



SAFETY DATA SHEET



Issuing Date 13-Oct-2017

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Revision Number 1.01

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name Montelukast Sodium Tablets, Chewable Tablets, and Oral Granules
Active Ingredient Montelukast Sodium

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Pharmaceutical
Uses advised against Other than Relevant Use

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier ACTAVIS, Inc.
400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054
800-272-5525 [08:00 AM --> 05:00 PM]
TEVA
1090 Horsham Road
North Wales, PA 19454
215-591-3000 [08:00 AM --> 05:00 PM]

For further information, please contact

E-mail Address TevaSDSRequest@tevapharm.com

1.4. Emergency Telephone Number

Emergency Telephone Number United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
International: 01-703-527-3887 (Chemtrec) [24-hours]

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Exempt from requirements - regulated as a medicinal product.

2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Chemical Name	EC No	REACH Reg. No	CAS-No	Weight %
Montelukast Sodium	-	Not available	151767-02-1	Proprietary
Excipients	-	Not available	-	Remainder

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact	Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
Skin Contact	Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.
Inhalation	Remove person to fresh air. If signs/symptoms continue, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

See product insert.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry powder. Halons.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid all unnecessary contact.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Evacuate the danger area and alert emergency team

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Take up mechanically and collect in suitable container for disposal.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with: label.

7.3. Specific end use(s)

Exposure Scenario

No information available.

Other Guidelines

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Not Determined: Mixture

Biological occupational exposure limits

No information available.

Derived No Effect Level (DNEL)

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

Provide engineering control.

Personal protective equipment

Eye/face protection

Use eye protection appropriate for the task.

Skin protection:

- Body protection

Use protective clothing appropriate for the task.

- Hand protection

Use appropriate protective gloves.

Respiratory Protection

Use appropriate respiratory protection.

Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

No information available

Physical State

Tablets, granules

Flash Point

No information available

9.2. Other information

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical Stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Heat, flames and sparks.

10.5. Incompatible materials.

None in particular.

10.6. Hazardous decomposition products

None under normal use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

acute toxicity

No hazard expected under normal handling conditions.

skin corrosion/irritation

No hazard expected under normal handling conditions.

serious eye damage/irritation

No hazard expected under normal handling conditions.

respiratory or skin sensitization

No hazard expected under normal handling conditions.

germ cell mutagenicity

No hazard expected under normal handling conditions.

carcinogenicity

No hazard expected under normal handling conditions.

reproductive toxicity

No hazard expected under normal handling conditions.

STOT - single exposure

No hazard expected under normal handling conditions.

STOT - repeated exposures

No hazard expected under normal handling conditions.

aspiration hazard

No hazard expected under normal handling conditions.

Other Information

No hazard expected under normal handling conditions. .

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity effects

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

None known

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused Products	Dispose of in accordance with local regulations.
Contaminated Packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

SECTION 14: Transport information

14.1.

UN-No -

14.2.

Proper Shipping Name -

14.3. Transport hazard class(es)

ADR / RID / ADN (land transport) -
IMDG (sea transport) -
IATA / ICAO (air transport) -

14.4.

Packing Group -

14.5. Environmental hazards

Marine Pollutant -

14.6. Special precautions for user

Emergency No. -
ADR/RID-Labels -

14.7.

Technical name -
Ship type -
Annex II -

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of: GHS

15.2. Chemical Safety Assessment

No information available

SECTION 16: Other information

CLP/GHS - Regulation

Hazard Statements

Training appropriate for workers is required to ensure protection of human health and environment.

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
N.T.P. - NATIONAL TOXICOLOGY PROGRAM
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
ECHA (European chemicals agency) databases
FDA (Food & Drug administration) database
EMA (European Medicines agency) documents
ChemAdvisor
Chemspider database

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Revision Note

Not applicable

Disclaimer

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End of Safety Data Sheet