolonged exposure if swallowed. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

EYE

• Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).

Slight abrasive damage may also result.

SKIN

The material is not thought to be a skin irritant (as classified using animal models).

Abrasive damage however, may result from prolonged exposures.

- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

The material is not thought to produce respiratory irritation (as classified using animal models).

- Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
- Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

■ Limited evidence exists that the substance may cause irreversible but non-lethal mutagenic effects following a single exposure.

CHRONIC HEALTH EFFECTS

■ Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Harmful: danger of serious damage to health by prolonged exposure if swallowed.

This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects.

Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material. Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of

appropriate studies using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.

· CAUTION: May produce immunosuppression in individuals occupationally exposed to the material.

Exposure to immunosuppressives may aggravate infectious diseases.

Chronic exposure to therapeutic doses of compounds which produce immunosuppression has been associated with development of lymphomas (occasionally malignant) and mammary tumours. These may be secondary effects induced by activation of endogenous retroviruses.

Patients on immunosuppressive medications have a 10- to 100-fold increased risk of cancer compared to the general population. Furthermore, people who currently have or have already been treated for cancer have a higher rate of tumor progression and recurrence than patients with an intact immune system.

Patients receiving immunosuppressive regimens involving combinations of drugs, as part of an immunosuppressive regimen are at increased risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to the intensity and duration of immunosuppression rather than to the use of any specific agent

Increased incidences of neoplasms, in mice and humans, have been reported after long-term immunosuppression by azathioprine and cyclosporin. Cyclosporin has been classified as a human carcinogen, by IARC, based on development of lymphomas after repeated and prolonged exposures to therapeutic doses.

Mycophenolate mofetil is associated with increased risk of first trimester pregnancy loss and increased risk of congenital malformations, especially external ear and facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, and kidney

A study was conducted in uranium miners to establish whether exposure to mutagenic mycotoxins might be involved in the high cancer risk for these workers. Throat swabs indicated that there was a statistically significant increase in aberrant cells in all groups of miners. Also detected were decreased unscheduled DNA synthesis values in lymphocytes and lipid peroxidation levels in plasma. The authors suggest that the finding of mycotoxins in the throat swabs (including mycophenolic acid) supports the idea that the increased risk of larynx cancer may be due to exposure to these.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME

%

Section 4 - FIRST AID MEASURES

SWALLOWED

 \cdot IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. \cdot Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

EYE

• If this product comes in contact with the eyes: • Wash out immediately with fresh running water. • Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

Treat symptomatically.

General supportive measures and symptomatic treatment should be followed in all cases of overdosage. Although dialysis may be used to remove the inactive metabolite MPAG, it would not be expected to remove clinically significant amounts of the active moiety MPA due to the 98% plasma protein binding of MPA. By interfering with enterohepatic circulation of MPA, activated charcoal or bile acid sequestrants, such as cholestyramine, may reduce the systemic MPA exposure.

Section 5 - FIRE FIGHTING MEASURES					
Vapour Pressure (mmHG):	Negligible				
Upper Explosive Limit (%):	Not available.				
Specific Gravity (water=1):	544-552 kg/m3				
Lower Explosive Limit (%):	Not available				

EXTINGUISHING MEDIA

· Water spray or fog.

· Foam.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.

· Wear breathing apparatus plus protective gloves.

When any large container (including road and rail tankers) is involved in a fire,

consider evacuation by 100 metres in all directions.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.

• Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), other pyrolysis products typical of burning organic material. Dusts with Minimum Ignition Energies (MIEs) ranging between 20 and 100 mJ may be sensitive to ignition. They require that:

plant is grounded

· personal might also need to be grounded

· the use of high resistivity materials (such as plastics) should be restricted or avoided during handling or in packaging

The majority of ignition accidents occur within or below this range.

Dynamic decomposition: 200 C (air open cup): Decomposition 170 j/g (method: radex dynamic decomposition test - temp. progr. 0.75 deg C/min, examined up to 360 deg. C.)

Combustibility test: SiO2: 3 = local burning or glowing showing very little tendency to spread (Method: Combustibility test safety laboratory Standard conditions: 2= after vignitiuon the fire dies out rapidly (100 deg C) (method: Combustibility test safety laboratory)

Dust Explosion: Positive heavy dust explosion (method 20 I ball at 10'000 Joule)

Positive: Min Ignition Energy (MIE) 10-30 mJ (method Mike31 (minimal ignition energy test with induction).

Deflagration: no suspicion (Method Sicherheitsinstitut due to decomposition test)

Drop weight test: negative (Method Drop-weight test)

FIRE INCOMPATIBILITY

Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses: Gloves: Respirator: Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

Environmental hazard - contain spillage.

- \cdot Clean up waste regularly and abnormal spills immediately.
- \cdot Avoid breathing dust and contact with skin and eyes.
- \cdot Wear protective clothing, gloves, safety glasses and dust respirator.
- \cdot Use dry clean up procedures and avoid generating dust.

· Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).

- · Dampen with water to prevent dusting before sweeping.
- \cdot Place in suitable containers for disposal.
- MAJOR SPILLS
- Environmental hazard contain spillage.
- Moderate hazard.
- · CAUTION: Advise personnel in area.
- · Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- · Avoid all personal contact, including inhalation.
- · Wear protective clothing when risk of exposure occurs.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

· Do NOT cut, drill, grind or weld such containers.

In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

Glass container.

- · Polyethylene or polypropylene container.
- · Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

Observe manufacturer's storing and handling recommendations.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records • mycophenolate sodium: CAS:37415-62-6

PERSONAL PROTECTION



RESPIRATOR

• particulate.

Consult your EHS staff for recommendations

EYE

- · Chemical protective goggles with full seal
- · Shielded mask (gas-type)

• Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
- · frequency and duration of contact,
- · chemical resistance of glove material,
- · glove thickness and
- · dexterity
- Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than

240 minutes according to EN 374) is recommended.

· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.

· Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- · Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- · Double gloving should be considered.
- · PVC gloves.
- · Protective shoe covers.
- · Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- · polychloroprene
- nitrile rubber
- · butyl rubber
- · fluorocaoutchouc
- · polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

· For quantities up to 500 grams a laboratory coat may be suitable.

· For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.

· For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

- · For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- · Eye wash unit.

· Ensure there is ready access to an emergency shower.

· For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

For potent pharmacological agents:

Powders

To prevent contamination and overexposure, no open handling of powder should be allowed.

· Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.

· In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.

• Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.

• An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).

· Powder should be put into solution or a closed or covered container after handling.

· If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

Solutions Handling:

• Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.

· Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.

· In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate area. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

· Ensure gloves are protective against solvents in use.

Unless written procedures, specific to the workplace are available, the following is intended as a guide:

• For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets *; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*,

· HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid. Mixes with water.			
State	Divided solid	Molecular Weight	342.32
Melting Range (°F)	363- 365	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	6.7
Decomposition Temp (°F)	392	pH (as supplied)	Not applicable

Autoignition Temp (°F)	842 (BAM)	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	544-552 kg/m3
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

White solid; mixes with water (>100 g/l, 25 C). Solubilities: (m/V): 1-octanol 0.22%; ethanol 0.6%.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

· Presence of incompatible materials.

· Product is considered stable.

STORAGE INCOMPATIBILITY

Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

mycophenolate sodium

TOXICITY AND IRRITATION

MYCOPHENOLATE SODIUM:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

Oral (Mouse) LD50: 1176 mg/kg -For free acid

Intraperitoneal (Mouse) LD50: 568 mg/kg Eyes (rabbit): Mild - Draize *

Subcutaneous (Mouse) LD: >400 mg/kg Skin (rabbit): non-Irritant *

Intravenous (Mouse) LD: 400 mg/kg

Oral (Rabbit) LD50: >6000 mg/kg *

Oral (Mouse) LD50: 2500 mg/kg *

Oral (Rat) LD50: 500 mg/kg *

• NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.

Somnolence, muscle weakness, ataxia, diarrhoea, normocytic anaemia, paternal effects, activity as an anti-cancer agent recorded.

Skin: Non-sensitising * Animal experiments showed both mutagenic and teratogenic effects *

* Novartis

Possible signs and symptoms of acute overdose could include the following: haematological abnormalities such as leukopenia and neutropenia, and gastrointestinal symptoms such as abdominal pain, diarrhea, nausea and vomiting, and dyspepsia

The incidence of adverse events for (mycophenolic acid) was determined in randomised, comparative, active-controlled, double-blind, double-dummy trials in prevention of acute rejection in de novo and maintenance kidney transplant patients.

The principal adverse reactions associated with administration include constipation, nausea, and urinary tract infection in de novo patients and nausea, diarrhoea and nasopharyngitis in maintenance patients.

The following additional adverse reactions have been associated with the exposure to MPA when administered as a sodium salt or as mofetil ester:

Gastrointestinal: Colitis (sometimes caused by CMV), pancreatitis, esophagitis, intestinal perforation, gastrointestinal hemorrhage, gastric ulcers, duodenal ulcers, and ileus

Resistance Mechanism Disorders: Serious life-threatening infections such as meningitis and infectious endocarditis have been reported occasionally and there is evidence of a higher frequency of certain types of serious infections such as tuberculosis and atypical mycobacterial infection.

Respiratory:Interstitial lung disorders, including fatal pulmonary fibrosis, have been reported rarely with MPA administration and should be considered in the differential diagnosis of pulmonary symptoms ranging from dyspnea to respiratory failure in posttransplant patients receiving MPA derivatives.

Cases of progressive multifocal leukoencephalopathy (PML), sometimes fatal, have been reported in patients treated with mycophenolate mofetil (MMF). Mycophenolate mofetil (MMF) is metabolised to mycophenolic acid (MPA)

Congenital malformations have been reported in offspring of patients exposed to mycophenolate mofetil (MMF) during pregnancy. Use during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of congenital malformations, especially external ear and other facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, oesophagus, and kidney. In the National Transplantation Pregnancy Registry (NTPR), there were data on 33 MMF-exposed pregnancies in 24 transplant patients; there were 15 spontaneous abortions (45%) and 18 live-born infants. Four of these 18 infants had structural malformations (22%). In postmarketing data (collected from 1995 to 2007) on 77 women exposed to systemic MMF during pregnancy, 25 had spontaneous abortions and 14 had a malformed infant or fetus. Six of 14 malformed offspring had ear abnormalities

The incidence of malignancies and lymphoma is consistent with that reported in the literature for this patient population. Lymphoma developed in 2 de novo patients (0.9%), (one diagnosed 9 days after treatment initiation) and in 2 maintenance patients (1.3%) (one was

AIDS-related), receiving Myfortic with other immunosuppressive agents in the 12-month controlled clinical trials. Nonmelanoma skin carcinoma occurred in 0.9% de novo and 1.8% maintenance patients. Other types of malignancy occurred in 0.5% de novo and 0.6% maintenance patients

Section 12 - ECOLOGICAL INFORMATION

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. This material and its container must be disposed of as hazardous waste. Avoid release to the environment.

Refer to special instructions/ safety data sheets.

Ecotoxicity

Ingredient mycophenolate sodium

I OW

Persistence: Water/Soil Persistence: Air No Data Available

Bioaccumulation 1 OW

Mobility MED

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

| Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

· Reduction

· Reuse

· Recycling

· Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.





DOT: Symbols: G Hazard class or Division: 9 Identification Numbers: UN3077 PG: III Label Codes: 9 Special provisions: 8, 146, 335, B54, IB8, IP3, N20, T1, TP33 Packaging: Exceptions: 155 Packaging: Non- bulk: 213 Packaging: Exceptions: 155 Quantity limitations: No limit Passenger aircraft/rail: Quantity Limitations: Cargo No limit Vessel stowage: Location: A aircraft only: Vessel stowage: Other: None Hazardous materials descriptions and proper shipping names: Environmentally hazardous substance, solid, n.o.s Air Transport IATA: ICAO/IATA Class: 9 ICAO/IATA Subrisk: None UN/ID Number: 3077 Packing Group: III Special provisions: A97 Cargo Only Packing Instructions: 400 kg Maximum Qty/Pack: 956 Passenger and Cargo Passenger and Cargo Packing Instructions: 400 kg Maximum Qty/Pack: 956 Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity Packing Instructions: 30 kg G Maximum Qty/Pack: Y956 Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. *(CONTAINS MYCOPHENOLATE SODIUM) Maritime Transport IMDG: IMDG Class: 9 IMDG Subrisk: None UN Number: 3077 Packing Group: III

Section 15 - REGULATORY INFORMATION

No data for mycophenolate sodium (CAS: , 37415-62-6)

Section 16 - OTHER INFORMATION

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 Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at: www.chemwatch.net/references.

• The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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