Section 1 - Identification

(a) Product Identifier: Diltiazem Hydrochloride Injection

(b) Product Code: 70860-301

Common/Trade Name: Diltiazem Hydrochloride

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

Chemical Family: Calcium Channel Antagonist

(c) Product Use: Pharmaceutical, Injectable

Product Type: Regulated Prescription Drug

Container Information: Vial

(d) Distributor: Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515

(e) Emergency Telephone: 855-273-0154

Section 2 - Hazards Identification

(a) Classification: **OSHA Classification:** Not classified

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	None
Physical Hazards	None
Health Hazards	None
Symbol(s)	None
Hazard Statement(s)	None
Precautionary Statement(s):	None
Hazards Not Otherwise Classified:	None
Supplementary Information:	While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
1,5-benzothiazepin-4(5H)one,3-(acetyloxy)-5-[2-(dimethylamino)ethyl]-2, 3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride, (+)-*cis*-	Diltiazem Hydrochloride/ Diltiazem HCl	5 mg per mL	33286-22-5	N/A
Citric Acid	Citric Acid	0.75 mg per mL	77-92-9	N/A
Sodium Citrate Dihydrate	Sodium Citrate	0.65 mg per mL	6132-04-3	N/A
Sorbitol Solution	Sorbitol Solution	71.4 mg per mL	50-70-4	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s.*	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s.*	7647-01-0	N/A
Water for Injection	Water	q.s.*	7732-18-5	N/A
Nitrogen	Nitrogen	q.s.*	7727-37-9	N/A

*q.s. – quantity sufficient

Section 4 – First Aid Measures

Eye Exposure: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Exposure: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Injection: In cases of accidental injection, wash and disinfect area, seek medical attention.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Symptoms of Exposure Headache; nausea; difficulty breathing; coughing; wheezing; constipation; diarrhea; dizziness; lightheadedness; swelling of feet or lower legs; flushing; skin rash; eye irritation; tiredness; weakness.

Medical Conditions Aggravated by Exposure Hypersensitivity to any of the components of the product; pre-existing cardiovascular disease or liver ailments. For nonsteroidal anti-inflammatory drugs (NSAIDs): Asthma; aspirin allergy; active alcoholism; anemia; impaired kidney or liver function; cardiovascular disorders; bleeding disorders; peptic ulcer or gastrointestinal bleeding; hypertension; stomatitis.

Notes to Physician: Treat supportively and symptomatically. See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures

(a) Extinguishing Media Use extinguishing media for type of surrounding fire.

(b) Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, sulfur oxides and other hazardous combustion products

(c) Special Protective Equipment / Precautions: Wear self-contained breathing apparatus and full and protective gear.

Section 6 - Accidental Release Measures

Spill: Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Release to Air: Information not available.

Release to Water: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Section 7 - Handling and Storage

General Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Storage Conditions: .Store refrigerated between 2° and 8° C (36° and 46° F). **Do not freeze.**

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Diltiazem Hydrochloride	OSHA ACGIH -----	TLV PEL STEL	NE NE NE

(b) Engineering Controls

Ventilation: No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

(c) Individual Protection Measures

Respiratory Protection:	Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Eye Protection:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with sideshields.
Skin Protection:	*Hand*: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. *Body*: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. *Other*: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Additional Exposure Precautions:	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.

Section 9 - Physical and Chemical Properties

(a)	**Appearance**	Clear, colorless, sterile, nonpyrogenic solution
(b)	**Odor**	Not available
(c)	**Odor Threshold**	Not available
(d)	**pH**	3.7 to 4.1
(e)	**Melting Point:**	Not available
(f)	**Initial Boiling Point:**	Not available
(g)	**Flash Point**	Not available
(h)	**Evaporation Rate:**	Not available
(i)	**Flammability**	Not available
(j)	**Upper Lower Flammability or Explosion Limits**	Not available
(k)	**Vapor Pressure:**	Not available
(l)	**Vapor Density:**	Not available
(m)	**Relative Density**	Not available
(n)	**Solubility(ies)**	Soluble in water
(o)	**Partition Coefficient: n-octanol/water**	Not available
(p)	**Auto-ignition Temperature**	Not available
(q)	**Decomposition Temperature**	Not available
(r)	**Viscosity**	Not available

Section 10 - Stability and Reactivity

(a)	**Reactivity**	Data not available.
(b)	**Chemical Stability**	Material is stable under normal conditions
(c)	**Possibility of Hazardous Reactions**	No dangerous reaction known under conditions of normal use.
(d)	**Conditions to Avoid**	Data not available
(e)	**Incompatible Materials**	Oxidizing material.

(f)	**Hazardous Decomposition Products**	Under normal conditions of storage and use, hazardous decomposition products should not be produced

Section 11 - Toxicological Information

(a)	**Likely Routes of Exposure**	Dermal contact. Eye contact. Inhalation. Ingestion.
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
(c)	**Delayed and immediate effects and also chronic effects from short- and long-term exposure**	No data available.

(d) Acute Toxicity

There is no data available.

(e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

Section 12 - Ecological Information

(a)	**Ecotoxicity**	Do data available
(b)	**Persistence and degradability**	Do data available
(c)	**Bioaccumulative potential**	Do data available
(d)	**Mobility in soil**	Do data available
(e)	**Other Adverse Effects**	Do data available

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good. Read safety instructions, SDS and emergency procedures before handling.
IMDG: Not regulated as a dangerous good.

(a)	**UN Number**	Not Applicable
(b)	**UN Proper Shipping Name**	Not Applicable
(c)	**Transport Hazard Class(es)**	Not Applicable
(d)	**Packing Group**	Not Applicable
(e)	**Environmental Hazards**	Not Applicable
(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	Not Applicable
(g)	**Special Precautions**	Not Applicable

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Not regulated
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 304: Not regulated
SARA 313 - Not on this list

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information
contact:

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847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.