EMERGENCY OVERVIEW

MYCOPHENOLATE MOFETIL TABLET contains Mycophenolate Mofetil and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name: Mycophenolate Mofetil Tablets
Formula: C_{23}H_{31}NO_{7}
Chemical Name: 2-morpholinoethyl (E)-6-(1,3-dihydro-4-hydroxy-6-methoxy-7-methyl-3-oxo-5-isobenzofuranyl)-4-methyl-4-hexenoate
Therapeutic Category: Mycophenolate mofetil is an immunosuppressive agent; inosine monophosphate dehydrogenase (IMPDH) inhibitor

Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India
Contact for information: Tel.: +91 79 26868100 Fax: +91 79 26862365
Emergency telephone No.: Tel.: +91 79 26868100

Section 2. Composition / information on ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
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<tbody>
<tr>
<td>Principle Component:</td>
<td></td>
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<tr>
<td>Mycophenolate Mofetil</td>
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<td>128794-94-5</td>
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<tr>
<td>Inactive Ingredients:</td>
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<tr>
<td>colloidal silicon dioxide</td>
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<tr>
<td>titanium dioxide</td>
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<td>13463-67-7</td>
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</table>
**Section 3. Health Hazards Information**

**Dose and Administration**
A dose of 1 g administered orally twice a day (daily dose of 2 g) is recommended for use in renal transplant patients. Although a dose of 1.5 g administered twice daily (daily dose of 3 g) was used in clinical trials and was shown to be safe and effective, no efficacy advantage could be established for renal transplant patients.

**Adverse Effects**
The principal adverse reactions associated with the administration of mycophenolate mofetil Tablets include diarrhea, leukopenia, sepsis, vomiting, and there is evidence of a higher frequency of certain types of infections e.g., opportunistic infection.

**Over Dose Effect**
The experience with overdose of Mycophenolate Mofetil tablets in humans is very limited. The events received from reports of overdose fall within the known safety profile of the drug. The highest dose administered to renal transplant patients in clinical trials has been 4 g/day. In limited experience with cardiac and hepatic 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, principally neutropenia, leading to a need to reduce or discontinue dosing.

**Contraindications**
Allergic reactions to mycophenolate mofetil Tablets have been observed; therefore, mycophenolate mofetil Tablets and mycophenolate mofetil tablets are contraindicated in patients with a hypersensitivity to mycophenolate mofetil, mycophenolic acid or any component of the drug product.

**Pregnancy Comments**
Mycophenolate mofetil (MMF) can cause fetal harm when administered to a pregnant woman. Use of MMF during pregnancy is associated with an increased risk of first trimester pregnancy loss and an increased risk of congenital malformations, especially external ear and other facial abnormalities including cleft lip and palate, and anomalies of the distal limbs, heart, esophagus, and kidney.

**Pregnancy Category**
D

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**Section 4. First aid measures**

**General**
Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

**Overdose Treatment**
MPA and 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.
Material Safety Data Sheet

MYCOPHENOLATE MOFETIL TABLETS

Strength: 250 mg  Pack Size: 100/500/1000 Tablets per bottle  Revision No.: 00

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**Section 5. Fire - fighting measures**

<table>
<thead>
<tr>
<th>Flash point</th>
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<th><strong>Upper Flammable Limit:</strong></th>
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<tr>
<td>Auto-Ignition Temperature:</td>
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<td><strong>Lower Flammable Limit:</strong></td>
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</tbody>
</table>

**Extinguishing Media**

- Water Spray
- Dry chemical
- Carbon dioxide
- or foam as appropriate for surrounding fire and material.

**Fire and Explosion Hazard**

This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.

**Fire Fighting Procedure**

As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

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**Section 6. Storage / Spill / Disposal Measures**

**Storage**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86° F). Dispense in a tight, light-resistant container with a child-resistant cap.

**Spill Response**

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site. Should a spill occur, wipe up using paper towels wetted with water to remove spilled powder.

**Disposal**

Dispose the waste in accordance with all applicable Federal, State and local laws.

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**Section 7. Exposure controls and personal protection**

**Respiratory Protection**

Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Mycophenolate mofetil tablets should not be opened or crushed. Avoid inhalation or direct contact with skin or mucous membranes of the powder contained in mycophenolate mofetil tablets.

**Skin Protection**

Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.

**Eye protection**

Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

**Protective Clothing**

Protective clothing is not normally necessary, however it is good practice to use apron.
Section 8. Physical and chemical properties

**Appearance**
Mycophenolate Mofetil Tablets, 500 mg are white to off-white, capsule-shaped, biconvex film-coated tablets imprinted with “ZA49” on one side and the other side plain.

**Solubility in water**
No Data Available

**Odour**
Odourless

**Boiling point**
No Data Available

**Melting Point**
No Data Available

**Evaporation rate**
No Data Available

**Vapour density**
No Data Available

**Reactivity in water**
No Data Available

**Evaporation rate**
No Data Available

**Specific gravity**
No Data Available

**Percentage Volatile by volume**
No Data Available

**Vapour pressure**
No Data Available

**Other information**
Carvedilol is a white to almost white crystalline powder practically insoluble in water, slightly soluble in alcohol, practically insoluble in dilute acids.

Section 9. Physical Hazards

**Condition to avoid**
Avoid exposure to extreme heat, light and moisture.

**Stable**
Stable under normal ambient and anticipated storage and handling conditions.

**Decomposition Products**
No Data Available

**Hazardous Reaction**
No data available.

**Incompatibilities**
No data available.

Section 10. Toxicological information

**General**
Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

**Target organ**
Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

**other**
Mycophenolate mofetil tablets should not be crushed.
Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

HANDLING AND DISPOSAL

Mycophenolate mofetil has demonstrated teratogenic effects in rats and rabbits. Mycophenolate mofetil tablets should not be crushed and 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. If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water. Should a spill occur, wipe up using paper towels wetted with water to remove spilled powder.

Date of issue: 22/09/2008


The information contained herein is based on the state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.