

## MATERIAL SAFETY DATA SHEET

**Montelukast Sodium Tablets, USP 10 mg, Montelukast Sodium Oral Granules, USP 4 mg, and Montelukast Sodium Chewable Tablets, USP 4 mg and 5 mg**

### **EMERGENCY OVERVIEW**

**Montelukast Sodium Tablets, USP, Montelukast Sodium Oral Granules, USP 4 mg, and Montelukast Sodium Chewable Tablets, USP 4 mg and 5 mg** contain an active drug substance Montelukast Sodium, USP and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

**WARNING:** Accidental ingestion of large amounts may be harmful

### **SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**Common Name** : Montelukast Sodium Tablets, USP 10 mg,  
Montelukast Sodium Oral Granules, USP 4 mg,  
Montelukast Sodium Chewable Tablets, USP 4 mg and 5 mg.

**Chemical name** : Sodium salt of 1-[[[(1R)-1-[3-[(1E)-2-(7-chloro-2quinolinyl) ethenyl] phenyl]-3-[2-1-hydroxy-1methylethyl] phenyl] propyl] thio] methyl] cyclopropane acetic acid

**Molecular formula** : C<sub>35</sub>H<sub>35</sub>ClN<sub>2</sub>NaO<sub>3</sub>S

**Molecular weight** : 608.17 g/ mole

**Company Identification** : **Ajanta Pharma USA Inc.**  
Bridgewater, NJ 08807  
Made in India

**Contact Information** : 855-664-7744

**Product Category** : Anti-asthmatic, Anti allergic rhinitis.

### **SECTION 2 - COMPOSITION, INFORMATION ON INGREDIENTS**

<b>Active Ingredient</b>	<b>CAS#</b>	<b>Exposure Limit</b>
Montelukast Sodium	151767-02-1	None established

### **SECTION 3 - HAZARDS IDENTIFICATION**

- Emergency Overview** : Physical State-Tablets and Granules
- Montelukast Sodium Tablets, USP 10 mg are beige colored, film-coated tablets, circular, biconvex tablets, with code 'MO1' engraved on one side and plain on the other side.
- Montelukast Sodium Oral Granules, USP 4 mg are white granules with 500 mg net weight, packed in a child - resistant foil sachet.
- Montelukast Sodium Chewable Tablets, USP 4 mg are pink colored, slightly mottled, circular, biconvex, uncoated tablets, with code 'MT1' engraved on one side and plain on the other side.
- Montelukast Sodium Chewable Tablets, USP 5 mg are pink colored, slightly mottled, circular, biconvex, uncoated tablets, with code 'MT2' engraved on one side and plain on the other side.
- Potential Health Effects:** : **WARNING!**  
Accidental ingestion of large amounts may be harmful.
- : Eye Contact: Not expected to be a hazardous to the eye in final pharmaceutical form.
- Skin Contact: Not expected to be a hazardous to the skin. In extreme cases may cause hypersensitive reactions resulting in rash, redness, itching and inflammation.
- Ingestion: May be harmful if ingested in large quantity. Ingestion may cause gastrointestinal disturbances, headaches, hypersensitivity reactions, drowsiness and sleep disorders.

#### SECTION 4 - FIRST AID MEASURES

- Eye Exposure** : Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention if symptoms persist.
- Skin Exposure** : Wash exposed area with soap and water. Flush skin with plenty of water for at least 15 minutes. Get medical attention if symptoms occur.
- Ingestion** : Do NOT induce vomiting. If conscious and alert, rinse mouth and drink 2-4 cupfuls of milk or water.

#### SECTION 5 - FIRE FIGHTING MEASURES

- Flammability** : Not Applicable
- Flash Point** : Not Applicable

<b>Extinguishing Media</b>	:	Use water spray, dry chemical, chemical foam, or alcohol-resistant foam, carbon dioxide or material appropriate for fire in surrounding area.
<b>Special Fire Fighting Procedures</b>	:	Wear full protective clothing and self-contained breathing apparatus.
<b>Unusual Fire/Explosion Hazards</b>	:	Not Applicable
<b>Hazardous Combustion by Products</b>	:	Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sulfur, oxides of sodium, hydrogen chloride

<b>SECTION 6 - ACCIDENTAL RELEASE MEASURES</b>
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<b>Spills/Leaks</b>	:	Clean up spills immediately. Sweep up and place into a suitable container for disposal.
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<b>SECTION 7 - HANDLING AND STORAGE</b>
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<b>Handling</b>	:	Wash thoroughly after handling. Avoid contact with eyes or skin. Avoid ingestion and inhalation.
<b>Storage</b>	:	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from moisture and light. Store in original package.

<b>SECTION 8 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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<b>Appearance</b>	:	Refer Section 3-Hazards Identification, Emergency Overview
<b>Solubility in water</b>	:	Freely soluble in water
<b>Melting point</b>	:	Partially melts at about 135°C.
<b>pH</b>	:	About 9.4.

<b>SECTION 9- STABILITY AND REACTIVITY</b>
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<b>Chemical Stability</b>	:	Stable under normal temperatures and humidity condition.
<b>Conditions to Avoid</b>	:	Incompatible materials, strong oxidants.
<b>Incompatibilities with Other Materials</b>	:	Strong oxidizing agents, strong bases.
<b>Hazardous Decomposition Products</b>	:	Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide, nitrogen. Hazardous Polymerization: Has not been reported.
<b>Conditions to Avoid</b>	:	Excessive heat, light and moisture.

**SECTION 10- TOXICOLOGICAL INFORMATION**

<b>Toxicological Information</b>	:	<p><b>Carcinogenicity :</b>  <b>Species:</b> Sprague-Dawley rats, Mice  <b>Conclusion:</b> No evidence of tumorigenicity was seen in carcinogenicity studies.</p> <p><b>Mutagenesis:</b>  <b>Species:</b> Rats, Mice  <b>Conclusion:</b> No evidence of mutagenic or clastogenic was seen in studies.</p> <p><b>Impairment of Fertility:</b>  <b>Species:</b> Female Rats  <b>Conclusion:</b> No effects on female fertility or fecundity were observed.</p> <p><b>Reproductive Toxicology Studies:</b>  <b>Species:</b> Rats, Rabbits  <b>Conclusion:</b> No teratogenicity was observed.</p>
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**SECTION 11 - ECOLOGICAL INFORMATION**

**Ecological Information:** Runoff from fire control or dilution water may lead to pollution.

**SECTION 12 - DISPOSAL CONSIDERATIONS**

Dispose of in a manner consistent with federal, state, and local regulations or company operating procedures. Disposal by incineration is recommended.  
 At home: Discard away from children's reach.

**SECTION 13 - TRANSPORT INFORMATION**

This product is not subject to the regulations for the safe transport of hazardous chemicals.

<b>DOT</b>	:	Not regulated as a hazardous material by DOT.
<b>IATA</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Non Hazardous - Not Regulated

**SECTION 14 - REGULATORY INFORMATION**

**DEA** : Montelukast Sodium, USP is not a controlled substance.

- FDA** : Montelukast Sodium, USP is an approved prescription medication.
- Inventory Status** : This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.  
This material is not listed on the DSL Inventory but is exempt.

**SECTION 15– OTHER DATA**

Not Applicable.

**Date:** 22-Nov-2021

**SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION**