

Product Name: Cardizem LA
Issued: Jun-12-2013

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Cardizem LA

Synonyms: Cardizem LA tablets; Cardizem LA 120mg Tablets; Cardizem LA 180 mg Tablets; Cardizem LA 240mg Tablets; Cardizem LA 300 mg Tablets; Cardizem LA 360 mg Tablets; Cardizem LA 420 mg Tablets; Diltiazem HCL Extended Release Tablets; Diltiazem Tablets; Dilfar; Dilfar Tablets; Herbesser; Herbesser Tablets

Trade name: Cardizem

List Number: 3045; 3061; 3062; 3063; 3064; 3069; G877

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Manufactured for:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute oral toxicity	Category 4
Reproductive toxicity	Category 2
Specific target organ systemic toxicity (repeated exposure)	Category 2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xn - Harmful

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Section 2. Hazards identification

Risk Phrases: R22 - Harmful if swallowed
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed
R63 - Possible risk of harm to the unborn child

2.2 Label elements



Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed
H361 - Suspected of damaging fertility or the unborn child
H373 - May cause damage to organs through prolonged or repeated exposure

P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P281 - Use personal protective equipment as required
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P308 + P313 - IF exposed or concerned: Get medical advice/attention

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Diltiazem Hydrochloride 33286-22-5	20-40	Present	Xn; R22 Xn, R48/22 R63	Acute Tox. 4 (H302) STOT RE 2 (H373) Repro. 2 (H361)	No data available
Magnesium Stearate 557-04-0	Proprietary	Present		Not Hazardous*	No data available
Titanium Dioxide 13463-67-7	Proprietary	Present		Not Hazardous*	No data available
Talc, Nonasbestos Containing 14807-96-6	Proprietary	Present		Not Hazardous*	No data available
Polyethylene Glycols 25322-68-3	Proprietary	NA		Not Hazardous*	No data available
Colloidal Silicon Dioxide 7631-86-9	Proprietary	Present		Not Hazardous*	No data available

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Section 3. Composition/information on ingredients

Carnauba Wax 8015-86-9	Proprietary	Present		Not Hazardous*	No data available
Croscarmellose Sodium 9000-11-7	Proprietary	NA		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	Proprietary	Present		Not Hazardous*	No data available
Hydroxypropyl Methylcellulose 9004-65-3	Proprietary	NA		Not Hazardous*	No data available
Starch 9005-25-8	Proprietary	Present		Not Hazardous*	No data available
Polysorbate 80 9005-65-6	Proprietary	NA		Not Hazardous*	No data available
Sodium Starch Glycolate 9063-38-1	Proprietary	NA		Not Hazardous*	No data available
Mamma Copolymer (Methyl Acrylate-Methylmethacrylate Copolymer)	Proprietary	NA		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Clinical data suggests the following: edema, headaches, nausea, rash, excessive urination, cardiac changes, constipation, dyspepsia, decreased blood pressure, slow heart rate, sleep, muscle weakness, insomnia, dizziness.

Medical Conditions
Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: kidney, liver, heart. Concurrent use of medications. Hypersensitivity to the material and/or similar materials.

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4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

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Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Diltiazem Hydrochloride 33286-22-5	20 mcg/m ³ TWA	None
Magnesium Stearate 557-04-0	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None
Talc, Nonasbestos Containing 14807-96-6	Not Applicable	None
Polyethylene Glycols 25322-68-3	Not Applicable	None
Colloidal Silicon Dioxide 7631-86-9	Not Applicable	None
Carnauba Wax 8015-86-9	Not Applicable	None
Croscarmellose Sodium 9000-11-7	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Starch 9005-25-8	Not Applicable	None
Polysorbate 80 9005-65-6	Not Applicable	None
Sodium Starch Glycolate 9063-38-1	Not Applicable	None
Mamma Copolymer (Methyl Acrylate-Methylmethacrylate Copolymer)	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Magnesium Stearate 557-04-0	10 mg/m ³ total dust				
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Talc, Nonasbestos Containing 14807-96-6	2 mg/m ³ , respirable dust			10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	
Polyethylene Glycols 25322-68-3			1000 mg/m ³ TWA		
Colloidal Silicon Dioxide 7631-86-9	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate		4 mg/m ³ TWA	6 mg/m ³ (TWA) 2.4 mg/m ³ (TWA) 6 mg/m ³ (TWA)	
Croscarmellose Sodium 9000-11-7	10 mg/m ³ as nuisance dust, 3 mg/m ³ for respirable particulate				
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Starch 9005-25-8	10 mg/m ³ total dust for Starch			10 mg/m ³ (TWA) 4 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Sodium Starch Glycolate 9063-38-1	10 mg/m ³ , Total dust for Starch				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Titanium Dioxide 13463-67-7		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)

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Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m ³ (TWA)	2 mg/m ³ (TWA)	2 mg/m ³ (TWA)	3 mg/m ³ (STEL) 1 mg/m ³ (TWA)
Polyethylene Glycols 25322-68-3			1000 ppm (TWA)	
Colloidal Silicon Dioxide 7631-86-9			0.3 mg/m ³ (TWA)	18 mg/m ³ (STEL) 7.2 mg/m ³ (STEL) 18 mg/m ³ (STEL) 6 mg/m ³ (TWA) 2.4 mg/m ³ (TWA)
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Starch 9005-25-8		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 30 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)

8.2. Exposure controls

Engineering Controls:	No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.
Respiratory Protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
Other PPE Data:	Wear appropriate body coverings if contact may occur.
Environmental Exposure Controls:	Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	White Oval tablet
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.

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Vapor Density (Air = 1): Not determined.
Specific Gravity: Not determined.
Solubility(ies): Not determined.
Partition coefficient: n-octanol/water Not determined.
Autoignition Temp. (°C): Not determined.
Decomposition temperature (°C): Not determined.
Viscosity (centipoise): Not determined.
Explosion Severity: Not determined.
Oxidizer Properties: Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Diltiazem Hydrochloride 33286-22-5	LD50 =	470-810	mg/kg	Mice Rats
Polyethylene Glycols 25322-68-3	LD50 =	33,750	mg/kg	Rats

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Chemical Name	Acute Test	Value	Units	Species
Colloidal Silicon Dioxide 7631-86-9	LD50 =	3160	mg/kg	Rats
Croscarmellose Sodium 9000-11-7	LD50 >	5050	mg/kg	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Polysorbate 80 9005-65-6	LD50 =	25,000 - 36,570	mg/kg	Mice Rats
Mamma Copolymer (Methyl Acrylate- Methylmethacrylate Copolymer)	LD50 >	10,000	mg/kg	Rats Mice

Acute Toxicity - Dermal: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Polyethylene Glycols 25322-68-3	LD50 >	20,000	mg/kg	Rabbits
Croscarmellose Sodium 9000-11-7	LD50 >	2000	mg/kg	Rabbits
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 1 hour	Rats
Colloidal Silicon Dioxide 7631-86-9	LC 50 >	200	mg/L, 1 hour	Rats
Croscarmellose Sodium 9000-11-7	LC 50 >	0.13	mg/L, 4 hour	Rats
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m ³ , 4 hour	Rats

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Diltiazem Hydrochloride 33286-22-5	LD50 (sc) = LD50 (iv) =	260 - 550 38 - 61	mg/kg	Rats Mice Rats Mice	

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Diltiazem Hydrochloride 33286-22-5	Liver Kidney	Rats Dogs	25 20	mg/kg	Oral	6 months
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years
Colloidal Silicon Dioxide 7631-86-9	Respiratory System	Rats	126	mg/L	Inhalation	2 years

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Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Mamma Copolymer (Methyl Acrylate-Methylmethacrylate Copolymer)	None	Rats Dogs	125-500 40-160	mg/kg	Oral Not Specified	90 days 1 year

Reproductive Effects: Active Ingredient : In animals adverse reproductive effects include: fetal toxicity, fetal abnormalities.
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Diltiazem Hydrochloride 33286-22-5	Rats Rabbits Mice	80 12.5 25	mg/kg	Intraperitoneal	During Gestation

Carcinogenicity: Active ingredient : Not carcinogenic in animal study.
Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years
Talc, Nonasbestos Containing 14807-96-6	Lungs	Rats	18	Inhalation	mg/m ³ , 6 hours	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Diltiazem Hydrochloride 33286-22-5	Negative	Negative	No Data.	Negative

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	Proprietary	5000	Brachydanio rerio	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	Proprietary	7600	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Colloidal Silicon Dioxide 7631-86-9	Proprietary	440	Unicellular Green Algae	72 Hours

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12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- 14.1. UN Number:** Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

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

International Inventories

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Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Diltiazem Hydrochloride 33286-22-5	Present	-	-	Not listed.	-
Magnesium Stearate 557-04-0	Present	X	X	Not listed.	X
Titanium Dioxide 13463-67-7	Present	X	X	Not listed.	X
Talc, Nonasbestos Containing 14807-96-6	Present	X	X	Not listed.	X
Polyethylene Glycols 25322-68-3	-	X	X	Not listed.	X
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed.	X
Carnauba Wax 8015-86-9	Present	X	X	Not listed.	X
Croscarmellose Sodium 9000-11-7	-	X	X	Not listed.	X
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Starch 9005-25-8	Present	X	X	Not listed.	X
Polysorbate 80 9005-65-6	-	X	X	Not listed.	X
Sodium Starch Glycolate 9063-38-1	-	X	X	Not listed.	X
Mamma Copolymer (Methyl Acrylate- Methylmethacrylate Copolymer)	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Diltiazem Hydrochloride 33286-22-5	Present	-	-	X	-	HSR007028
Magnesium Stearate 557-04-0	Present	-	X	X	Present	
Titanium Dioxide 13463-67-7	Present	-	X	X	Present	
Talc, Nonasbestos Containing 14807-96-6	Present	-	X	X	Present	
Polyethylene Glycols 25322-68-3	Present	-	X	X	Present	
Colloidal Silicon Dioxide 7631-86-9	Present	-	X	X	Present	
Carnauba Wax 8015-86-9	-	-	X	X	Present	
Croscarmellose Sodium 9000-11-7	Present	-	X	X	Present	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	
Starch 9005-25-8	Present	-	X	X	Present	
Polysorbate 80 9005-65-6	Present	-	X	X	Present	
Sodium Starch Glycolate 9063-38-1	Present	-	X	X	Present	
Mamma Copolymer (Methyl Acrylate- Methylmethacrylate Copolymer)	-	-	-	-	-	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

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IECSC - China Inventory of Existing Chemical Substances
 AICS - Australian Inventory of Chemical Substances
 KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Diltiazem Hydrochloride	20-40	Not Listed	Not Listed	Not Listed
Magnesium Stearate	Proprietary	Not Listed	Not Listed	Not Listed
Titanium Dioxide	Proprietary	Not Listed	Not Listed	Not Listed
Talc, Nonasbestos Containing	Proprietary	Not Listed	Not Listed	Not Listed
Polyethylene Glycols	Proprietary	Not Listed	Not Listed	Not Listed
Colloidal Silicon Dioxide	Proprietary	Not Listed	Not Listed	Not Listed
Carnauba Wax	Proprietary	Not Listed	Not Listed	Not Listed
Croscarmellose Sodium	Proprietary	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	Proprietary	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	Proprietary	Not Listed	Not Listed	Not Listed
Starch	Proprietary	Not Listed	Not Listed	Not Listed
Polysorbate 80	Proprietary	Not Listed	Not Listed	Not Listed
Sodium Starch Glycolate	Proprietary	Not Listed	Not Listed	Not Listed
Mamma Copolymer (Methyl Acrylate-Methylmethacrylate Copolymer)	Proprietary	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Diltiazem Hydrochloride	20-40	No	Not Applicable	Not applicable
Magnesium Stearate	Proprietary	No	Not Applicable	Not applicable
Titanium Dioxide	Proprietary	No	Not Applicable	Not applicable
Talc, Nonasbestos Containing	Proprietary	No	Not Applicable	Not applicable
Polyethylene Glycols	Proprietary	No	Not Applicable	Not applicable
Colloidal Silicon Dioxide	Proprietary	No	Not Applicable	Not applicable
Carnauba Wax	Proprietary	No	Not Applicable	Not applicable
Croscarmellose Sodium	Proprietary	No	Not Applicable	Not applicable
Cellulose Microcrystalline	Proprietary	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	Proprietary	No	Not Applicable	Not applicable
Starch	Proprietary	No	Not Applicable	Not applicable
Polysorbate 80	Proprietary	No	Not Applicable	Not applicable
Sodium Starch Glycolate	Proprietary	No	Not Applicable	Not applicable
Mamma Copolymer (Methyl Acrylate-Methylmethacrylate Copolymer)	Proprietary	No	Not Applicable	Not applicable

Immediate Health: No
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Chemical Name	Percent	Proposition 65 Listed Materials
Diltiazem Hydrochloride	20-40	developmental toxicity; initial date 2/23/01.

WHMIS Hazard Class: Not determined.

NFPA Rating:
 Health: 1
 Fire: 1

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Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R22 - Harmful if swallowed, R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed, R63 - Possible risk of harm to the unborn child

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed, H373 - May cause damage to organs (a,b,c) through prolonged or repeated exposure if inhaled, H361 - Suspected of damaging fertility or the unborn child if inhaled

Document Authored By: Global Occupational Toxicology (D-03QC)

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Supersedes the SDS dated: Dec-09-2011

Disclaimer:

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