

Mycophenolate mofetil

sc-200971



The Power is Question

Material Safety Data Sheet

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

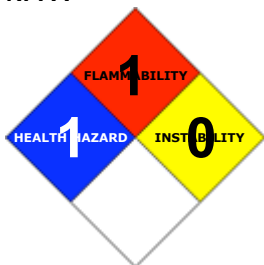
PRODUCT NAME

Mycophenolate mofetil

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



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

C23-H31-N-O7, "2-(morpholino)ethyl-(E)-6-(1, 3-dihydro-4-hydroxy-6-methoxy-7-methyl-, 3-oxo-5-isobenzofuranyl)-4-methylhexanoate, "2-morpholinoethyl (E)-6-(1, 3-dihydro-4-hydroxy-6-methoxy-, 7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate., "4-hexenoic acid, 6-(1, 3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-, "5-isobenzofuranyl)-4-methyl-, 2-(4-morpholinyl)ethyl ester, (E)-", RS-61442-000, CellCept, "Ro 106-1443/000", immunosuppressant

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	0		
Reactivity:	1		
Chronic:	3		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Harmful if swallowed.

Danger of serious damage to health by prolonged exposure.

May cause harm to the unborn child.

Possible risk of irreversible effects.

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

■ Skin contact is not thought to produce harmful health effects (as classified using animal models).

Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions.

■ 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 either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models).

Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

■ 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.

CHRONIC HEALTH EFFECTS

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

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.

NAME	CAS RN	%
mycophenolate mofetil	128794-94-5	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

· IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. · 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 or hair contact occurs: · Flush skin and hair with running water (and soap if available). · Seek medical attention in event of irritation.

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Other measures are usually unnecessary.

NOTES TO PHYSICIAN

■ for poisons (where specific treatment regime is absent):

-----BASIC TREATMENT

 · Establish a patent airway with suction where necessary.
 · Watch for signs of respiratory insufficiency and assist ventilation as necessary.
 Elimination half-life is 16-18 h.
 Excretion is mainly renal.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not Available
Specific Gravity (water=1):	Not Available
Lower Explosive Limit (%):	Not Available

EXTINGUISHING MEDIA

· Foam.
 · Dry chemical powder.

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), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

FIRE INCOMPATIBILITY

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

PERSONAL PROTECTION

Glasses:
 Chemical goggles.
 Gloves:
 Respirator:
 Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

■ Environmental hazard - contain spillage.
 · Clean up waste regularly and abnormal spills immediately.
 · Avoid breathing dust and contact with skin and eyes.
 · Wear protective clothing, gloves, safety glasses and dust respirator.
 · 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.
- 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 mofetil: CAS:128794-94-5

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

■ When handling very small quantities of the material eye protection may not be required.

For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- 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
- fluorocautchouc
- 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

- Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation. 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

State	Divided Solid	Molecular Weight	433.5
Melting Range (°F)	199- 210	Viscosity	Not Applicable
Boiling Range (°F)	Not Available	Solubility in water (g/L)	Partly Miscible
Flash Point (°F)	Not Available	pH (1% solution)	Not Applicable
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not Applicable
Autoignition Temp (°F)	Not Available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not Available	Specific Gravity (water=1)	Not Available
Lower Explosive Limit (%)	Not Available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

APPEARANCE

White crystalline powder; does not ix well with water (13 mg/l). Soluble in acetone and methanol; sparingly soluble in ethanol;

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 mofetil

TOXICITY AND IRRITATION

MYCOPHENOLATE MOFETIL:

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

TOXICITY	IRRITATION
Oral (Rat) LD50: 250 mg/kg *	
Oral (Rat) LD50: 500 mg/kg *	

Oral (Mouse) LD50: >4000 mg/kg *
Non-sensitising *
Not mutagenic (various in vivo and in vitro test systems) *
No carcinogenic (several species) *
Teratogenic (several species) *
*Roche MSDS

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.

GESAMP/EHS COMPOSITE LIST - GESAMP Hazard Profiles

Name / EHS TRN A1a A1b A1 A2 B1 B2 C1 C2 C3 D1 D2 D3 E1 E2 E3 Cas No / RTECS No _____
_____ Fatty 226 278 5 0 0 (R) 0 NI (0) (0) (1) (1) (1) NI 2 acids, 1 0 linear C12+ saturated with C12+
unsaturat ed / CAS:12879 4- 94- 5 /

Legend: EHS=EHS Number (EHS=GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships)
NRT=Net Register Tonnage, A1a=Bioaccumulation log Pow, A1b=Bioaccumulation BCF, A1=Bioaccumulation, A2=Biodegradation,
B1=Acuteaquatic toxicity LC/ECIC50 (mg/l), B2=Chronic aquatic toxicity NOEC (mg/l), C1=Acute mammalian oral toxicity LD50 (mg/kg),
C2=Acute mammalian dermal toxicity LD50 (mg/kg), C3=Acute mammalian inhalation toxicity LC50 (mg/kg), D1=Skin irritation & corrosion,
D2=Eye irritation & corrosion, D3=Long-term health effects, E1=Tainting, E2=Physical effects on wildlife & benthic habitats, E3=Interference
with coastal amenities, For column A2: R=Readily biodegradable, NR=Not readily biodegradable. For column D3: C=Carcinogen,
M=Mutagenic, R=Reprotoxic, S=Sensitising, A=Aspiration hazard, T=Target organ systemic toxicity, L=Lunginjury, N=Neurotoxic,
I=Immunotoxic. For column E1: NT=Not tainting (tested), T=Tainting test positive. For column E2: Fp=Persistent floater, F=Floater,
S=Sinking substances. The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard. (GESAMP/EHS
Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships)

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

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

! Puncture containers to prevent re-use and bury at an authorized landfill.

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.

· Recycle wherever possible.

· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION



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: 400 kg

Passenger and Cargo Passenger and Cargo

Packing Instructions: 911 Maximum Qty/Pack: 911

Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity

Packing Instructions: 30 kg G Maximum Qty/Pack: Y911

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S. *(CONTAINS MYCOPHENOLATE MOFETIL)

Maritime Transport IMDG:

IMDG Class: 9 IMDG Subrisk: None

UN Number: 3077 Packing Group: III

EMS Number: F-A , S-F Special provisions: 179 274 335 909

Limited Quantities: 5 kg Marine Pollutant: Yes

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(contains mycophenolate mofetil)

Section 15 - REGULATORY INFORMATION

mycophenolate mofetil (CAS: 128794-94-5) is found on the following regulatory lists;

"GESAMP/EHS Composite List - GESAMP Hazard Profiles","IMO IBC Code Chapter 17: Summary of minimum requirements","IMO Provisional Categorization of Liquid Substances - List 1: Pure or technically pure products"

Section 16 - OTHER INFORMATION

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ 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.

This document is copyright. Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH. TEL (+61 3) 9572 4700.

Issue Date: Nov-19-2009

Print Date:Mar-9-2011