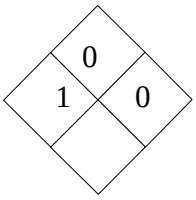
NOVARTIS



MATERIAL SAFETY DATA SHEET
NOVARTIS PHARMACEUTICALS CORPORATION
One Health Plaza
East Hanover, NJ 07936

24-Hour Emergency Telephone Number: 1-862-778-7000
Customer Interaction Center (MSDS requests): 1-888-669-6682
For Technical Information: 1-862-778-3680 (9:00 AM – 5:00 PM E.S.T.)

SECTION 1. PRODUCT IDENTIFICATION

PRODUCT NAME:	**Myfortic**Ò **Tablets, 180 and 360 mg**
SYNONYMS:	Mycophenolic Acid Tablets
THERAPEUTIC CATEGORY:	Immunosuppressant agent for management of organ transplants
GENERIC NAME:	None
CHEMICAL NAME:	(E)-6-(4-hydroxy-6-methoxy-7-methyl-3-oxo-1,3-dihydroisobenzofuran-5-yl)-4-methylhex-4-enoic acid salt
CHEMICAL FORMULA:	$C_{17}H_{19}O_6Na$
MOLECULAR WEIGHT:	342.32

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

COMPOSITION	CAS#	CONCENTRATION (by wt.)
Myfortic Active Ingredient	24280-93-1	Approx. 50%

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

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FINISHED PHARMACEUTICAL PRODUCT
REFER TO PHYSICIANS' DESK REFERENCE OR PACKAGE INSERT
IMMUNOSUPPRESANT AGENT
MAY CAUSE GASTROINTESTINAL DISORDERS
MAY CAUSE INCREASED SUSCEPTIBILITY TO INFECTION
MAY ADVERSELY AFFECT THE DEVELOPING FETUS

****

PRIMARY ROUTE(S) OF ENTRY:	Oral
EFFECTS OF OVEREXPOSURE:	Finished pharmaceutical product. Potential for exposure is reduced in this form.
Skin:	No hazard is expected from normal clinical use.
Eye:	No hazard is expected from normal clinical use.
Inhalation:	No hazard is expected from normal clinical use.
Ingestion:	No hazard is expected from normal clinical use.
THERAPEUTIC SIDE EFFECTS:	Anemia, leucopenia, constipation, nausea, diarrhea, vomiting, urinary tract infection, and insomnia.
TARGET ORGAN EFFECTS:	Affects the blood and blood-forming organs.
REPRODUCTIVE HAZARDS:	Pregnancy Category C. Experimental reproductive effects have been reported. (see section 11).
CARCINOGENICITY:	Not carcinogenic. (see section 11).
MUTAGENICITY:	Positive in two *in vitro* assays and one *in vivo* assay; negative in two *other in vitro* assays. (see Section 11).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Known hypersensitivity to Myfortic or any of its excipients.

SECTION 4. EMERGENCY AND FIRST AID MEASURES

Skin Contact:	Wash contaminated area with soap and water.
Eye Contact:	Flush with running water for 15 minutes holding eyelids open.
Inhalation:	No specific treatment is necessary since this product is not likely to be hazardous by inhalation if tablet is left intact.
Ingestion:	Get medical attention immediately; induce vomiting if victim is conscious.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point: Not applicable **Method Used**: Not applicable

Flammable Limits (% in air)

Lower: not applicable Upper: not applicable

Autoignition Temperature:	Not available
Extinguishing Media:	Use media suitable for fire in surrounding area.
Special Fire Fighting Procedures and Precautions:	Evacuate area and fight fire from safe distance.
Fire and Explosion Hazards:	Not available
Fire-Fighting Equipment:	Wear full protective clothing and positive pressure self-contained breathing apparatus.
Hazardous Products of Combustion:	COx

NFPA Ratings: Health = 1 Flammability = 0 Reactivity = 0 Special Hazard = None
Hazard Rating Scales: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe U = Unknown

SECTION 6. ACCIDENTAL RELEASE MEASURES

Steps to be taken if Material is Released or Spilled: Using appropriate protective equipment, sweep up and containerize spilled material. Avoid contamination of sewers and waterways.

SECTION 7. HANDLING AND STORAGE

Storage Temperature:	Do not store above 86°F (30°C).
Shelf Life:	See container packaging.
Special Sensitivity:	None known.
Handling and Storage Precautions:	None known.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection:	Not required under normal conditions of therapeutic administration and use.
Skin Protection:	Not required under normal conditions of therapeutic administration and use. Protective gloves should be worn if tablet is crushed.
Respiratory Protection:	Not required under normal conditions of therapeutic administration and use.
Ventilation Requirements:	Not required under normal conditions of therapeutic administration and use.
Additional Measures:	None

Exposure Limits (Definition of terms):

NPIEL: Novartis Pharma Internal Exposure Limit

Component	**Exposure Limit**
Mycophenolic acid	NPIEL = 0.01 mg/m^3

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	180 mg Tablet: round; 360 mg: ovaloid		
Color:	lime green (180 mg) or pale orange-red (360 mg)		
Boiling Point:	Not applicable	**Odor Threshold:**	Not available
Melting/Freezing Pt.:	Not applicable	**Odor Characteristics:**	Not available
pH:	Not available	**Vapor Pressure (mm Hg):**	Not applicable
Specific Gravity:	Not available	**Vapor Density:**	Not applicable
Soluble In:	Water	**% Volatile by Wt:**	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Stable (yes/no):	Yes
Hazardous Polymerization:	Will not occur.
Conditions and Materials to Avoid:	Protect from temperatures exceeding 86°F (30°C).
Incompatibility:	None known
Hazardous Decomposition Products:	None known

SECTION 11. TOXICOLOGICAL INFORMATION

No toxicological data on finished product; data is for drug substance.

Eye Irritation:	Mildly irritating
Skin Irritation/Sensitization:	Non irritating
Oral Toxicity:	LD_{50} > 352 mg/kg (rat)
Dermal Toxicity:	No data available.
Inhalation Toxicity:	No data available
Chronic/Carcinogenicity:	In a 104-week oral study in rats. Mycophenolate sodium was not tumorigenic at daily doses up to 9 mg/kg.
Mutagenicity:	Positive in the following test: Mouse lymphoma/thymidine kinase assay, micronucleus test in V79 Chinese hamster cells, and the *in vivo* mouse micronucleus assay. Negative in the following tests: *in vitro* Ames and chromosome aberration assay in human lymphocytes.
Reproductive Effects:	In a teratology study performed with mycophenolate sodium in rats, at a dose as low as 1 mg/kg, malformations in the offspring were observed. In teratology studies in rabbits, fetal resorptions and malformations occurred from 80 mg/kg/day, in the absence of maternal toxicity. There are no adequate and well-controlled studies in pregnant women. Myfortic should be used in pregnant women only if the potential benefit outweighs the potential risk to the fetus.

SECTION 12. ECOLOGICAL INFORMATION

No ecological data on finished product; data is for drug substance.

Biological elimination:
2 - 5 % (aerobic, CO_2)
Initial conc. 20.1 mg/l
Not readily degradable
Method: 92/69/EC (L383) C.4-C * Carbon dioxide (CO2) evolution
Value from salt form

Algae toxicity: EbC50: 0.017 mg/l
EbC10: 0.008 mg/l
NoEC: 0.0046 mg/l
(Species: Selenastrum capricornutum. Green algae,
Exp. time: 96 h)
Method: 92/69/EC (L383) C.3 * Algal inhibition test.
Value from salt form

Bacteria toxicity (respiration inhibition):
EC10: 69 mg/l
EC20: 164 mg/l
EC50: 2213 mg/l
(Species: activated sludge, Exp. time: 3 h)
Method: Inhibition of Oxygen Consumption by activated sludge (87/302/EEC), Part C
Value from salt form
Avoid release into soil, rivers or drains.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Disposal Method: All wastes must be disposed of in accordance with local, state and federal laws and regulations. (Contact local or state environmental agency for specific rules).

EPA Hazardous Waste Number: None

SECTION 14. TRANSPORTATION INFORMATION

Ground Regulations:

Proper Shipping Description:	Drugs, N.O.I. NMFC Item 60000
DOT Proper Shipping Name:	Not Applicable
DOT Hazard Class:	Not Applicable
DOT Identification Number:	Not Applicable
Packing Group:	Not Applicable
Hazard Label:	Not Applicable
Package Weight Limits:	Not Applicable
Special Requirements:	Not Applicable
Exceptions:	Not Applicable
Non-Bulk Requirements:	Not Applicable
Bulk Requirements:	Not Applicable
Reportable Quantity (lbs.):	Not Applicable
Stowage:	Not Applicable
Other Requirements:	Not Applicable

Air Regulations:

Proper Shipping Description:	Drugs, N.O.I. NMFC Item 60000
IATA Proper Shipping Name:	Not Applicable
IATA Hazard Class:	Not Applicable
IATA Identification Number:	Not Applicable
Packing Group:	Not Applicable
Hazard Label:	Not Applicable
Special Requirements:	Not Applicable
Max. wgt/pkg - Passgr. Aircraft:	Not Applicable
Max. wgt/pkg - Cargo Only Air:	Not Applicable

SECTION 15. REGULATORY INFORMATION

OSHA (Occupational Safety & Health Administration): This Material Safety Data Sheet contains the information required by the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200).

OSHA PSM (Process Safety Management): Not listed (29 CFR 1910.119, Appendix A)

NJ TCPA (Toxic Catastrophe Prevention Act): This product contains NONE of the substances subject to the reporting requirements of Section N.J.A.C. 7:31 of this act.

TSCA (Toxic Substance Control Act): Not applicable

CERCLA (Comprehensive Response Compensation & Liability Act): Not listed

SARA Title III (Superfund Amendments & Reauthorization Act):

Section 302 Extremely Hazardous Substances:	Not listed
Section 311/312 Hazard Categories:	None
Section 313 Reportable Ingredients:	Not listed

RCRA (Resource Conservation & Recovery Act): Not listed

Other State Regulatory Information:

New Jersey: NJ RTK Threshold Planning Quantity = 10,000 lbs.

Other USA Regulations: None

California Proposition 65: The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. *This product does not contain any ingredient known to the State of California to cause cancer or reproductive toxicity.*

Canada (WHMIS): **N**ot listed

EEC Classification (European Economic Community): **Warning Symbol:** not available.
Risk Phrases: not available.
Safety Phrases: not available.

SECTION 16. OTHER INFORMATION

Reason for Issue: New

Written By:	C. Perino	**Date:** 08 Mar 04
Approved By:	J. Affuso	**Date** 10 Mar 04

To the best of our knowledge, the information contained herein is accurate. However, Novartis Pharmaceuticals Corporation does not assume any liability whatsoever for the accuracy or completeness of the information contained herein except for the product's administration/use as intended. Final determination of the suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards which exist.