

Section 1: Identification

Common Name/Trade Name	DILTIAZEM 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)	CRD-401 (2S,3S)-(+)-cis-3-Acetoxy-5-(2-dimethylaminoethyl)-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-onehydrochloride	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4)	
Signal Word	Warning	
Hazard Statement(s)	H302	Harmful if swallowed
Pictogram(s)		
Precautionary Statement(s)	P264 P270 P301+P312 P330 P501	Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. 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	CRD-401 (2S,3S)-(+)-cis-3-Acetoxy-5-(2-dimethylaminoethyl)-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-onehydrochloride
Common Name	(+)-cis-Diltiazem hydrochloride
CAS Number	33286-22-5
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
If Inhaled	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
In Case of Skin Contact	Wash off with soap and plenty of water. Consult a physician.
In Case of Eye Contact	Flush eyes with water as precaution.
If Swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most Important Symptoms and Effects	The most important known symptoms and effects are described in the labeling (see section 2.2) and/or section 11.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Special Hazards Arising From the Substance/Mixture	Carbon oxides, nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas.
Special PPE and/or Precautions for Firefighters	Wear self contained breathing apparatus for fire fighting if necessary.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Avoid breathing dust.
Methods and Materials Used for Containment	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
Cleanup Procedures	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal. Do not let product enter drains.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Conditions for Safe Storage	Keep container tightly closed in a dry and well-ventilated place. Keep in dry place.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Contains no substances with occupational exposure limit values.
Appropriate Engineering Controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
PPE - Eye/Face Protection	Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
PPE - Skin Protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
PPE - Body Protection	Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
PPE - Respiratory Protection	For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirators cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	Form: Solid Colour: White
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	Melting point/range: 212 °C (414 °F)
Solubility	Water solubility ca.50 g/l
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	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 data available
Chemical Stability	Stable under recommended storage conditions.
Possibility of Hazardous Reactions	No data available
Conditions to Avoid	No data available
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Other decomposition products-No data available

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50 Oral - rat - 560 mg/kg Remarks: Behavioral: Antipsychotic.
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 Sensitization	No data available
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Carcinogenicity ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
Carcinogenicity NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
Carcinogenicity OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
Reproductive Toxicity	No data available
Specific Target Organ Toxicity - Single Exposure	No data available
Specific Target Organ Toxicity - Repeated Exposure	No data available
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	No data available
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	Offer surplus and non-recyclable solutions to licensed disposal company.
Waste Treatment Methods Packaging	Dispose of as unused product.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

SARA 302 Components: SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302. SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. SARA 311/312 Hazards: Acute Health Hazard, Chronic Health Hazard. Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Act. Pennsylvania Right To Know Components: (2S-cis)-3-Acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride. CAS-No. 33286-22-5 New Jersey Right To Know Components: (2S-cis)-3-Acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride CAS-No. 33286-22-5. California Prop. 65. Components: WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. (2S-cis)-3-Acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride CAS-No. 33286-22-5 Revision Date 2007-09-28.

Section 16: Other Information

Prepared By	Scarlotte Smith
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