SAFETY DATA SHEET

Section 1: Identification	
Material	**Mycophenolate Mofetil Tablets USP 500 mg**
Recommended use	Pharmaceutical Product
Manufacturer	**Hetero Labs Limited, Unit-III** **22-110, IDA,** Unit III, Jeedimetla, Hyderabad-500055, 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 tablets have been observed; therefore, Mycophenolate mofetil tablets 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
Microcrystalline Cellulose	9004-34-6
Povidone	9003-39-8
Croscarmellose sodium	74811-65-7
Magnesium stearate	557-04-0
Opadry Purple	NA

Section 4: First-Aid Measures	
Ingestion	Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.
Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately
Skin Contact	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.
Eye Contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. 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	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 tablets 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 µg/mL), small amounts of MPAG are removed. By increasing excretion of the drug, MPA can be removed by bile acid sequestrants, such as cholestyramine.
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 suitable protective clothing, gloves and eye/face protection
Environmental Precautions	Avoid release to the environment.

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 tablets should not be crushed. Follow applicable special handling and disposal procedures
Storage	Storage: Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Dispense in light-resistant containers, such as the manufacturer's original containers.

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	Tablet
Description	Lavender color, capsule shaped, biconvex, film coated tablets debossed with "M12" on one side and "H" on the other side . Bottle of 100 tablets NDC 31722-879-01 Bottle of 500 tablets NDC 31722-879-05

Section 10: Stability and Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport

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.

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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