

SAFETY DATA SHEET

Mycophenolate Mofetil for Injection, USP

1. IDENTIFICATION

Product Identifier:	Mycophenolate Mofetil for Injection, USP
Synonyms:	2-(4-Morpholinyl)ethyl ester
National Drug Code (NDC):	17478-422-40
Recommended Use:	Pharmaceutical. Mycophenolate Mofetil for Injection, USP is indicated for the prophylaxis of organ rejection in patients receiving allogenic, renal, cardiac or hepatic transplant.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classifiable.	
Health Hazards:	Acute Toxicity, Oral	Category 4
	Germ Cell Mutagenicity	Category 2
	Reproductive Toxicity	Category 1B
	Specific Target Organ Toxicity – Repeated Exposure	Category 1
	Hazardous to the aquatic environment, Acute Hazard	Category 1



Symbol(s):	
Signal Word:	Warning.
Hazard Statement(s):	H302 Harmful if swallowed. H341 Suspected of causing genetic defects. H360 May damage fertility or the unborn child.

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Precautionary Statement(s):	H372	Causes damage to organs through prolonged or repeated exposure.
	H400	Very toxic to aquatic life.
	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	P264	Wash hands thoroughly after handling.
	P270	Do not eat, drink or smoke when using this product.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
	P308 + P313	IF exposed or concerned: Get medical advice/attention.
	P405	Store locked up.
	P501	Dispose of contents/containers in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Mycophenolate Mofetil	2-(4-Morpholinyl)ethyl ester	128794-94-5	C ₂₃ H ₃₁ NO ₇	469.96	50%

The formula also contains Polysorbate 80, 25 mg and Citric Acid, 5 mg. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust pH.

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4. FIRST AID MEASURES

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Solution is not considered hazardous under normal conditions of use. Common side effects are: Blood in the urine, chest pain or discomfort, cough or hoarseness, fever or chills, increased cough, lower back or side pain, painful or difficult urination, shortness of breath, swelling of the feet or lower legs.
Medical Conditions Aggravated by Exposure:	See package insert for more information.
Notes to Physician:	Treat supportively and symptomatically. After accidental exposure women should get medical advice from a physician.

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5. FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or water spray.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: No data available.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Collect solids (avoid dust formation) and hand over to waste removal. Collect spilled solutions with inert adsorbent and hand over to waste removal.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil. If the substance reaches waters or sewer system, inform the competent authority. Dilute the leaked substance by water spray jet as far as necessary in order to minimize the hazard; hold the draining water/mixture of substance back by all means available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store powder and reconstituted/infusion at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Specific End Use: Pharmaceutical drug product.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Mycophenolate Mofetil	TWA	0.01 mg/m ³

TWA: Time Weighted Average.

Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection:	Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	Wear chemically compatible gloves for handling solutions and ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
General Hygiene Considerations:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	White to off-white powder.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	2.4 to 4.1.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.

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Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Slightly soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	No information available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No information available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No information available.
Incompatible Materials:	Strong oxidizing agents.
Hazardous Decomposition Products:	No information available.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	May be harmful if inhaled.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Mycophenolate Mofetil	Rat	Oral	LD ₅₀	250 - 500 mg/kg
Mycophenolate Mofetil	Mouse	Oral	LD ₅₀	>4,000 mg/kg

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Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Dosage	Effect(s)
Mycophenolate Mofetil	Reproductivity Study	Rat	4.5 mg/kg/day	Malformations were observed in the generation of offspring in the absence of maternal toxicity
Mycophenolate Mofetil	Reproductivity Study	Rat	6 mg/kg/day	Fetal resorptions and malformations occurred in the absence of maternal toxicity
Mycophenolate Mofetil	Reproductivity Study	Rabbit	90 mg/kg/day	Fetal resorptions and malformations occurred in the absence of maternal toxicity
Mycophenolate Mofetil	Reproductivity Study	Rat	<20 mg/kg	No effects on male fertility

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Mycophenolate Mofetil	Bacterial mutation assay	Chinese hamster ovary cell chromosomal aberration	Negative
Mycophenolate Mofetil	In vivo mouse micronucleus assay	Mouse	Positive
Mycophenolate Mofetil	Lymphoma assay	Mouse	Positive

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Systemic Effects:

No data available.

Reproductive Effects:

Pregnancy Category D. Use of Mycophenolate Mofetil during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of congenital malformation, especially external ear and other facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, kidney and nervous system.

Carcinogenicity:

Not carcinogenic.

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National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Mycophenolate Mofetil	Daphnia magna	EC ₅₀	>100 mg/l	48 hours

Terrestrial Toxicity: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Environmentally hazardous substance, solid, n.o.s	UN3077	9	III

International Air Transport Association (IATA):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Environmentally hazardous substance, solid, n.o.s	UN3077	9	III

International Maritime Dangerous Good (IMDG):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Environmentally hazardous substance, solid, n.o.s	UN3077	9	III

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15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Mycophenolate Mofetil	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Mycophenolate Mofetil	Listed	Listed	Not listed

California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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