



SAFETY DATA SHEET

Section 1: Identification	
Material	Mycophenolate Mofetil Capsules USP 250 mg
Recommended use	Pharmaceutical Product
Manufacturer	Hetero Labs Limited Unit V, Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301 India
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Fire and Explosion	Expected to be non-combustible
Health	Allergic reactions to Mycophenolate mofetil capsules have been observed; therefore, Mycophenolate mofetil capsules are contraindicated in patients with a hypersensitivity to mycophenolate mofetil (MMF), mycophenolic acid (MPA) or any component of the drug product.
Environment	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Mycophenolate Mofetil	128794-94-5
Magnesium Stearate	557-04-0
Povidone	9003-39-8
Pregelatinized Starch	9005-25-8
Croscarmellose Sodium	74811-65-7
Empty Hard Gelatin Capsule Shells Size '1'	NA
Section 4: First-Aid Measures	
Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.



Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs
Eye Contact	Flush eyes with plenty of water. Get medical attention.
NOTES TO HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	<p>Possible signs and symptoms of acute overdose include hematological abnormalities such as leukopenia and neutropenia, and gastrointestinal symptoms such as abdominal pain, diarrhea, nausea, vomiting, and dyspepsia. The experience with overdose of Mycophenolate mofetil capsules in humans is limited. The reported effects associated with overdose fall within the known safety profile of the drug. The highest dose administered to kidney transplant patients in clinical trials has been 4 g/day. In limited experience with heart and liver transplant patients in clinical trials, the highest doses used were 4 g/day or 5 g/day. At doses of 4 g/day or 5 g/day, there appears to be a higher rate, compared to the use of 3 g/day or less, of gastrointestinal intolerance (nausea, vomiting, and/or diarrhea), and occasional hematologic abnormalities, particularly neutropenia. MPA and the phenolic glucuronide metabolite of MPA (MPAG) are usually not removed by hemodialysis. However, at high MPAG plasma concentrations ($>100\text{ }\mu\text{g/mL}$), small amounts of MPAG are removed. By increasing excretion of the drug, MPA can be removed by bile acid sequestrants, such as cholestyramine.</p>



Section 5: Fire-Fighting Measures	
Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Section 6: Accidental Release Measures	
Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal
Section 7: Handling and Storage	
Handling	Mycophenolate mofetil (MMF) has demonstrated teratogenic effects in humans. Mycophenolate mofetil capsules should not be opened or crushed. Avoid inhalation or direct contact with skin or mucous membranes of the powder contained in Mycophenolate mofetil capsules. Follow applicable special handling and disposable procedures.
Storage	Storage: Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
Section 8: Exposure Controls/Personal Protection	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.	
Section 9: Physical and Chemical Properties	
Physical Form	Capsule



Description	<p>Blue/Brown colored size '1', hard gelatin capsules, imprinted with "H" on cap and "M1" on body, filled with white to off white powder. They are supplied as follows:</p> <table><tr><td>Bottle of 100 Capsules</td><td>NDC 31722-878-01</td></tr><tr><td>Bottle of 500 Capsules</td><td>NDC 31722-878-05</td></tr></table>	Bottle of 100 Capsules	NDC 31722-878-01	Bottle of 500 Capsules	NDC 31722-878-05
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Section 10: Stability and Reactivity

Stable under recommended storage conditions

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week oral carcinogenicity study in mice, MMF in daily doses up to 180 mg/kg was not tumorigenic. The highest dose tested was 0.4 times the recommended clinical dose (2 g/day) in renal transplant patients and 0.3 times the recommended clinical dose (3 g/day) in cardiac transplant patients when corrected for differences in body surface area (BSA). In a 104-week oral carcinogenicity study in rats, MMF in daily doses up to 15 mg/kg was not tumorigenic. The highest dose was 0.07 times the recommended clinical dose in kidney transplant patients and 0.05 times the recommended clinical dose in heart transplant patients when corrected for BSA. While these animal doses were lower than those given to patients, they were maximal in those species and were considered adequate to evaluate the potential for human risk.

The genotoxic potential of MMF was determined in five assays. MMF was genotoxic in the mouse lymphoma/thymidine kinase assay and the in vivo mouse micronucleus assay. MMF was not genotoxic in the bacterial mutation assay, the yeast mitotic gene conversion assay or the Chinese hamster ovary cell chromosomal aberration assay.

MMF had no effect on fertility of male rats at oral doses up to 20 mg/kg/day. This dose represents 0.1 times the recommended clinical dose in renal transplant patients and 0.06 times the recommended clinical dose in cardiac



	transplant patients when corrected for BSA. In a female fertility and reproduction study conducted in rats, oral doses of 4.5 mg/kg/day caused malformations (principally of the head and eyes) in the first generation offspring in the absence of maternal toxicity. This dose was 0.02 times the recommended clinical dose in renal transplant patients and 0.01 times the recommended clinical dose in cardiac transplant patients when corrected for BSA. No effects on fertility or reproductive parameters were evident in the dams or in the subsequent generation.
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Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name : N/A
IATA UN/ID No : N/A
IATA Hazard Class : N/A
IATA Packaging Group : N/A
IATA Label : N/A

IMDG - Not Regulated

IMDG Proper shipping Name : N/A
IMDG UN/ID No : N/A
IMDG Hazard Class : N/A
IMDG Flash Point : N/A
IMDG Label : N/A

DOT - Not Regulated

DOT Proper shipping Name : N/A
DOT UN/ID No : N/A
DOT Hazard Class : N/A
DOT Flash Point : N/A
DOT Packing Group : N/A
DOT Label : N/A



Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws

Section 16: Other Information

Issue Date: 13-12-2024

Version: 00

Further information

Revision date: NA

Revision notes: NA

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