

MATERIAL SAFETY DATA SHEET

Version No: MSDS/MYCC/DP-001

Effective Date: January 25, 2013

Mycophenolate Mofetil Capsules 250 mg

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Mycophenolate Mofetil Capsules 250 mg

Marketing Authorisation Holder

Accord Healthcare, Inc.,
1009 Slater Road,
Suite 210-B,
Durham, NC 27703, USA.
Telephone: 1-919-941-7878
Fax- 1-919-941-7881

Manufacturer

Intas Pharmaceuticals Ltd.
Plot No. 457, 458
Village-Matoda,
Bavla Road, Ta. Sanand,
Dist. Ahmedabad-382 210,
Gujarat, India

US Emergency Phone: Call CHEMTREC Day or Night: 1-800-424-9300

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Active: Mycophenolate mofetil

Inactive: Croscarmellose sodium, Magnesium stearate, Povidone (K-90), Microcrystalline cellulose, Hydroxypropylcellulose, Talc.

Capsule shell: FD&C blue # 2, Gelatin, Iron oxide red, Sodium lauryl sulphate, Titanium dioxide, Iron oxide yellow, TekPrint™ SW 9008 Black

SECTION 3 - HAZARDS IDENTIFICATION

Emergency Overview

Form capsules

Hazard Overview May cause allergic reactions.
Harmful if swallowed.
May cause birth defects based on animal data.

Potential Health Effects Exposure: Inhalation, Ingestion, Skin contact, Eye contact
Target Organs: eye, skin, gastrointestinal system, Immune System

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Acute Effects: May cause eye irritation., May cause skin irritation., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

Chronic Effects: May cause allergic reactions., May cause immune system suppression.

Carcinogenicity: formulation not listed by NTP, IARC or OSHA

Additional Health Information

Reproductive Toxicity: May cause birth defects based on animal data. Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure. It is also advisable for nursing mothers to exercise caution regarding exposure.

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Eye contact: In case of contact with eyes rinse thoroughly with plenty of water and get medical advice

Skin contact: remove immediately contaminated clothes, wash affected skin with plenty of water

Inhalation: in case of inhalation remove to fresh air and seek medical aid

Ingestion: consult physician

SECTION 5 - FIRE FIGHTING MEASURES

Extinguishing Media: Water spray jet, dry powder, foam, carbon dioxide

Specific hazards: Toxic emissions may be given off in a fire

Protection of fire-fighters: Use self-contained breathing apparatus

Special method for fire-fighting: Cool endangered containers with water spray

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SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions: ensure adequate ventilation

Environmental protection: avoid release to the environment

Methods for cleaning up:

- Scoop or shovel spilled material into a suitable labeled open head drum
- Secure the drum cover and move the container to a safe holding area
- Clean spill area thoroughly
- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.
- Check area for residual material and repeat clean up if detected

SECTION 7 - HANDLING AND STORAGE

Handling

Technical measures : local exhaust ventilation necessary

Storage

- keep containers tightly closed
- room temperature
- store in a dry place
- protected from light

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection:

Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.

- respiratory protection not necessary

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Eye protection:

Safety glasses

Hand protection:

Protective gloves

Body protection:

Protective clothing

Industrial hygiene:

Immediately change contaminated clothing. Wash hands and face after working with substance.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical state and appearance: Solid.

Odor: Odorless

Solubility (Water): Slightly soluble

Solubility (Other): Freely soluble in acetone, soluble in methanol, and sparingly soluble in ethanol

SECTION 10 - STABILITY AND REACTIVITY

Stability: The product is stable.

Conditions to avoid: high temperatures

Materials to avoid: strong acids, oxidizing agents

Polymerization: Will not occur.

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity: LD₅₀ 250 to 500 mg/kg (oral, rat)

Local effects: skin: non-irritant, eye: non-irritant

Sensitization: non-sensitizing

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Mutagenicity: not mutagenic (various in vivo and in vitro test systems)

Carcinogenicity: not carcinogenic (several species)

Reproduction toxicity: teratogenic (several species)

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Do not allow product to enter drinking water supplies, waste water or soil.

SECTION 13 - DISPOSAL INFORMATION

Waste must be disposed of in accordance with state, local and other environmental control regulations.

SECTION 14 - TRANSPORTATION INFORMATION

Not classified by transport regulations, proper shipping name non-regulated.

SECTION 15 - REGULATORY INFORMATION

International Regulatory Information:

Hazard Code: T, N

Risk Phrases: R22, R50/53, R61

Safety Phrases: S22, S36/37/38, S45, S53

SECTION 16 - OTHER DATA

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special,

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