LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	**Mycophenolic Acid* Delayed-Release Tablets, USP** **180 mg and 360 mg** **(* as mycophenolate sodium)**
Manufacturer	**Concord Biotech Limited** Valthera, Ahmedabad - 382225 Gujarat, India
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

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Fire and Explosion	Expected to be non-combustible.
Health	Mycophenolic acid delayed-release tablets are contraindicated in patients with a hypersensitivity to mycophenolate sodium, mycophenolic acid, mycophenolate mofetil, or to any of its excipients. Reactions like rash, pruritus, hypotension, and chest pain have been observed in clinical trials and post marketing reports.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	**CAS**
Mycophenolate Sodium USP	37415-62-6

Section 4: First-Aid Measures

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	**Signs and Symptoms** There have been anecdotal reports of deliberate or accidental overdoses with mycophenolic acid delayed-release tablets, whereas not all patients experienced related adverse reactions. In those overdose cases in which adverse reactions were reported, the reactions fall within the known safety profile of the class. Accordingly an overdose of mycophenolic acid delayed-release tablets could possibly result in oversuppression of the immune system and may increase the susceptibility to infection including opportunistic infections, fatal infections and sepsis. If blood dyscrasias occur (e.g., neutropenia with absolute neutrophil count <1.5 x 10^3 /mcL or anemia), it may be appropriate to interrupt or discontinue mycophenolic acid delayed-release tablets. Possible signs and symptoms of acute overdose could include the following: hematological abnormalities such as leukopenia and neutropenia, and gastrointestinal symptoms such as abdominal pain, diarrhea, nausea and vomiting, and dyspepsia. **Treatment and Management** General supportive measures and symptomatic treatment should be followed in all cases of overdosage. Although dialysis may be used to remove the inactive metabolite mycophenolic acid glucuronide (MPAG), it would not be expected to remove clinically significant amounts of the active moiety, mycophenolic acid, due to the 98% plasma protein binding of mycophenolic acid. By interfering with enterohepatic circulation of mycophenolic acid, activated charcoal or bile sequestrates, such as cholestyramine, may reduce the systemic mycophenolic acid exposure.

Section 5: Fire-Fighting Measures

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

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

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Handling	Keep out of reach and sight of children. Mycophenolic acid delayed-release tablets should not be crushed or cut in order to maintain the integrity of the enteric coating. Teratogenic effects have been observed with mycophenolate sodium. If for any reason, the mycophenolic acid delayed-release tablets must be crushed, avoid inhalation of the powder, or direct contact of the powder, with skin or mucous membranes.
Storage	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in a tight container (USP).

Section 8: Exposure Controls/Personal Protection

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

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Physical Form	360 mg tablet: Pink to light pink colored, enteric coated, ovaloid biconvex tablet, debossed with “C2” on one side and plain on other side, containing 360 mg mycophenolic acid (MPA) as mycophenolate sodium. Bottles of 120 with child resistance closure, NDC 70748-218-16

180 mg tablet: Lime green colored, enteric coated, round biconvex tablet, debossed with “C1” on one side and plain on other side, containing 180 mg mycophenolic acid (MPA) as mycophenolate sodium.

Bottles of 120 with child resistance closure, NDC 70748-217-16

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week oral carcinogenicity study in rats, mycophenolate sodium was not tumorigenic at daily doses up to 9 mg per kg, the highest dose tested. This dose resulted in approximately 0.6 to 1.2 times the systemic exposure (based on plasma AUC) observed in renal transplant patients at the recommended dose of 1440 mg per day. Similar results were observed in a parallel study in rats performed with MMF. In a 104-week oral carcinogenicity study in mice, MMF was not tumorigenic at a daily dose level as high as 180 mg per kg (which corresponds to 0.6 times the recommended mycophenolate sodium therapeutic dose, based on body surface area).

The genotoxic potential of mycophenolate sodium was determined in five assays. Mycophenolate sodium was genotoxic in the mouse lymphoma/thymidine kinase assay, the micronucleus test in V79 Chinese hamster cells, and the *in vivo* mouse micronucleus assay. Mycophenolate sodium was not genotoxic in the bacterial mutation assay (*Salmonella typhimurium* TA 1535, 97a, 98, 100, and 102) or the chromosomal aberration assay in human lymphocytes.

Mycophenolate mofetil generated similar genotoxic activity. The genotoxic activity of mycophenolic acid (MPA) is probably due to the depletion of the nucleotide pool required for DNA synthesis as a result of the pharmacodynamic mode of action of MPA (inhibition of nucleotide synthesis).

Mycophenolate sodium had no effect on male rat fertility at daily oral doses as high as 18 mg per kg and exhibited no testicular or spermatogenic effects at daily oral doses of 20 mg per kg for 13 weeks (approximately 2 times the systemic exposure of MPA at the recommended therapeutic dose). No effects on female fertility were seen up to a daily dose of 20 mg per kg (approximately 3 times the systemic exposure of MPA at the recommended therapeutic dose).

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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

Section 14: Transport Information

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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

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

Section 16: Other Information

Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.