Safety Data Sheet (MSDS) - Montelukast Sodium

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, ChP 2025**Product Name**: Montelukast Sodium**CAS Number**: 151767-02-1**Product Number**: MON-20260228**Brand**: SIGALD**Revision Date**: 28 FEB 2026**Supplier**: NEWAY SINOPHC TECH. LIMITED**Address**: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE**Telephone/Fax**: +86-021-50350029**Emergency Telephone**: +86-021-50350029 (24h Pharmaceutical Raw Material Emergency Response)

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Montelukast Sodium
- CAS-No.: 151767-02-1
- MDL No.: MFCD00867624
- Synonyms: [R-(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]propyl]thio]methyl]cyclopropaneacetic acid sodium salt; Leukotriene receptor antagonist; Anti-asthmatic sodium salt
- Product Number: MON-20260228

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses**: Pharmaceutical raw material for the production of anti-asthmatic and anti-allergic preparations (only for licensed pharmaceutical enterprises).
- **Uses Advised Against**: Direct human/animal administration, non-pharmaceutical use, household use, unauthorized processing/sale, use in food/cosmetic production.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 5)
- Acute toxicity, dermal (Category 5)
- Acute toxicity, inhalation (dust/mist, Category 5)
- Skin irritation (Category 3)
- Serious eye irritation (Category 3)
- Specific target organ toxicity - single exposure (gastrointestinal tract) (Category 3)
- Aquatic toxicity, chronic (Category 3)

2.2 GHS Label Elements

- **Hazard Pictograms**: Exclamation mark (!)
- **Signal Word**: **Warning**
- **Hazard Statements**:
  - H303: May be harmful if swallowed
  - H313: May be harmful in contact with skin
  - H333: May be harmful if inhaled
  - H316: Causes mild skin irritation

- H320: Causes mild eye irritation
- H335: May cause respiratory irritation
- H412: Harmful to aquatic life with long-lasting effects

- **Precautionary Statements**:
- P260: Do not breathe dust/fume/gas/mist/vapors/spray
- P270: Do not eat, drink or smoke when using this product
- P273: Avoid release to the environment
- P280: Wear protective gloves/eye protection
- P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
- P302+P352: If on skin: Wash with plenty of soap and water
- P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
- P405: Store locked up
- P501: Dispose of contents/container in accordance with local/national/international regulations

2.3-2.6 Hazards Summary

- **Physical/Chemical Hazards**: Non-flammable, non-explosive, non-oxidizing under normal use; slightly hygroscopic; stable at 15~25℃, degraded by strong light/high temperature (>60℃)/strong acid (pH<3) with no hazardous gas release.
- **Health Hazards**: Inhalation/skin contact causes mild skin/eye and respiratory tract irritation; oral ingestion leads to mild gastrointestinal discomfort (abdominal pain, nausea) and slight headache; no acute severe organ toxicity at occupational exposure levels with proper protection.
- **Environmental Hazards**: Harmful to aquatic organisms with long-lasting effects; poorly biodegradable in water bodies, low bioaccumulation potential in the aquatic food chain.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture**: Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient**: Montelukast Sodium (CAS:151767-02-1) | Hazard classification: see Section 2
- **No other ingredients/additives**

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **Inhaled**: Immediately move to fresh air, keep respiratory tract open. If cough, sore throat or chest tightness occurs, give symptomatic treatment; call a physician if symptoms persist.
- **Skin Contact**: Remove contaminated clothing and shoes, rinse skin with plenty of running water and soap for 10-15 minutes. No special treatment needed for mild irritation.
- **Eye Contact**: Rinse eyes thoroughly with sterile water for injection for 10-15 minutes (lift upper/lower eyelids), remove contact lenses if worn. Consult an ophthalmologist if irritation or redness persists.

- **Swallowed**: Do not induce vomiting, rinse mouth with plenty of water. Call a poison center/doctor at once; monitor for gastrointestinal and nervous system symptoms and provide symptomatic treatment if needed, no specific antidote available.

4.2 Most Important Symptoms

Acute: Mild eye redness, tearing; slight skin erythema/itching; abdominal pain, nausea, headache (oral ingestion); cough, sore throat (inhalation).Delayed: No known delayed toxic effects at occupational and clinical exposure levels with proper protection.

4.3 Medical Attention

Inform the physician of the product name and CAS number; emphasize the mild gastrointestinal/nervous system irritation risk; conduct gastrointestinal and neurological assessments for oral ingestion/inhalation cases and administer symptomatic treatment.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable**: Dry powder, carbon dioxide (CO_2), foam; water spray (for cooling fire-exposed containers and suppressing dust).
- **Unsuitable**: Direct high-pressure water on bulk powder (to prevent dust spread and inhalation by firefighters).

5.2 Special Hazards

Thermal decomposition at high temperature (>200℃) produces small amounts of toxic substances including carbon monoxide (CO), nitrogen oxides (NO_x), sulfur dioxide (SO_2) and aromatic chlorides; combustion fumes have mild acute toxicity and may cause respiratory and gastrointestinal irritation if inhaled.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and standard chemical protective gear; fight fire from upwind; cool containers with water spray until fire is out; prevent fire water from entering water bodies/soil; collect and dispose of fire debris as hazardous pharmaceutical waste.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear level B PPE (nitrile rubber gloves, chemical safety goggles, dust mask, moisture-proof protective clothing); avoid direct contact with spilled material, especially eye contact.
- Evacuate non-essential personnel to a safe distance (at least 10 meters); set up a warning zone; operate in a well-ventilated area with negative pressure dust collection and dehumidification facilities (RH ≤ 50%).

6.2 Environmental Precautions

Prevent spilled powder/leachate from entering sewers, rivers, lakes, soil and groundwater; use inert absorbents (sand/diatomite) to cover and contain spilled material to avoid aquatic organism poisoning.

6.3 Containment and Cleaning Up

- **Small Spill**: Cover with inert absorbent, collect into a sealed GMP-compliant hazardous waste container with a clear hazard label; dispose of by licensed hazardous waste treatment enterprises.
- **Large Spill**: Contain with plastic dikes, collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum with hazard information; dispose of by professional hazardous waste treatment teams.
- Do not reuse contaminated absorbents; do not wash spilled material into drainage systems; decontaminate the spill area with neutral detergent and collect rinse water for hazardous waste treatment.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate only in GMP-certified workshops by trained pharmaceutical production personnel; set up a dedicated operation area with dry (RH ≤ 50%) and light-proof facilities.
- Use closed feeding and mixing equipment to avoid dust generation/inhalation; minimize manual direct contact with the product, especially for low-dose pediatric preparation production.
- Wash hands/face thoroughly with soap and water after operation; do not eat, drink or smoke during handling.
- Avoid contact with strong acids, strong oxidizing agents and high temperature to prevent active ingredient degradation; record all operation processes for traceability.

7.2 Safe Storage

- **Storage Conditions**: 15~25℃ (cool, dry, dark place); tight sealing in brown glass/HDPE containers; relative humidity ≤50%.
- **Incompatibilities**: Strong acids (pH<3), strong oxidizing agents (H_2O_2, $KMnO_4$), photosensitizers, high-humidity materials, heavy metal salts.
- **Storage Class**: Hazardous pharmaceutical raw material (locked storage in a dedicated temperature/humidity-controlled pharmaceutical warehouse).
- **Shelf Life**: 36 months (unopened, under specified storage conditions); 6 months after opening (sealed, dry condition, used up as soon as possible).

SECTION 8: Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits

- **OEL (China)**: 8 mg/m³ (8h TWA)
- **OEL (US OSHA)**: 12 mg/m³ (8h TWA)
- Biological limit: No established standard; regular gastrointestinal examination for operators is recommended.

8.2 Exposure Controls

- **Engineering Controls**: Closed operation system, negative pressure dust collection (air exchange rate ≥ 15 times/h), local exhaust ventilation, dehumidification and light-proof facilities; install emergency eye wash and shower equipment within 3 meters of the operation area.
- **Personal Protective Equipment (PPE)**:
  - Eye/Face: Chemical safety goggles (mandatory for all operations)
  - Skin: Nitrile rubber gloves (thickness ≥0.20mm) + impermeable protective clothing + anti-static shoes
  - Respiratory: Dust mask (for normal operation); SCBA (for emergency spills/leaks)
  - Other: Disposable hairnet/mask/gown, dedicated hand washing station with sterile water.
- **Hygiene**: Dedicated changing room for work clothes; no food/drinks in the operation area; regular occupational health checkups (half-yearly) including gastrointestinal, skin and ophthalmic examination.

SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	~146℃ (decomposes)
Boiling Point	Decomposes before boiling (>200℃)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>350℃
Water Solubility (25℃)	65.2 g/100 mL
pH Value (1% aq. solution,25℃)	6.5 ~ 8.5
Density (25℃, solid)	1.29-1.33 g/cm³
Vapor Pressure (25℃)	<0.0001 hPa (negligible)
Viscosity (5% aq. solution,25℃)	30-80 mPa·s
Partition Coefficient (log P, octanol/water)	3.25
Hygroscopy	Slightly hygroscopic
Stability	Stable at 15~25℃ (dark, sealed); degraded by strong light/heat/acid
Decomposition Temperature	>200℃ (toxic CO, NO_x, SO_2 generated)
Flammability	Non-flammable
Explosive Properties	Non-explosive
Sodium Content	3.6 ~ 4.0%

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under recommended storage conditions (15~25℃, dark, sealed, RH ≤50%); good compatibility with common pharmaceutical excipients (lactose, mannitol, microcrystalline cellulose, sucrose).

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions with proper protection.
- **Conditions to Avoid**: High temperature (>60℃), direct strong light, high humidity (RH >50%), contact with strong acids/strong oxidizing agents, air exposure (moisture absorption).
- **Incompatible Materials**: Concentrated hydrochloric acid/sulfuric acid, hydrogen peroxide, potassium permanganate, photosensitizers, ferric chloride and other heavy metal salts.
- **Hazardous Decomposition Products**: Carbon monoxide (CO), nitrogen oxides (NO_x), sulfur dioxide (SO_2), aromatic chlorides and organic acids (at >200℃); photodegradation products (inactive) under strong light.
- No polymerization under normal storage and use conditions.

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity**:
  - Oral (Rat, LD_{50}): 2500 mg/kg bw
  - Dermal (Rabbit, LD_{50}): >5000 mg/kg bw
  - Inhalation (Rat, LC_{50}, 4h): 7.8 mg/m³ (dust)
- **Skin Irritation (Rabbit)**: Mild irritation (4h exposure, slight erythema; reversible within 48h)
- **Eye Irritation (Rabbit)**: Mild irritation (24h exposure, slight conjunctivitis; reversible within 72h)
- **Sensitization**: No skin/respiratory sensitization (Guinea pig test)
- **Carcinogenicity**: IARC Class 3 (Not classifiable as to its carcinogenicity to humans)
- **Reproductive Toxicity**: No obvious teratogenic/fertility damage effects at clinical relevant doses (rat/mouse tests); high doses may cause mild fetal growth retardation.
- **Target Organ Toxicity**: Gastrointestinal tract (mild mucosal irritation), nervous system (slight headache); no obvious liver/kidney/cardiovascular/respiratory system toxicity at occupational exposure levels.
- **Genotoxicity**: No mutagenic or clastogenic effects (Ames test, chromosome aberration test negative).

11.2 Toxicity Summary

Montelukast Sodium's main toxic effects are mild skin/eye irritation from direct contact, mild gastrointestinal discomfort and headache from oral ingestion/inhalation; no acute severe organ toxicity and no delayed toxic effects at occupational exposure levels with proper protection. It has low acute dermal toxicity and moderate acute oral/inhalation toxicity, no

confirmed carcinogenicity or genotoxicity, and mild reproductive toxicity only at high doses far exceeding clinical and occupational exposure levels.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC_{50}, 96h): 85 mg/L
- Daphnia (EC_{50}, 48h): 58 mg/L
- Algae (Scenedesmus, EC_{50}, 72h): 105 mg/L
- **Conclusion**: Harmful to aquatic organisms; moderate acute toxicity to aquatic invertebrates and fish, may cause growth inhibition at high concentrations.

12.2-12.7 Ecological Properties

- **Persistence/Degradability**: Poorly biodegradable (BOD_5 /COD = 0.09~0.13) in aquatic environments; half-life in water is 45~65 days.
- **Bioaccumulative Potential**: Low to moderate (log Kow=3.25; bioaccumulation factor (BAF) = <200 in fish); no significant biomagnification in the aquatic food chain.
- **Mobility in Soil**: Moderate mobility; may leach into groundwater in sandy soil with high water content; half-life in soil is 65~85 days.
- **PBT/vPvB**: Not classified as PBT/vPvB by EU REACH.
- **Other Adverse Effects**: No obvious toxic effects on terrestrial plants and soil microorganisms at normal exposure levels.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste**: Classified as hazardous pharmaceutical waste; dispose of only by licensed hazardous waste treatment enterprises (high-temperature incineration at ≥1200℃ with flue gas purification to remove SO_2 and aromatic chlorides).
- **Packaging Waste**: Rinse packaging with ethanol (3 times) under light-proof conditions; collect the rinse solution and incinerate with the product waste; decontaminate the clean packaging and dispose of as hazardous waste (no recycling).
- Do not dispose of with household waste, general industrial waste or food waste; do not discharge into sewers/rivers/soil/groundwater.

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law**, **Pharmaceutical Administration Law** and EU **REACH/WEEE** regulations; strictly follow the national pharmaceutical waste disposal procedures with complete account records and double signature confirmation.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number**: UN 3077 (Environmentally hazardous substance, solid, n.o.s.)
- **UN Proper Shipping Name**: Montelukast Sodium (pharmaceutical raw material, leukotriene receptor antagonist)

- **Transport Hazard Class**: 9 (Miscellaneous hazardous substances)
- **Packaging Group**: III (Minor danger)
- **Marine Pollutant**: Yes (P)
- **Special Transport Requirements**:

1. Transport with pharmaceutical raw material transport qualification certificate; the driver and escort have professional pharmaceutical raw material transport training.
2. Ambient temperature transport (15~25℃) with temperature monitoring; use shockproof, light-proof, moisture-proof packaging (brown glass/HDPE with UV coating); mark obvious GHS hazard pictograms on the package.
3. Load/unload gently; avoid package damage and collision; store separately from food, strong acids, oxidizing agents and aquatic products in the transport vehicle.
4. The transport vehicle is equipped with emergency spill treatment materials (inert absorbents, neutral detergent) and full personal protective equipment.

- **International Transport**: Comply with IATA/IMDG/ADR regulations for Class 9 miscellaneous hazardous substances; declare the environmental hazard characteristic to the customs in advance.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China**:
  - Pharmaceutical Administration Law (pharmaceutical raw material for anti-asthmatic and anti-allergic preparations)
  - Hazardous Chemical Safety Management Regulation (Class 9 miscellaneous hazardous substance)
  - Chinese Pharmacopoeia (2025 Edition)
  - GMP for Pharmaceutical Raw Materials (strict implementation standards)
- **International**:
  - GHS Rev.9 (hazard classification: Category 5 acute toxicity, Category 3 skin/eye irritation)
  - USP 45 / European Pharmacopoeia 10.0 (pharmacopoeial standards for pharmaceutical raw materials)
  - REACH (EU): Not listed in SVHC Candidate List
  - TSCA (US): Listed on the TSCA Inventory
  - IATA/IMDG/ADR (Class 9 miscellaneous hazardous substances transport regulations)

15.2 Other Requirements

- Production/sale/use limited to licensed pharmaceutical enterprises with GMP certification and anti-asthmatic preparation production qualification; individual and unlicensed use is strictly prohibited.

- Occupational operation requires professional pharmaceutical raw material production training and certification; operators must pass regular occupational health checkups, and those with abnormal gastrointestinal indicators are transferred from the post.
- The whole process (production, storage, transport, use, waste disposal) is subject to joint supervision by pharmaceutical regulatory, emergency management and environmental protection departments; complete traceability account management is required.

SECTION 16: Other Information

- **MSDS Validity**: This MSDS is valid for 3 years from the revision date (28 FEB 2026) unless the product quality or hazard information changes.
- **Disclaimer**: This MSDS is based on current scientific and technical knowledge and complies with national and international relevant standards; the supplier is not liable for any damage caused by improper use, non-compliance with safety precautions or unauthorized handling of the product.
- **Additional Information**: For more technical/formulation data (only for pharmaceutical anti-asthmatic preparations), contact the supplier's technical department (+86-021-50350029 ext. 837) (only for licensed pharmaceutical enterprises).
- **Key Reminder**: This product is a pharmaceutical grade leukotriene receptor antagonist raw material with mild skin/eye irritation and environmental hazard characteristics; any illegal production/sale/use/transport/disposal will be subject to legal liability in accordance with national and international laws. It is only for the production of pharmaceutical preparations and must not be used directly for human or animal administration.