



300 Northfield Road
 Bedford, OH 44146
 Telephone: (800) 562-4797
 -or- (440) 232-3320

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Diltiazem Hydrochloride Injection 5mg/ml (5mL, 10mL and 25mL vials)

Chemical Names: 1,5-benzothiazepin-4(5H)one,3-(acetyloxy)-5-[2-(dimethylamino)ethyl]-2,3 dihydro-2-(4-methoxyphenyl)-,monohydrochloride,(+)-cis-

Synonyms: Cardizem® Injectable; Angizem, Calcard

Manufacturer's Name: BEN VENUE LABORATORIES, INC.

Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146

Emergency Telephone Number: Chemtrec: 1(800)424-9300

Telephone Number for Info.: (440)232-3320 or (800)562-4797

Medical Emergency: Professional Services 1(800)521-5169

Date Prepared: January 8, 1996

Date Revised: January 17, 2000

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

| <u>Component</u> | <u>%</u> | <u>CAS#</u> | <u>OSHA PEL</u> | <u>ACGIH TLV</u> | <u>Other Limits Recommended</u> |
|---|----------|-------------|-----------------|------------------|---------------------------------|
| Diltiazem Hydrochloride | 0.5% | 33286-22-5 | NONE | NONE | 0.2 mg/m ³ |
| Citric Acid Monohydrate | 0.075% | 5949-29-1 | NONE | NONE | NONE |
| Sodium Citrate Dihydrate | 0.065% | 6132-04-3 | NONE | NONE | NONE |
| Sorbitol Solution | 7.14% | 50-70-4 | NONE | NONE | NONE |
| Water for Injection (adj. to 1ml) | 92.22% | 7732-18-5 | NONE | NONE | NONE |
| Sodium Hydroxide/Hydrochloric Acid for pH adjustment | | | | | |

Diltiazem Hydrochloride is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Under normal use, Diltiazem Hydrochloride presents little hazard and is not rapidly absorbed through intact skin. Product may be absorbed orally. Product is an antianginal; antihypertensive.

Health Hazard (Acute & Chronic): Diltiazem is a drug used to treat arterial fibrillation, flutter and tachycardia. Product affects the circulatory system; possible allergic reaction may result. Animal studies show possible fetotoxicity.

Carcinogenicity: NTP? NO **IARC Monographs?** None

OSHA Regulated? NO

Signs & Symptoms of Exposure: May cause heart irregularities, heart arrhythmias; may irritate eyes, skin, and respiratory tract. May also cause headache, nausea, dizziness, rash, and weakness.

Medical Conditions Generally Aggravated by Exposure: Heart conditions other than arterial fibrillation or flutter and paroxysmal supraventricular tachycardias.

BVL Hazard Category: 2

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 minutes.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: Seek medical attention from a physician immediately

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately
If necessary, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not applicable

Flammable Limits: LEL: NA **UEL:** NA

Extinguishing Media: Use water or type ABC aqueous-based multi-purpose extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous based and is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Diltiazem Hydrochloride with absorbent material and dispose of according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposure by ventilating area; clean up spill immediately or prevent evaporation.

Release to Water: Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above; wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method: Incineration in an approved/permitted incinerator is recommended.
Refer to local, state, and federal rules.

Precautions to be taken in handling and storing: Store under refrigeration at 2-8°C; Do not freeze.

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, use a disposable dust/mist respirator (N95). Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: None

Work/Hygienic Practices: Wash hands following use; no eating, drinking, or smoking while handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Appearance and Odor: clear, colorless;
no noticeable odor

Evaporation Rate: Unknown

Solubility in Water: Will mix with water

pH: range 3.7 to 4.1

Specific Gravity: Unknown

Melting Point: Not applicable

Boiling Point: 100°C (approx.)

Vapor Pressure: Approximate to water

Vapor Density: Approximate to water

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable **Conditions to Avoid:** None

Incompatibility (Materials to Avoid): None known

Hazardous Decomposition or Byproducts: As with any burning material carbon monoxide, carbon dioxide, nitrogen oxides and other oxides may result.

Hazardous Polymerization: None

Conditions to Avoid: Store product under refrigeration 2-8°C. Do not freeze. Can be stored at room temperature for up to one month only.

Section XI - TOXICOLOGICAL INFORMATION

For Diltiazem Hydrochloride (active ingredient):

LD₅₀ mouse, oral = 415-740 mg/kg

LD₅₀ rat, oral = 560-810 mg/kg

LD₅₀ mouse, intravenous = 60 mg/kg

LD₅₀ rat, intravenous = 38 mg/kg

LD₅₀ dog, oral >50 mg/kg

LD₅₀ monkey, oral = 360 mg/kg

LD₅₀ rat, subcutaneous = 520 mg/kg

LD₅₀ mouse, subcutaneous = 260 mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Diltiazem. Handle in a manner to prevent spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.
Review local, state, and federal regulations.

Section XIV - TRANSPORTATION INFORMATION

Diltiazem Hydrochloride is not a DOT Hazardous Material.
Diltiazem Hydrochloride is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO
Listed on the California Proposition 65 list as Code D

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address therapeutic use of this material.
2. Store this product under refrigeration from 2-8°C. Do not freeze.
3. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.