SAFETY DATA SHEET

Issuing Date 30-May-2013 **Revision Date** 04-Jun-2015 **Revision Number** 2

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

Product identifier

Product Name **Pseudoephedrine Hydrochloride 120 mg - 12 Hour Extended-Release Tablets**

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).

Acute toxicity - Oral	Category 4

GHS Label elements, including precautionary statements

Emergency Overview

Signal word **Warning**

Hazard Statements
Harmful if swallowed



Appearance White **Physical state** Solid **Odor** None

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response

Ingestion
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
Rinse mouth

Precautionary Statements - Storage
None

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity
2.15% of the mixture consists of ingredient(s) of unknown toxicity

Other information

No information available

Interactions with Other Chemicals
Use of alcoholic beverages may enhance toxic effects.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Chemical Name	CAS No	Weight-%	Trade Secret
Pseudoephedrine hydrochloride	345-78-8	10 - 30	*
Hydroxypropyl methylcellulose	8063-82-9	10 - 30	*
Magnesium stearate	557-04-0	1 - 5	*
Titanium dioxide	13463-67-7	0.1 - 1	*

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

4. FIRST AID MEASURES

First aid measures

General Advice Show this safety data sheet to the doctor in attendance.

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 Do NOT induce vomiting. Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

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. Keep out of the reach of children.

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
Hydroxypropyl methylcellulose 8063-82-9	-	-	IDLH: 500 mg/m³ Mn TWA: 1 mg/m³ Mn STEL: 3 mg/m³ Mn
Magnesium stearate 557-04-0	TWA: 10 mg/m³	-	
Titanium dioxide 13463-67-7	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust (vacated) TWA: 10 mg/m³ total dust	IDLH: 5000 mg/m³

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
Appearance White
Color No information available

Odor None
Odor Threshold No information available

Property	Values	Remarks Method
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. Harmful if swallowed. (based on components).

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
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
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 May cause adverse effects on the bone marrow and blood-forming system. 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 Blood. Central Nervous System (CNS). Kidney. Respiratory system. Eyes. 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)
1,801.00 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

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste
Hydroxypropyl methylcellulose 8063-82-9	Toxic

14. TRANSPORT INFORMATION

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

TDG Not regulated

MEX Not regulated

ICAO Not regulated

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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

Chemical Name	CAS No	Weight-%	SARA 313 - Threshold Values %
Hydroxypropyl methylcellulose - 8063-82-9	8063-82-9	10 - 30	1.0

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)
This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Hydroxypropyl methylcellulose 8063-82-9		X		

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

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Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Hydroxypropyl methylcellulose 8063-82-9			X	X	X
Titanium dioxide 13463-67-7	X	X	X		

International Regulations

Mexico

National occupational exposure limits

Component	Carcinogen Status	Exposure Limits
Titanium dioxide 13463-67-7 (0.1 - 1)		Mexico: TWA= 10 mg/m³ Mexico: STEL= 20 mg/m³

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

Prepared By

Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

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Revision Note No information available

Disclaimer

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End of Safety Data Sheet