

SAFETY DATA SHEETS

This SDS packet was issued with item:

078941049

N/A

Safety Data Sheet



Section 1: Identification

Product identifier

- Product Name** • **Diltiazem hydrochloride tablets (Authorized generic for Cardizem TAB) 30-120 mg**
- Synonyms** • Diltiazem hydrochloride
- Product Code** • 368682006100; 368682006506; 368682007107; 368682007503; 368682008104; 368682008500; 368682009101; NDC 68682-006-10; NDC 68682-006-50; NDC 68682-007-10; NDC 68682-007-50; NDC 68682-008-10; NDC 68682-008-50; NDC 68682-009-10
- Product Description** • Prescription pharmaceutical product.

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Diltiazem HCl is a nondihydropyridine calcium channel blocker indicated for treatment of hypertension.
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Valeant Pharmaceuticals International, Inc.
2150 St. Elzear West
Laval H7L 4A8
Canada
valeant.com
- Telephone (General)** • 1-800-321-4576
- Supplier** • Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals N. America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com
- Telephone (General)** • 1-800-321-4576

Emergency telephone number

- Supplier** • 1-800-535-5053 - US - Infotrac
- Supplier** • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS Revision 3

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

Classification of the substance or mixture

UN GHS

- Acute Toxicity Oral 4
- Reproductive Toxicity 2
- Specific Target Organ Toxicity Single Exposure 2

Label elements

UN GHS

WARNING



- Hazard statements**
- Harmful if swallowed
 - May cause damage to organs (cardiovascular system).
 - Suspected of damaging fertility or the unborn child.
 - May cause damage to organs.

Precautionary statements

- Prevention**
- Do not handle until all safety precautions have been read and understood.
 - Avoid breathing dust, fume, gas, mist, vapours and/or spray.
 - Use personal protective equipment as required.
 - Wash thoroughly after handling.
- Response**
- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
 - IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

- Storage/Disposal**
- Store in a well-ventilated place. Keep container tightly closed.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	Identifiers	%
Colloidal silicon dioxide	CAS:7631-86-9 EINECS:231-545-4	N/A
D&C Yellow #10	CAS:8004-92-0	N/A
Diltiazem hydrochloride	CAS:33286-22-5 EINECS:251-443-3	13.64%
FD&C Blue #1	NDA	N/A
Hydroxypropyl methyl cellulose	CAS:9004-64-2	N/A
Lactose monohydrate	CAS:64044-51-5	N/A
Magnesium stearate	CAS:557-04-0 EINECS:209-150-3	N/A
Methylparaben	CAS:99-76-3 EINECS:202-785-7	N/A
Microcrystalline cellulose	CAS:9004-34-6 EINECS:232-674-9	N/A
Opadry YS-5-7044	NDA	N/A

N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

- Inhalation**
- Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.
- Skin**
- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. Immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash, blistering) develops, get medical attention.
- Eye**
- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get medical attention immediately if symptoms occur.
- Ingestion**
- No specific treatment is necessary since this material is not hazardous by ingestion when used in accordance with product literature. If quantities exceeding the recommended intake are accidentally ingested, get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- Events observed following diltiazem overdose included bradycardia, hypotension, heart block, and cardiac failure.

Indication of any immediate medical attention and special treatment needed

- Notes to Physician**
- Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.
- Antidotes**
- In the event of overdose or exaggerated response, institute appropriate supportive measures and gastrointestinal decontamination. Diltiazem does not appear to be removed by peritoneal or hemodialysis. Limited data suggest that plasmapheresis or charcoal hemoperfusion may hasten diltiazem elimination following overdose. Based on the known pharmacological effects of diltiazem and/or reported clinical experiences, the following measures may be considered: Bradycardia: Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockage, administer isoproterenol cautiously. High-degree AV Block: Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing. Cardiac Failure: Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics. Hypotension: Use vasopressors (e.g., dopamine or norepinephrine). Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

- Unsuitable Extinguishing Media**
- No data available

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- No data available

- Hazardous Combustion Products**
- No data available.

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to

prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.
- Emergency Procedures**
- Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

Environmental precautions

- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures**
- LARGE SPILLS:** Use HEPA vacuum to clean up spill. If HEPA vacuum is not available, dampen spilled tablets with water prior to cleaning up to prevent dust cloud.

Section 7 - Handling and Storage

Precautions for safe handling

- Handling**
- Minimize dust generation and accumulation. Use good safety and industrial hygiene practices. Avoid breaking capsules.

Conditions for safe storage, including any incompatibilities

- Storage**
- Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Colloidal silicon dioxide (7631-86-9)	TWAs	Not established	Not established	6 mg/m3 TWA	Not established
Microcrystalline cellulose (9004-34-6)	TWAs	10 mg/m3 TWA	10 mg/m3 TWAEV (containing no Asbestos and <1% Crystalline silica, total dust)	10 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable dust)	15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)

Exposure controls

- Engineering Measures/Controls**
- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE.** Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory

- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face	<ul style="list-style-type: none"> Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.
Hands	<ul style="list-style-type: none"> Wear protective gloves when handling bulk product before closed in final packaging.
Skin/Body	<ul style="list-style-type: none"> Avoid contact with skin.
General Industrial Hygiene Considerations	<ul style="list-style-type: none"> Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.
Environmental Exposure Controls	<ul style="list-style-type: none"> No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Light green, round tablet.
Color	Light green.	Odor	No odor.
Taste	Bitter		
General Properties			
Boiling Point	Not relevant	Melting Point/Freezing Point	187 to 210 °C(368.6 to 410 °F)
Decomposition Temperature	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Water Solubility	Soluble
Solvent Solubility	Chloroform; Methanol	Viscosity	Not relevant
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Hazardous polymerization will not occur.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Light, heat and humidity.

Incompatible materials

- Strong oxidizing agents.

Hazardous decomposition products

- When heated to decomposition, toxic fumes of nitrous oxides, sulfur oxides, hydrogen chloride and carbon oxides may be emitted.

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Diltiazem hydrochloride (13.64%)	33286-22-5	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 508 mg/kg; Ingestion/Oral-Rat LD50 • 560 mg/kg; Behavioral: Antipsychotic

GHS Properties	Classification
Acute toxicity	UN GHS 3 • Acute Toxicity - Oral 4
Skin corrosion/Irritation	UN GHS 3 • Classification criteria not met
Serious eye damage/Irritation	UN GHS 3 • Classification criteria not met
Skin sensitization	UN GHS 3 • Classification criteria not met
Respiratory sensitization	UN GHS 3 • Classification criteria not met
Aspiration Hazard	UN GHS 3 • Classification criteria not met
Carcinogenicity	UN GHS 3 • Classification criteria not met
Germ Cell Mutagenicity	UN GHS 3 • Classification criteria not met
Toxicity for Reproduction	UN GHS 3 • Toxic to Reproduction 2
STOT-SE	UN GHS 3 • Specific Target Organ Toxicity Single Exposure 2
STOT-RE	UN GHS 3 • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected. Exposure to dust from broken capsules may cause irritation.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may cause irritation.

Skin

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may cause irritation.

Eye

- Acute (Immediate)**
 - May cause mild eye irritation with direct contact to eye.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - May affect the heart and/or cardiovascular system. Symptoms may include hypotension, bradycardia, heart block and cardiac failure. Toxic if ingested in excess of prescription dose.
- Chronic (Delayed)**
 - No data available

Carcinogenic Effects		
	CAS	IARC
Colloidal silicon dioxide	7631-86-9	Group 3-Not Classifiable

Reproductive Effects

- Pregnancy category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times (on a mg/kg basis) the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was an increased incidence of stillbirths at doses of 20 times the human dose or greater. Diltiazem is excreted in human milk. One report

suggests that concentrations in breast milk may approximate serum levels.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Diltiazem hydrochloride	33286-22-5	No	Yes	No
Methylparaben	99-76-3	Yes	Yes	Yes

D&C Yellow #10	8004-92-0	Yes	No	Yes
Microcrystalline cellulose	9004-34-6	Yes	Yes	Yes
Colloidal silicon dioxide	7631-86-9	Yes	Yes	Yes
Lactose monohydrate	64044-51-5	No	No	No
Hydroxypropyl methyl cellulose	9004-64-2	Yes	No	Yes
Magnesium stearate	557-04-0	Yes	Yes	Yes

Canada

Labor		
Canada - WHMIS 1988 - Classifications of Substances		
• Methylparaben	99-76-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Microcrystalline cellulose	9004-34-6	Uncontrolled product according to WHMIS classification criteria (including microcrystalline and paper fibers)
• D&C Yellow #10	8004-92-0	Not Listed
• Diltiazem hydrochloride	33286-22-5	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hydroxypropyl methyl cellulose	9004-64-2	Uncontrolled product according to WHMIS classification criteria
• Colloidal silicon dioxide	7631-86-9	Uncontrolled product according to WHMIS classification criteria
Canada - WHMIS 1988 - Ingredient Disclosure List		
• Methylparaben	99-76-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• D&C Yellow #10	8004-92-0	Not Listed
• Diltiazem hydrochloride	33286-22-5	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hydroxypropyl methyl cellulose	9004-64-2	Not Listed
• Colloidal silicon dioxide	7631-86-9	1 %

United States - California

Environment		
U.S. - California - Proposition 65 - Carcinogens List		
• Methylparaben	99-76-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• D&C Yellow #10	8004-92-0	Not Listed
• Diltiazem hydrochloride	33286-22-5	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hydroxypropyl methyl cellulose	9004-64-2	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Methylparaben	99-76-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• D&C Yellow #10	8004-92-0	Not Listed
• Diltiazem hydrochloride	33286-22-5	developmental toxicity, 2/27/2001
• Lactose monohydrate	64044-51-5	Not Listed
• Hydroxypropyl methyl cellulose	9004-64-2	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Methylparaben	99-76-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• D&C Yellow #10	8004-92-0	Not Listed
• Diltiazem hydrochloride	33286-22-5	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hydroxypropyl methyl cellulose	9004-64-2	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Methylparaben	99-76-3	Not Listed
• Magnesium stearate	557-04-0	Not Listed
• Microcrystalline cellulose	9004-34-6	Not Listed
• D&C Yellow #10	8004-92-0	Not Listed
• Diltiazem hydrochloride	33286-22-5	Not Listed
• Lactose monohydrate	64044-51-5	Not Listed
• Hydroxypropyl methyl cellulose	9004-64-2	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed

Section 16 - Other Information

Revision Date	• 12/October/2016
Last Revision Date	• 12/October/2016
Preparation Date	• 12/October/2016
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