



HETERO LABS LIMITED

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SAFETY DATA SHEET

Section 1: Identification

Material	Levocetirizine Dihydrochloride Oral Solution, 2.5 mg/ 5 mL
Other means of identification	None.
Recommended Use	Treatment of perennial allergic rhinitis and Chronic Idiopathic Urticaria
Recommended restrictions	None Known
Manufacturer	Hetero Labs Limited Unit III
	22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854

Section 2: Hazard's Identification

Physical Hazards	Not Hazardous
Health Hazards	Not Hazardous
OSHA defined Hazards	Not Hazardous
Label Elements	
Hazard Symbol	None
Signal word	Warning
Hazard statement	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling
Storage	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].
Disposal	Incineration of waste at an approved USEPA incinerator is recommended.
Hazard(s) not otherwise Classified (HNOC)	None known

Section 3: Composition/ Information on Ingredients

%	2.5mg/5mL
CAS	130018-87-0

Section 4: First Aid Measures

Inhalation	If liquid is inhaled, remove to fresh air. Seek immediate medical attention
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Skin Contact	If Liquid comes in contact with skin and clothing, remove contaminated clothing and wash thoroughly with running water for at least 15 minutes. Use soap if available. Seek medical attention if irritation develops.
Eye contact	In case of contact with liquid, flush eyes with water for at least 15 minutes. Seek medical attention if irritation develops.
Ingestion	In case of acute overdose by ingestion, seek immediate medical attention.
Most Important symptoms/effects, acute and delayed	May cause mild eye irritation. Swallowing may cause sleepiness, fatigue, dry mouth and pharyngitis.
Indication of immediate medical attention and special treatment needed	Immediate medical attention is recommended for large unintended ingestion.
General Information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Section 5: Fire Fighting Measures

Suitable extinguishing media	Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	This product is not a fire hazard but may burn under fire conditions after the water has evaporated.
Special protective equipment And precautions for firefighters	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.
Firefighting equipment/Instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

Section 6: Accidental Release measures

Personal precautions, protective equipment and emergency procedures	Wear appropriate protective clothing and equipment as described in Section 8. Caution – spilled liquid may present a slip hazard.
Methods and materials for containment and cleaning up	Collect liquid with an inert absorbent and place in appropriate container for disposal. Clean area thoroughly.
Environmental Precautions	Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly with soap and water after handling.
Conditions for safe storage, including any incompatibilities	Store as indicated on product packaging in a secure location. Keep only in original package. Store at 20-25°C (68-77°F). Protect from light and moisture. Store away from food stuffs.

Section 8: Exposure controls/Personal Protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Ventilation should be matched to conditions.
Individual protection measures, such as personal protective equipment	
Eye/face protection	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
Skin protection	
Hand protection	For consumer use, no unusual precautions are necessary
Other	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.
Respiratory protection	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Section 9: Physical and chemical Properties

Appearance	Clear, colorless solution.
Physical state	Liquid.
Form	Liquid.
Color	Clear colorless.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.

Evaporation rate	Same as water.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit – lower (%)	Not available.
Flammability limit – upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Sparingly soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Section 10: Stability and Reactivity

Reactivity	Not reactive under normal conditions of use.
Chemical stability	Stable.
Possibility of hazardous reactions	None known.
Conditions to avoid	None known.
Incompatible materials	Avoid oxidizing agents.
Hazardous decomposition products	Thermal decomposition may yield carbon oxides.

Section 11: Toxicological Information

Information on likely routes of exposure

Inhalation	Not expected to be hazardous in final pharmaceutical form.
Skin contact	Not expected to be hazardous in final pharmaceutical form.
Eye contact	Not expected to be hazardous in final pharmaceutical form.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	Possible common side effects are: nausea, sleepiness, weakness, dizziness, feeling anxious, trouble sleeping, sexual problems, sweating, shaking, dry mouth
Information on toxicological effects	
Acute toxicity	Not expected to be acutely toxic.

Skin corrosion/irritation	Not available.
Serious eye damage/eye	Under normal conditions of intended use, this material does not pose a eye hazard.
Respiratory or skin sensitization	
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	This product is not expected to be mutagenic.
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA,
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Product is excreted in human milk. Human milk feeding by a mother is not expected to harm an infant, provided maternal serum calcium levels are appropriately monitored
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not classified.
Aspiration hazard	See package insert.

Section 12: Ecological Information

Ecotoxicity	No data is available.
Persistence and degradability	No data is available.
Bioaccumulative potential	No data is available.
Mobility in soil	No data is available.
Other adverse effects	None Known.

Section 13: Disposal considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

<u>IATA/ICAO – Not Regulated</u>		
IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A
<u>IMDG - Not Regulated</u>		
IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A

IMDG Flash Point	:	N/A
IMDG Label	:	N/A
<u>DOT - Not Regulated</u>		
DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: regulatory Information

US federal regulations 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.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No
	Delayed Hazard - No
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations Drug Enforcement Administration (DEA): Citalopram hydrobromide is not a controlled substance.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Not listed.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Section 16: Other Information

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Issue Date: 13-04-2019

Version: 00

Revision note: New

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.