

Safety Data Sheet

Section 1. Product and Company Identification

Product Name Montelukast sodium

Product ID M5756 **Chemical Name**

Singulair

(Synonyms)

LKT Laboratories, Inc.

545 Phalen Blvd. **Supplier**

St. Paul, MN 55130 USA

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Emergency Phone #

1-800-424-9300

Section 2. Hazards Identification

GHS Classification Serious eye damage (Category 1), H318

Reproductive toxicity (Category 2), H361

GHS Label elements including precautionary statements

Pictogram





Signal word

Danger

Hazard and precautionary statements

Hazard statements

H318 - Causes serious eye damage H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements

P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.

P280 - Wear eye protection/ face protection.
P281 - Use personal protective equipment as required.

P305 + P351 + P338 + P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician. P308 + P313 - IF exposed or concerned: Get medical advice/ attention.

P405 - Store locked up.

P501 - Dispose of contents/ container to an approved waste disposal plant.

HMIS Classification

Health hazard: 0 Chronic health hazard: * Flammability: 0
Physical hazard: 0

NFPA Rating

Health hazard: 0 Fire hazard: 0 Reactivity hazard: 0

Potential Health Effects

Inhalation - Harmful if inhaled. May cause respiratory tract irritation. Skin - May be harmful if absorbed through skin. May cause skin irritation.

Eyes - Causes serious eye damage.

Section 3.	Composition/Information	on on Ingredients
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Substances

Formula Wt. **Formula** C₃₅H₃₅CINO₃S Na

151767-02-1 CAS No. EC No.

Section 4. First Aid Measues

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

608.17

Eye Contact

Flush eyes with plenty of water for 15 minutes and consult a physician.

Skin Contact

Wash off with soap and plenty of water. Consult a physician.

Inhalation

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Section 5 . Firefighting Measures

Flash Point

407.7C

Extingushing Media

Use water spray, alcohol-resistant foam, dry chemical powder, and carbon dioxide.

Firefighting Procedures

Wear self-contained breathing apparatus and protective clothing for fire fighting if necessary.

Carbon oxides and sulfur oxides.

Unusual Fire Hazards

Section 6. Accidental Release Measures

Personal Precautions

Use personal protective equipment. Avoid dust formation. Avoid breathing dust, vapors, mist, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and materials for containment and cleanup

Avoid raising dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Section 7. Handling and Storage

Handling

Further processing of solid material may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Storage Conditions

Store in a dry and well-ventilated place in a tightly closed container. Recommended storage temperature: Ambient

Hazardous Decomposition Products

Other Remarks

Storage class (TRGS 510): Non combustible solids. This product is hygroscopic.

Section 8. Exposure Controls/Personal Protection

Personal protective EXPOSURE CONTROLS

equipment Contains no substances with occupational exposure limit values.

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday

PERSONAL PROTECTION

Exe/face protection: Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry bandle.

Body protection: Complete suit protecting against chemicals. They type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approve under appropriate government standards such as NIOSH (US) OR CEN (EU).

Section 9. Physical and Chemical Properties

Solid Off-white to pale yellow solid hygroscopic. **Physical State** Color

750.5C Not available. **Boiling Point** Volatility

134 - 136°C Not available. **Melting Point Density**

Soluble in ethanol and DMSO. 9.4 - 10.2**Solubility** pН

407.7C Not available. Ignition

Flash Point temperature

Not available. Not available. **Autoignition** Lower explosion limit

temperature

Not available. Not available.

Vapor Upper explosion limit pressure

Not available. Not available. Water solubility Odor

Partition coefficient: log Pow: 2.3 at 20°C Not available. Odor n-octanol/water Threshold

Relative vapor density Not available. Not available. **Evaporation**

rate

Section 10. Stability and Reactivity

Hygroscopic. Stable under recommended storage condtions.

Stability

Strong oxidizing agents. **Materials To Avoid**

Hazardous Decomposition Products

Possibility of Not available. hazardous reactions

Conditions to avoid

Not available.

Section 11. Toxicological Information

Oral LD50 Not available. Skin Not available.

corrosion/irritation

Inhalation LC50 Not available. Serious eye Not available.

damage/irritation

Dermal LD50 Not available. Respiratory or Not available.

skin sensitization

Other information on Not available. Germ cell mutagenicity Not available.

acute toxicity

Reproductive Toxicity Suspected of damaging fertility. Suspected of

Aspiration Hazard Not available.

damaging the unborn child. Suspected human reproductive toxicant.

Specific organ toxicity Not available. Synergistic effects Not available.

Specific organ toxicity Not available.

single exposure (GHS)

repeated exposure (GHS)

Additional Information RTECS: Not available

To the best of our knowledge, the chemical, physical and toxicological properties have not

been thoroughly investigated.

Teratogenicity Not available. Signs and symptoms Not available. of exposure

Potential Inhalation - Harmful if inhaled. May cause respiratory tract irritation.

Health Effects Skin - May be harmful if absorbed through skin. May cause skin irritation.

Eyes - Causes serious eye damage.
Ingestion - May be harmful if swallowed.
Reproductive toxicity - Suspected of damaging fertility or the unborn child.

Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated

carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Section 12. Ecological Information

Toxicity Not available.

Mobility in soil Not available.

Persistence and degradability Not available.

Other adverse effects Not available.

Bioaccumulative potential No bioaccumulation is to be expected (log Pow ≤ 4).

Section 13. Disposal Considerations

Waste Disposal

Dispose of material according to all federal, state, and local regulations. Offer material to a licensed, professional waste disposal company to dispose of as unused product.

Section 14. Transport Information

DOT (US) Not dangerous goods.

IATA Not dangerous goods.

IMDG Not dangerous goods.

Further Information

Section 15. Regulatory Information

Reach No.

SARA 302 Components No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Components Chronic health hazard

Massachusetts Right No components are subject to the Massachusetts Right to Know Act. **To Know Components**

Pennsylvania Right Montelukast Sodium CAS #: 151767-02-1 **Revision Date To Know Components**

New Jersey Right Montelukast Sodium CAS #: 151767-02-1 **Revision Date To Know Components**

California Prop 65 This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any Components other reproductive harm.

Section 16. Other Information

Other information

The information in this document is believed to be correct but is not necessarily complete. LKT does not guarantee the accuracy of the information. The burden of verifying the information in this document rests solely upon the user.

Updated 4/19/2019

For emergencies in the USA, call CHEMTREC 800-424-9300