


Section 1: Identification

Common Name/Trade Name	LEVOCETIRIZINE DIHYDROCHLORIDE	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	N/A	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, oral (Category 4), Skin corrosion/irritation (Category 1A)	
Signal Word	Danger	
Hazard Statement(s)	H302 H314	Harmful if swallowed Causes severe skin burns and eye damage
Pictogram(s)		
Precautionary Statement(s)	P260 P264 P280 P301+P330+P331 P301+P312 P303+P361+P353 P304+P340 P305+P351+P338 P501	Do not breathe dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED Rinse mouth. Do NOT induce vomiting. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN (or hair) Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	Levocetirizine
Common Name	Levocetirizine Dihydrochloride
CAS Number	130018-87-0
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
If Inhaled	Remove victim to uncontaminated area. Allow the victim to rest. Seek medical advice (show the label where possible).
In Case of Skin Contact	Wash immediately and thoroughly with water and soap. If skin irritation occurs: Get medical advice/attention.
In Case of Eye Contact	Immediately flush eyes thoroughly with water for at least 30 minutes. If exposure is severe or irritation develops, seek medical attention.
If Swallowed	IF SWALLOWED: Get medical advice/attention. Never give anything by mouth to an unconscious person.
Most Important Symptoms and Effects	No additional information available

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	water spray, extinguishing powder, carbon dioxide, foam. Use the extinguishing material recommended for the primary cause of fire.
Special Hazards Arising From the Substance/Mixture	No additional information available.
Special PPE and/or Precautions for Firefighters	Prevent material from entering waterways, sewers or surface draining systems. Wear self-contained breathing apparatus and protective suit.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Wear appropriate personal protective equipment in case of accidental release.
Methods and Materials Used for Containment	Avoid release to the environment.
Cleanup Procedures	Clean up any spills as soon as possible, using an absorbent material to collect it. Keep in suitable, closed containers for disposal. Clean contaminated surfaces with an excess of water. Avoid raising dust. Ventilate area. Concerning personal protective equipment to use, see section 8.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid creating or spreading dust. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and when leaving work. Do not wear contaminated clothing.
Conditions for Safe Storage	Use good housekeeping practices during storage, transfer, handling, to avoid excessive dust accumulation. Store at room temperature.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	In-house Occupational Exposure Limit (OEL): 0.03 mg/m ³ (8 hours)
Appropriate Engineering Controls	All liquid/powder handling operations should be performed in a contained manner using a suitably designed and performance verified containment system. Both local exhaust and general room ventilation are usually required. Minimize charging mechanisms. Use in combination with respiratory protective equipment until containment performance monitoring has verified that the respiratory protective equipment is not required. Ground equipment electrically. Access forbidden to unauthorized personnel.
PPE - Eye/Face Protection	Use safety glasses and in case of splash risk face shield. Use equipment for eye protection tested and approved under appropriate standards such as EN 166 (EU). Eye protection must be defined after a workplace risk assessment.
PPE - Skin Protection	The type of protective equipment must be selected after a workplace risk assessment. At a minimum, a laboratory coat or equivalent protective clothing is required for work with this product.
PPE - Body Protection	The type of protective equipment must be selected after a workplace risk assessment. At a minimum, a laboratory coat or equivalent protective clothing is required for work with this product.
PPE - Respiratory Protection	Where workplace risk assessment shows air-purifying respirators are required, conduct an exposure assessment to determine the type and amount of containment. The respirator must have an Assigned Protection Factor (APF) adequate to the workplace exposure. Use respirators and components tested and approved under appropriate standards such as CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	Solid Crystal
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	0.0055
Odor Threshold	No data available
Vapor Density	No data available
pH	1.5 (5%
Relative Density	No data available
Melting Point/Freezing Point	220C
Solubility	V
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	1.32 (=
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No additional information available.
Chemical Stability	Stable in use and storage conditions as recommended in item 7.
Possibility of Hazardous Reactions	No additional information available.
Conditions to Avoid	No additional information available.
Incompatible Materials	No additional information available.
Hazardous Decomposition Products	On heating/burning: release of corrosive gases/vapors hydrogen chloride.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Harmful if swallowed. LD50 Oral Mouse 804 mg/kg Rat 472 mg/kg, oral dog >320 mg/kg. Maximal non-lethal dose (MNLD), acute, oral rat mouse =240 mg/kg. MNLD dog = 320 mg/kg. NOEL, subacute, oral rat 25 mg/kg (4 weeks). NOEL subacute oral dog 15 mg/kg (4 weeks)
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	MNLD acute, injection female rat 47 mg/kg.
Acute Toxicity - Eye	Serious eye damage, category 1, implicit pH: 1.5 (5% water solution)
Skin Corrosion/Irritation	Causes severe skin burns and eye damage pH 1.5 (5% water solution)
Serious Eye Damage/Irritation	Due to lack of data the classification is not possible.
Respiratory or Skin Sensitization	Not classified (Lack of data)
Germ Cell Mutagenicity	Not classified as mutagenic (Data which is conclusive for non classification)
Carcinogenicity IARC	No data available Not classified as carcinogenic (Data which is conclusive for non classification)
Carcinogenicity ACGIH	No data available Not classified as carcinogenic (Data which is conclusive for non classification)
Carcinogenicity NTP	No data available Not classified as carcinogenic (Data which is conclusive for non classification)
Carcinogenicity OSHA	No data available Not classified as carcinogenic (Data which is conclusive for non classification)
Reproductive Toxicity	Not classified as reprotoxic (Data which is conclusive for non classification)
Specific Target Organ Toxicity - Single Exposure	Not classified (Lack of data)
Specific Target Organ Toxicity - Repeated Exposure	Not classified (Lack of data)
Aspiration Hazard	Not classified (Lack of data)

Section 12: Ecological Information

Toxicity	Not classified. Data which is conclusive for non-classification. EC50 Daphnia 1, >100 mg/l Daphnia acute test (OECD 202) - 48h. EC50 other aquatic organisms 1, 750 mg/l Activated Sludge respiration inhibition test (OECD 209). NOEC (acute), 100 mg/l Daphnia acute test (OECD 202)-48h. NOEC (additional information) NOEC, Activated Sludge respiration inhibition test (OECD 209): 320 mg/l.
Persistence and Degradability	Readily biodegradable. OECD 301B method
Bio-accumulative Potential	Log Pow 1.32 (=Log D) at pH 7.4.
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Dispose of waste product or used containers according to local regulations. Ensure all national/local regulations are observed.
Waste Treatment Methods Packaging	Dispose of waste product or used containers according to local regulations. Ensure all national/local regulations are observed.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	UN 3261
UN Proper Shipping Name	CORROSIVE SOLID, ACIDIC, ORGANIC, N.O.S.
Transport Hazard Class(es)	8
Packaging Group	II
Environmental Hazards	N/A

Section 15: Regulatory Information

No REACH Annex XVII restrictions. Levocetirizine is not on the REACH Candidate list.
--

Section 16: Other Information

Additional Information	N/A
Prepared By	Scarlotte Smith
Revision Date	04/08/2020 11:59

Disclaimer

Letco Medical, LLC believes that the above information is correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.