



# MATERIAL SAFETY DATA SHEET

## Mycophenolate Mofetil Capsules and Tablets

### STRIDES ARCOLAB LIMITED

Opp. IIM, Bilekahalli,  
Bannerghatta Road.  
Bangalore-76, India

---

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Mycophenolate Mofetil Capsules and Tablets

**Chemical Name** 2-morpholinoethyl (E)-6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate.

**Molecular Formula:** C<sub>23</sub>H<sub>31</sub>NO<sub>7</sub>

**Molecular Weight:** 433.5

**Indications:** Mycophenolate mofetil is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. Mycophenolate mofetil should be used concomitantly with cyclosporine and corticosteroids.

**Synonyms:** None

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**ACTIVE INGREDIENT/ CAS NUMBER:** Mycophenolate Mofetil / 128794-94-5

### 3. HAZARDS IDENTIFICATION

**Emergency Overview:**

**Physical State:** Capsules or Capsule shaped tablets

The 250 mg capsules contains white to off white colored free flowing powder filled in size “1” hard gelatin capsules with Ivory Cap / Ivory body printed ‘SAL’ on cap & ‘726’ on body in black.

The 500 mg tablets are pinkish brown colored, capsule shaped, film coated tablets with ”SAL” engraved on one side and engraved “725” on other side.

**Odor:** No data available.

**Primary route(s) of Entry:** Ingestion.

**POTENTIAL HEALTH EFFECTS:**

**Inhalation:** Not expected to be an inhalation hazard in final pharmaceutical form.

**Eye Contact:** Not expected to be a hazard to the eye in final pharmaceutical form.

**Skin Contact:** Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.

**Ingestion:** May be harmful if ingested. Ingestion may cause nausea, vomiting, diarrhea, pain and hypertension.

**Effects of Overexposure:** The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause nausea, vomiting, diarrhea, and in rare cases neutropenia.

**Target Organs:** Gastrointestinal tract, Immune system.

**4. FIRST AID MEASURES**

**Eye Exposure:** Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

**Skin Exposure:** Wash with soap and water. Get medical attention if symptoms occur.

**Inhalation:** Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.

**Ingestion:** Call a physician or poison control center immediately.

**5. FIRE AND EXPLOSION HAZARDS**

**Flammability:** Lower: N/A Upper: N/A

**Flash Point:** No applicable

**Extinguishing Media:** Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

**Unusual Fire/Explosion Hazards:** None known.

**Hazardous Combustion Products:** Carbon dioxide, carbon monoxide, nitrogen oxides

**Special Fire Fighting Procedures:** Wear full protective clothing and self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE INFORMATION

### STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED:

Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.

## 7. PRECAUTIONS FOR SAFE HANDLING AND USE

**Precautions Handling Significant Quantities of Product:** Observe good industrial hygiene practices

**Storage Conditions:** Store at 20° to 25°C (68° to 77°F). [See USP controlled room temperature].

Dispense in light-resistant containers, such as the manufacturer's original containers.

## 8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

**Exposure Limits:** None

**Engineering Controls:** Not required when handling capsules, tablets or containers. Ventilation should be matched to conditions.

**Respiratory Protection:** Not required when handling capsules, tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

**Personal Protection:** Not required when handling capsules or tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves

**Recommended Facilities:** Eye wash, washing facilities

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Capsules containing congealed liquid mixture or Pinkish brown capsules shaped tablets

**Odor:** No applicable information found

**Boiling Point:** No applicable information found

**Melting Point:** Not applicable

**Specific Gravity:** No applicable information found

**Evaporation Rate:** No applicable information found

**Water Solubility:** Soluble

**Vapor Density:** No applicable information found

**Vapor Pressure:** No applicable information found

## 10. STABILITY AND REACTIVITY

**Stability:** Stable

**Incompatibility:** Not Known

**Hazardous Decomposition:** Oxides of carbon, oxides of nitrogen.

**Conditions to avoid:** Excessive heat, light

**Hazardous Polymerization:** Will not occur.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity:**

**Active Ingredient:** No data available

Mycophenolate Mofetil is a teratogen.

**Carcinogenicity:** Not listed as a carcinogen by NTP, IARC Monographs or OSHA

## 12. ENVIRONMENTAL IMPACT INFORMATION

No applicable ecological information found.

## 13. DISPOSAL INFORMATION

**Waste Disposal Considerations:** Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.

**At home:** Discard away from children's reach.

## 14. TRANSPORT INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.

DOT: Not regulated

TDG: Not regulated

IATA: Not regulated

IMDG: Not regulated

## **15. REGULATORY INFORMATION**

DEA: Mycophenolate Mofetil is not a controlled substance.

FDA: Mycophenolate Mofetil is an approved prescription medication.

Inventory Status: This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

This material is not listed on the DSL Inventory but is exempt.

## **16. OTHER DATA**

ABBREVIATIONS:

N/A – not applicable