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**: \( \text{C}_{23}\text{H}_{31}\text{NO}_{7} \)

**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
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