



Material Safety Data Sheet (MSDS)

Product Name: Montelukast Sodium IP Grade

MSDS Generate Date: 20-05-2017

Revision Date: 30-12-2024

Supplier:

Rawpharma Biz Pvt Ltd
1101- City Centre 2,
Science City Road,
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1. Identification of the Substance/Preparation and Company

Product Name: Montelukast Sodium IP Grade

Chemical Name: Sodium [R-(E)-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropaneacetate

Molecular Formula: C₃₅H₃₅ClNaO₃S

Molecular Weight: 608.17 g/mol

Synonyms: Montelukast Sodium, MK-0476 Sodium Salt

CAS No.: 151767-02-1

Grade: IP Grade

2. Hazard Identification

- **Classification:** Not classified as hazardous under normal laboratory and manufacturing use.
- **Hazard Statements:** May cause mild irritation to eyes, skin, or respiratory tract.
- **Signal Word:** Warning
- **Potential Health Effects:**
 - **Inhalation:** May cause irritation of mucous membranes.
 - **Skin Contact:** May cause mild irritation on prolonged contact.
 - **Eye Contact:** May cause redness and watering.
 - **Ingestion:** May cause gastrointestinal discomfort.
- **Environmental Hazards:** Not expected to be hazardous to the environment in normal use.

3. Composition / Information on Ingredients

Montelukast Sodium IP Grade is composed primarily of Montelukast Sodium (CAS No. 151767-02-1) with a purity of not less than 99%, meeting the requirements of Indian Pharmacopoeia (IP) specifications. No hazardous impurities or stabilizing additives are intentionally present in concentrations requiring declaration.

4. First Aid Measures

- **Inhalation:** Move person to fresh air. Seek medical attention if symptoms persist.
- **Skin Contact:** Wash with soap and water. Remove contaminated clothing.
- **Eye Contact:** Rinse cautiously with water for several minutes. Seek medical advice if irritation continues.
- **Ingestion:** Rinse mouth. Seek medical advice if discomfort occurs.

5. Fire Fighting Measures

- **Suitable Extinguishing Media:** Water spray, CO₂, dry chemical, or foam.
- **Unsuitable Media:** None known.

- **Special Hazards:** Emits toxic fumes of carbon oxides, nitrogen oxides, and sulfur compounds when heated.
 - **Protective Equipment:** Use self-contained breathing apparatus and protective clothing.
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6. Accidental Release Measures

- **Personal Precautions:** Use personal protective equipment. Avoid inhalation or contact.
 - **Environmental Precautions:** Avoid discharge into drains or water sources.
 - **Clean-Up Method:** Sweep up and place in labeled container for disposal according to local regulations.
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7. Handling and Storage

- **Handling:** Avoid breathing dust. Avoid contact with eyes, skin, and clothing.
 - **Storage:** Store in a tightly closed container in a cool, dry, well-ventilated area. Protect from moisture and direct sunlight.
 - **Storage Temperature:** 15°C – 25°C recommended.
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8. Exposure Controls / Personal Protection

- **Engineering Controls:** Use local exhaust ventilation where dust formation occurs.
 - **Personal Protection:**
 - **Respiratory:** Use dust mask or respirator if exposure limits are exceeded.
 - **Eye Protection:** Safety goggles.
 - **Skin Protection:** Protective gloves and clothing.
 - **Hygiene Measures:** Wash hands after handling material.
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9. Physical and Chemical Properties

- **Appearance:** Off-white to light yellow powder
- **Odor:** Odorless or faint characteristic
- **pH (1% solution):** 7.0 – 9.0

- **Melting Point:** 167 – 170°C
 - **Boiling Point:** Not applicable (decomposes)
 - **Solubility:** Soluble in water and ethanol
 - **Bulk Density:** Approx. 0.4 – 0.6 g/cm³
 - **Stability:** Stable under normal conditions
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10. Stability and Reactivity

- **Chemical Stability:** Stable under normal conditions.
 - **Conditions to Avoid:** Heat, humidity, and sunlight.
 - **Incompatible Materials:** Strong oxidizing agents.
 - **Hazardous Decomposition Products:** Carbon oxides, nitrogen oxides, sulfur oxides.
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11. Toxicological Information

- **Acute Toxicity:** Not acutely toxic in small quantities.
 - **Skin Irritation:** Mild irritant.
 - **Eye Irritation:** Mild irritant.
 - **Sensitization:** Not known to cause sensitization.
 - **Mutagenicity / Carcinogenicity:** No data indicating mutagenic or carcinogenic potential.
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12. Ecological Information

- **Ecotoxicity:** No data available. Not expected to be harmful to aquatic organisms.
 - **Persistence & Degradability:** Expected to be biodegradable.
 - **Bioaccumulative Potential:** Low potential.
 - **Mobility in Soil:** Low.
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13. Disposal Considerations

- **Waste Disposal Method:** Dispose of in accordance with local, regional, and national regulations.
- **Contaminated Packaging:** Dispose of container as per hazardous waste management guidelines.

14. Transport Information (Detailed)

UN Number: Not applicable (non-hazardous for transport).

Proper Shipping Name: Montelukast Sodium IP Grade

Transport Hazard Class: Not regulated as hazardous material.

Packing Group: Not applicable

Environmental Hazards: None known

Marine Pollutant: No

Transport Guidance:

- Handle with care to prevent damage to packaging.
- Avoid exposure to moisture during transport.
- Keep containers tightly closed and stored upright.
- Transport in compliance with local ADR, IMDG, and IATA regulations (though not classified as dangerous goods).

Mode of Transport:

- **By Road (ADR/RID):** Not regulated.
- **By Air (IATA):** Non-hazardous; pack in sealed containers.
- **By Sea (IMDG):** Non-hazardous; store below deck away from heat.
- **By Rail:** Non-hazardous; ensure secure packaging.

15. Regulatory Information

- **Regulation Compliance:**
 - Conforms to Indian Pharmacopoeia (IP) Standards.

- Not listed as hazardous under OSHA, REACH, or GHS classification.
- No restricted chemical substances under Indian regulatory norms.

16. Other Information

Disclaimer:

The information provided in this Material Safety Data Sheet is believed to be accurate and reliable to the best of our knowledge.

- **MSDS Generate Date:** 20-05-2017
- **Revision Date:** 30-12-2024
- **Website:** www.rawpharmabiz.com
- MSDS are based on the manufacturer's provided information.