

Material Safety Data Sheet

MYCOPHENOLATE CAPSULES 250 mg

SECTION 1 - PRODUCT

Mycophenolate Capsules

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

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:

Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

Unusual fire and explosion hazards:

Emits toxic fumes under fire conditions

Special fire fighting procedures:

Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions: ensure adequate ventilation

Environmental protection: void release to the environmen

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:

Required when dusts are generated.

Eye protection:

Required.

Hand protection:

Required.

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

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 - TRANSPORTATION INFORMATION

Not applicable.

SECTION 14 - DISPOSAL INFORMATION

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

SECTION 15 - OTHER DATA

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