

4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. Oxygen may be administered if breathing is difficult. Get medical attention if symptoms appear.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available.
Flash point:	Not available.
Autoignition temperature:	Not available.
Flammable limits	Not available.
in air-lower (%):	
Flammable limits	
in air-upper (%):	Not available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). In case of fire, stop leak if safe to do so
Environmental precautions:	Not applicable
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Wash thoroughly after handling.

Storage:

Technical measures
/Storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store between 2 and 8°C (35.6 to 46.4°F). Store in original container. Do not freeze.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Product id: 1087902

Product name: Diltiazem Hydrochloride Injection

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Diltiazem Hydrochloride 33286-22-5	None	None	None	None	None	None
Sodium Citrate 18996-35-5	None	None	None	None	None	None
Sorbitol 50-70-4	None	None	None	None	None	None
Citric Acid Anhydrous 77-92-9	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: Good general ventilation should be sufficient to control airborne levels. No special containment is required.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid
Appearance: Not available.
Color: Clear
Odor: Not available.
pH: 3.7 to 4.1
Molecular weight: Not applicable.
Boiling point/range: Not available.
Melting point/range: Not available.
Density: Not available.
Vapor pressure: No data available
Evaporation rate: Not determined
Solubility: Soluble in water.
Partition coefficient (n-octanol/water): Not available.
Viscosity: Not available.
% Volatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: This product is stable.

Polymerization: No data available

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10. STABILITY AND REACTIVITY

Hazardous decomposition products: No data available.

Materials to avoid: No data available.

11. TOXICOLOGICAL INFORMATION

Component	LD50 Dermal	LC50 Inhalation	LD50 Oral
Diltiazem Hydrochloride 33286-22-5	271 mg/kg (rat)	-	560 mg/kg (rat)
Sodium Citrate 18996-35-5	-	-	1700 mg/kg (rat)
Sorbitol 50-70-4	-	-	15900 mg/kg (rat)
Citric Acid Anhydrous 77-92-9	-	-	3000 mg/kg (rat)
Water 7732-18-5	-	-	90 mL/kg (rat)

Acute toxicity: Signs and Symptoms of overexposure may result in low blood pressure, increased liver enzymes, slow heart beat, and cardiac failure.

Chronic toxicity: Target organs: heart.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. Not carcinogenic at all dose levels evaluated based on animal data.

Mutagenic effects: Not mutagenic in a standard battery of genetic toxicological tests.

Reproductive toxicity: No impairment to fertility based on animal data. Considered fetotoxic. See patient package insert for additional information.

FDA Pregnancy Category C

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Diltiazem Hydrochloride 33286-22-5	None.	None.	None.	None.
Sodium Citrate 18996-35-5	85 mg/L EC50 24 h	1516 mg/L LC50 Lepomis macrochirus 96 h	None.	14mg/LEC50Photobacterium um phosphoreum15min
Sorbitol 50-70-4	None.	None.	None.	None.
Citric Acid Anhydrous 77-92-9	120 mg/L EC50 72 h	1516 mg/L LC50 Lepomis macrochirus 96 h	None.	= 14 mg/L EC50 Photobacterium phosphoreum
Water 7732-18-5	None.	None.	None.	None.

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Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
UN Number: None
DOT Packing Group: None
DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
TDG UN/NA Number: None
TDG Packing Group: None
TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
ADR Proper shipping name: None
ADR UN/NA number: None
ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
IATA UN Number: None
IATA Primary Hazard: None
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
IMDG Hazard Class and Division: None
IMDG Packing Group: None
IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:

Product id: 1087902

Product name: Diltiazem Hydrochloride Injection

15. REGULATORY INFORMATION

Diltiazem Hydrochloride	<1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Sorbitol	5-7	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Anhydrous	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Water	92	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Diltiazem Hydrochloride	Present	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Citrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sorbitol	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Citric Acid Anhydrous	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

This product contains component(s) known to the State of California to cause cancer or reproductive/developmental harm.

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product does not comply with EINECS

Risk Phrases:

NONE

Safety Phrases:

NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:
New MSDS format. Change to product codes. Changes to Section 7. Changes to Section 8.

Additional information:

Not Available.

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End of safety data sheet:

Product id: 1087902

Product name: Diltiazem Hydrochloride Injection