Section 1: Identification

Common Name/Trade Name	DOXEPIN HCL USP	
Supplier Information	Letco Medical 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)	1-Propanamine, 3-dibenz[b,e]oxepin-11(6H)ylidene-N,N-dimethyl-, hydrochloride	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, oral (Category 3), Specific target organ toxicity, single exposure (Category 3) (narcotic effects)	
Signal Word	Danger	
Hazard Statement(s)	H301 H336	Toxic if swallowed May cause drowsiness or dizziness
Pictogram(s)		
Precautionary Statement(s)	P264 P271 P301+P310 P304+P340 P312 P330 P403+P233 P405 P501	Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area. IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Store in a well ventilated place. Keep container tightly closed. Store locked up. 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	1-Propanamine, 3-dibenz[b,e]oxepin-11(6H)ylidene-N,N-dimethyl-, hydrochloride
Common Name	Doxepin Hydrochloride
CAS Number	1229-29-4
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 enter 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	Move to fresh air. Call a physician if symptoms develop or persist.
In Case of Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
If Swallowed	Rinse mouth. If ingestion of a large amount does occur, call poison control center immediately
Most Important Symptoms and Effects	No data available

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Use fire-fighting media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
Special Hazards Arising From the Substance/Mixture	No unusual fire or explosion hazards noted.
Special PPE and/or Precautions for Firefighters	Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedure and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and Materials Used for Containment	Sweep or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see Section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Precautions for Safe Handling	As a general rule, when handling chemicals, avoid all contact and inhalation of dust, mist, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for Safe Storage	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No exposure standards allocated.
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures. Handle in accordance with good industrial hygiene and safety practice.
PPE - Eye/Face Protection	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g. bearing the ANSI Z87 or CSA Stamp) is preferred. Maintain eyewash facilities in the work area.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should us nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
PPE - Body Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should avoided due to the risk of latex allergy. For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
PPE - Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place. (applicable U.S. regulation OSHA 29 CFR 1910.34)

Section 9: Physical and Chemical Properties

Appearance	Form: Powder Solid Colour: White crystalline powder.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Slight amin-like-odor.
Vapor Pressure	0.0000003 kPa at 25 °C
Odor Threshold	No data available
Vapor Density	No data available
pH	4.5-5.1
Relative Density	No data available
Melting Point/Freezing Point	Melting point 365 - 375.8 °F (185 - 191 °C)
Solubility	Solubility in water- Freely soluble
Initial Boiling Point and Boiling Range	309.2 - 314.6 °F (154 - 157 °C) at 0.03 mmHg
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	No data available
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	None known
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral Mouse 180 mg/kg Rat 147 mg/kg
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	No data available
Respiratory or Skin Sensitazation	Allergic contact dermatitis has been reported.
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC.
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	Due to lack of data the classification is not possible. This material is not considered to be carcinogen by NTP.
Carcinogenicity OSHA	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by OSHA.
Reproductive Toxicity	< 100 mg/kg Reproductively study Result: Some increase in neonatal death but no increase in gross malformations. Species: Rabbit < 270 mg/kg/day Reproductively study Result: Postnatal survival was decreased but no congenital defects were found. Species: Rat
Specific Target Organ Toxicity - Single Exposure	Narcotic effects.
Specific Targer Organ Toxicity - Repeated Exposure	Due to lack of data the classification is not possible.
Aspiration Hazard	Based on available data, the classification criteria are not met.

Section 12: Ecological Information

Toxicity	No ecotoxicity data noted for the ingredients.
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Waste Treatment Methods Packaging	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see Disposal instructions).
Special Precautions Landfill or Incinerations	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
Other Information	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14: Transport Information

UN Number	2811
UN Proper Shipping Name	Toxic solid, organic, n.o.s. (Doxepin Hydrochloride)
Transport Hazard Class(es)	6.1
Packaging Group	III
Environmental Hazards	No data available

Section 15: Regulatory Information

CERCLA/SARA Hazardous Substances -Not applicable. One or more components are not listed on TSCA. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard Categories: Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard -No SARA 302 Extremely hazardous substance: No SARA 311/312 Hazardous Chemical: No Other federal regulations: Safe Drinking Water Act (SDWA) Not regulated. Food and Drug Administration (FDA) Not regulated. US state regulations: 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 toxins.

Section 16: Other Information

Prepared By	Scarlotte Smith
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