

SAFETY DATA SHEET

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Loratadine; Pseudoephedrine Sulfate Tablets (10/240mg)

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name OHM Labs

Supplier Address 600 College Rd
Princeton
NJ
08540
US

Supplier Phone Number Phone:1-800-406-7984
Fax:609-720-5604
Contact Phone609-720-5337

Supplier Email andrea.caldwell@ranbaxy.com

Emergency telephone number

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

GHS Label elements, including precautionary statements

Emergency Overview



Appearance White**Physical state** Solid**Odor** No information available**Precautionary Statements - Prevention**

Obtain special instructions before use

Precautionary Statements - Response

None

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

None

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

86.68% of the mixture consists of ingredient(s) of unknown toxicity

Other information

May cause slight eye irritation

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Calcium carbonate	471-34-1	5 - 10	*
Cellulose	9004-34-6	1 - 5	*
Titanium dioxide	13463-67-7	1 - 5	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES**First aid measures****Eye contact**

Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

Skin contact

Wash with soap and water.

Inhalation

Remove to fresh air.

Ingestion Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects No information available.

Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with eyes.

Other Information Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Calcium carbonate 471-34-1	-	TWA: 15 mg/m ³ TWA: 5 mg/m ³ (vacated) TWA: 15 mg/m ³ (vacated) TWA: 5 mg/m ³	TWA: 5 mg/m ³ respirable dust TWA: 10 mg/m ³ total dust
Cellulose 9004-34-6	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits Immediately Dangerous to Life or Health

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Solid	Odor	No information available
Appearance	White	Odor Threshold	No information available
Color	No information available		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No data available	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	No data available	None known	
Water Solubility	Soluble in water	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	No data available	None known	
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	
Explosive properties	No data available		
Oxidizing properties	No data available		

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

10. STABILITY AND REACTIVITY**Reactivity**

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

None known based on information supplied.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure****Product Information**

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Calcium carbonate 471-34-1	= 6450 mg/kg (Rat)	-	-
Cellulose 9004-34-6	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
Titanium dioxide 13463-67-7	> 10000 mg/kg (Rat)	-	-

Information on toxicological effects

Symptoms No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Sensitization No information available.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Cellulose 9004-34-6		-	-	-
Titanium dioxide 13463-67-7		Group 2B		X

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Chronic Toxicity Contains a known or suspected carcinogen. Titanium dioxide has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B) by inhalation. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

Target Organ Effects Eyes. Lungs. Respiratory system. Skin. Gastrointestinal tract (GI).

Aspiration Hazard No information available.

Numerical measures of toxicity Product Information

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)
8,800.00 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and Degradability

No information available.

Bioaccumulation

No information available

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

California Hazardous Waste Codes 311

14. TRANSPORT INFORMATION

DOT	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A

TDG	Not regulated
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MEX	Not regulated
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ICAO	Not regulated
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IATA	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A

IMDG/IMO	Not regulated
Hazard Class	N/A

RID Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Complies
DSL All components are listed either on the DSL or NDSL.

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

Chemical Name	California Proposition 65
Titanium dioxide - 13463-67-7	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Calcium carbonate 471-34-1	X	X	X		
Cellulose 9004-34-6	X	X	X	-	X
Titanium dioxide 13463-67-7	X	X	X		

International Regulations



Mexico**National occupational exposure limits**

Component	Carcinogen Status	Exposure Limits
Calcium carbonate 471-34-1 (5 - 10)		Mexico: TWA 10 mg/m ³ Mexico: STEL 20 mg/m ³
Cellulose 9004-34-6 (1 - 5)		Mexico: TWA 10 mg/m ³ Mexico: STEL 20 mg/m ³
Titanium dioxide 13463-67-7 (1 - 5)		Mexico: TWA= 10 mg/m ³ Mexico: STEL= 20 mg/m ³

*Mexico - Occupational Exposure Limits - Carcinogens***Canada****WHMIS Hazard Class**

Not determined

16. OTHER INFORMATION

NFPA	Health Hazards 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 1	Flammability 0	Physical Hazard 0	Personal Protection X

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Revision Note No information available

Disclaimer

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End of Safety Data Sheet