APOTEX
ADVANCING GENERICS

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Apo-Loratadine Tablets; Loratadine Tablets USP**

Recommended use : Pharmaceutical industry: Dosage form
Therapeutic category: Histamine H_1 Receptor Antagonist

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

Supplier :

Canada
Apotex Inc.
150 Signet Drive
Toronto, Ontario
M9L 1T9
416-749-9300

U.S.
Apotex Corp.
2400 N. Commerce Parkway
Suite 400
Weston, FLA 33326
Telephone: (954)384-8007
Toll Free: 1-800-706-5575

Emergency phone : United States/Canada (Chemtrec) 1-800-424-9300 or
+1 703-527-3887 (24 hours)
For general information call:
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Loratadine	79794-75-5	1-10
Magnesium stearate	557-04-0	1-10

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : Not applicable.

Synonyms : Brand Name: Claritin

Chemical family : Piperidine derivative

Molecular weight : Not applicable.

Chemical formula : Not applicable.

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Section 4. First Aid Measures

Eye contact : Flush with copious quantities of water. If irritation persists, obtain medical advice.

Skin contact : Flush with copious amounts of water. Seek medical attention if irritation persist.

Inhalation : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Ingestion : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

Potential acute and delayed health effects : Refer to Sec. 11

Section 5. Fire Fighting Measures

Specific hazard arising from the chemical : Not available.

During fire, gases hazardous to health may be formed.

Suitable extinguishing media and special protective equipment for firefighters : Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials. Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Methods and materials for containment and cleaning up : Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.

Protective equipment and personal precautions : Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, refer to section 8 of the SDS.

Section 7. Handling and Storage

Precautions for safe handling : Avoid breathing dust.

Conditions for safe storage : Store at room temperature (15 to 30°C). Protect from exposure to excessive moisture.

Section 8. Exposure Controls/Personal Protection

Engineering Controls : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

Personal Protection : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, appropriate PPE may be required that includes NIOSH approved respirators.

EYE/FACE PROTECTION: Wear approved safety eyewear if eye contact is possible.

SKIN PROTECTION: Where there is a risk of contact when handling, wear suitable skin protection (e.g., gloves, lab coat/uniform) having resistance to the product.

HYGIENE MEASURES: In the event clothing becomes contaminated, remove promptly. Launder before use. When handlings, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Occupational exposure limits : Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance : Tablets.

pH : Not available.

Melting point/ Freezing point : Not available.

Boiling point : Not available.

Volatility : Not available.

Specific gravity : Not available.

Evaporation rate : Not available.

Vapor density : Not available.

Relative density : Not available.

Vapor pressure : Not available.

Odor : Not available.

Odor threshold : Not available.

Conditions of instability : No additional remark.

Decompositon temperature : Not available.

Partition Coefficient: : Not available.

Viscosity : Not available.

Flash points : Not applicable.

Flammable limits : Not available.

Autoignition temperature : Not available.

Flammability : Emits toxic fumes under fire conditions.

Solubility : Not available.

Section 10. Stability and Reactivity

Reactivity : Not available.

Chemical Stability : The product is stable.

Possibility of hazardous reactions : Not available.

Hazardous decomp. products : When heated to decomposition material emits toxic fumes.

Incompatible materials/ Conditions to avoid : Protect from moisture.

Section 11. Toxicological Information

Information on the likely routes of exposure : As the product is a solid dosage form, the major route of entry is ingestion. Other routes of entry, including inhalation, skin and eye contact may occur only under certain circumstances.

Toxicity data : Loratadine:
LD50: >5000 mg/kg (oral-rat)
LD50: >5000 mg/kg (oral-mouse)
Magnesium stearate:
LD50 (oral-rat): Greater than 10 g/kg body weight (25% magnesium stearate suspended in corn oil)

Delayed and immediate effects and also chronic effects from short and long term exposure : Possible hypersensitization.
Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. In an 18-month study in male mice given 40 mg/kg loratadine there was a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than in controls. In a two-year study with rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg and males and females given 25 mg/kg.

Teratogenicity: Pregnancy Category B: Studies of children whose mothers had taken loratadine during pregnancy have not shown an association with major birth defects. No increased incidence of birth defects was observed in rats and rabbits at maternal doses up to 96 mg/kg/day. Oral doses up to 24 mg/kg/day in rats had no effect on male or female fertility or reproduction.

Mutagenicity: There was no evidence of mutagenic potential in reverse (Ames) or forward point mutation (CHO-HGPRT) assays, or in the assay for DNA damage (rat Primary Hepatocyte Unscheduled DNA Assay) or in two assays for chromosomal aberrations (Human Peripheral Blood Lymphocyte Clastogenesis Assay and the Mouse Bone Marrow Erythrocyte Micronucleus Assay). In the Mouse Lymphoma Assay, a positive finding occurred in the nonactivated but not in the activated phase of the study. Loratadine administration produced hepatic microsomal enzyme induction in the mouse at 40 mg/kg and in the rat at 25 mg/kg, but not at lower doses.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material, urinary retention, angle-closure glaucoma, symptomatic prostatic hypertrophy, bladder neck obstruction, and kidney or liver disease.
Patients sensitive to one of the antihistamines may be sensitive to this material also.

Symptoms related to the physical, chemical and toxicological characteristics : Adverse effects may include headache; fatigue; drowsiness; and dry mouth, nose, or throat. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.
Overdose may cause rapid heart rate, trouble sleeping, nervousness, dizziness, nausea, loss of appetite, drowsiness, and headache.

Section 12. Ecological Information

Ecotoxicity : Toxic to aquatic organisms. May cause long-term effects in the aquatic environment.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label	Additional information (e.g., special precautions, environmental hazards, transport in bulk)
TDG- road Canada/U.S.			Not regulated.			
ICAO-Air			Not regulated.			
ADR			Not regulated.			
IMDG Class			Not regulated.			

Section 15. Regulatory Information

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS

Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RxList Monographs
PDR Electronic Library
U.S. Pharmacopeia

Revision date: **3/19/2015**

Notice to Reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.