



DILTIAZEM HYDROCHLORIDE

Piramal Pharma Limited

Chemwatch Hazard Alert Code: 2

Chemwatch: 20439-4

Version No: 6.1.1.1

Safety Data Sheet

Issue Date: 11/12/2016

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SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	DILTIAZEM HYDROCHLORIDE
Chemical Name	diltiazem hydrochloride
Synonyms	C22-H27-Cl-N2-O4-S; 1,5-benzothiazepin-4(5H)-one,; 2,3-dihydro-3-(acetyloxy)-5-(2-dimethylamino)ethyl)-2-(4-methoxyphenyl)-, monohydrochloride, cis-(+); Altiazem; Anginyl; Angizem; Britiazim; Bruzem; Cadizem; Calcicard; Cardiem; Cardizem; Coras; CRD-401; CRP-401; Dilpral; Diltiazem Chloridate; Dilzem; Herbesser; Masdil; Tildiem; anti-adrenergic vasodilator
Chemical formula	C22H26N2O4S.ClH
Other means of identification	Not Available
CAS number	33286-22-5

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

Relevant identified uses	Vasodilator used in the management of angina pectoris. Calcium-channel blocker (blocks L-type calcium channels); regulates calcium ion release from intracellular stores in neutrophils.
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Details of the supplier of the safety data sheet

Registered company name	Piramal Pharma Limited
Address	Sy.No. 7-70,70/1 &70/2 Digwal Village, Kohir Mandal, Sangareddy District, Telangana 502321 India
Telephone	09652545670
Fax	Not Available
Website	Not Available
Email	b.jaganmohan.reddy@piramal.com

Emergency telephone number






Association / Organisation	Piramal Pharma Limited
Emergency telephone numbers	08451- 300999
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

Classification of the substance or mixture

ChemWatch Hazard Ratings


DILTIAZEM HYDROCHLORIDE

	Min	Max
Flammability	1	
Toxicity	2	
Body Contact	1	
Reactivity	1	
Chronic	2	

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Classification	Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 5, Carcinogenicity Category 2, Chronic Aquatic Hazard Category 3, Acute Toxicity (Dermal) Category 5, Reproductive Toxicity Category 2, Lactation Effects, Acute Aquatic Hazard Category 3
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Label elements

Hazard pictogram(s)	
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Signal word	Warning
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Hazard statement(s)

H302	Harmful if swallowed.
H333	May be harmful if inhaled.
H351	Suspected of causing cancer.
H412	Harmful to aquatic life with long lasting effects.
H313	May be harmful in contact with skin.
H361	Suspected of damaging fertility or the unborn child.
H362	May cause harm to breast-fed children.

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume.
P263	Avoid contact during pregnancy/while nursing.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.
P304+P312	IF INHALED: Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P330	Rinse mouth.

Precautionary statement(s) Storage

P405	Store locked up.
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Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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SECTION 3 Composition / information on ingredients

Substances

CAS No	%[weight]	Name
33286-22-5	>98	<u>diltiazem hydrochloride</u>

Mixtures

See section above for composition of Substances

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▸ Wash out immediately with fresh running water. ▸ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▸ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▸ Immediately remove all contaminated clothing, including footwear. ▸ Flush skin and hair with running water (and soap if available). ▸ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▸ If fumes or combustion products are inhaled remove from contaminated area. ▸ Lay patient down. Keep warm and rested. ▸ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▸ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▸ Transport to hospital, or doctor.
Ingestion	<ul style="list-style-type: none"> ▸ IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. ▸ For advice, contact a Poisons Information Centre or a doctor. ▸ Urgent hospital treatment is likely to be needed. ▸ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. ▸ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist. ▸ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. <p>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</p> <ul style="list-style-type: none"> ▸ INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. <p>NOTE: Wear a protective glove when inducing vomiting by mechanical means.</p>

Indication of any immediate medical attention and special treatment needed

The highly lipophilic characteristics, high protein binding and extensive volume of distribution of calcium channel blockers makes haemodialysis, diuresis, and haemoperfusion impractical. Calcium gluconate has been used successfully to reverse hypotension. In dog models relatively small amounts of calcium reverse negative inotropic effects, even when exacerbated by propranolol.

For significant overdose of calcium channel blockers:

- patients should receive cardiac monitoring for 4-6 hours and an electrocardiogram (ECG).
- patients with conduction effects or signs of myocardial depression should be admitted to a monitored bed.
- Asymptomatic patients may then be discharged after appropriate counselling.
- The usual therapeutic measures for hypotension and bradycardia (atropine, isoproterenol, pacings) are appropriate together with calcium infusions.
- Other calcium channel blockers, digoxin, beta-blockers and Class I drugs should be avoided.

Ellenhorn, M.J., and Barceloux D.G.; Medical Toxicology - Diagnosis and Treatment of Human Poisoning. 1988.

Treat symptomatically.

In the event of oral diltiazem overdose, treatment may include the following: Employ supportive measures in addition to gastrointestinal decontamination. For hypotension, administer vasopressors. For bradycardia administer atropine. If there is no response to vagal blockade, administer isoproterenol cautiously. For high-degree AV blocks, treat for bradycardia. Fixed high-degree AV block should be treated with cardiac pacing. For cardiac failure, administer inotropic agents (isoproterenol, dopamine or dobutamine) and diuretics. Limited data suggests that plasmapheresis of charcoal haemoperfusion may hasten elimination but peritoneal or haemodialysis is NOT effective. PDR 55 th ed. 2001 USP MSDS

SECTION 5 Firefighting measures

Extinguishing media

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

Special hazards arising from the substrate or mixture

Fire Incompatibility

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may

Continued...

DILTIAZEM HYDROCHLORIDE

result

Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). ▶ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion. <p>Combustion products include: carbon monoxide (CO) carbon dioxide (CO₂) hydrogen chloride phosgene nitrogen oxides (NO_x) sulfur oxides (SO_x) other pyrolysis products typical of burning organic material. May emit poisonous fumes.</p> <p>Dusts with Minimum Ignition Energies (MIEs) ranging between 20 and 100 mJ may be sensitive to ignition. They require that:</p> <ul style="list-style-type: none"> -plant is grounded -personnel might also need to be grounded -the use of high resistivity materials (such as plastics) should be restricted or avoided during handling or in packaging <p>The majority of ignition accidents occur within or below this range. The MIE of a dust/air mix depends on the particle size the water content and the temperature of the dust. The finer and the dryer the dust the lower the MIE.</p> <p>Dust Explosion Hazard Class 2</p> <p>Dusts fall into one of three Kst* classes. Class 1 dusts; Kst 1-200 m³/sec; Class 2 dusts; 201-299 m³/sec. Class 3 dusts; Kst 300 or more. Most agricultural dusts (grains, flour etc.) are Class 1; pharmaceuticals and other speciality chemicals are typically Class 1 or 2; most unoxidised metallic dusts are Class 3. Minimum Ignition Temperature (MIE): 30 lt;MIE lt;100 mJ</p>

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up waste regularly and abnormal spills immediately. ▶ Avoid breathing dust and contact with skin and eyes. ▶ Wear protective clothing, gloves, safety glasses and dust respirator. ▶ Use dry clean up procedures and avoid generating dust.
Major Spills	<p>Moderate hazard.</p> <ul style="list-style-type: none"> ▶ CAUTION: Advise personnel in area. ▶ Alert Emergency Services and tell them location and nature of hazard. ▶ Control personal contact by wearing protective clothing.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation.
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	<ul style="list-style-type: none"> ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps. ▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions) ▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame. ▶ Establish good housekeeping practices. ▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
Other information	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry area protected from environmental extremes. ▶ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Glass container is suitable for laboratory quantities ▶ Polyethylene or polypropylene container. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
DILTIAZEM HYDROCHLORIDE	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
diltiazem hydrochloride	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
diltiazem hydrochloride	E	≤ 0.01 mg/m ³

Notes:

Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.


Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware.

Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

Exposure controls

Appropriate engineering controls	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.</p> <p>HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.</p> <p>Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.</p> <p>A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p> <p>Assess operations based upon available dust explosion information to determine the suitability of preventative or protective systems as precautionary measures against possible dust explosions. If prevention is not possible, consider protection by use of containment, venting or suppression of dust handling equipment. Where explosion venting is considered to be the most appropriate method of protection, vent areas should preferably be calculated based on Kst rather than an St value. If nitrogen purging is considered as the protective system, it must operate with an oxygen level below the limiting oxygen concentration.</p>
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DILTIAZEM HYDROCHLORIDE

Personal protection	
Eye and face protection	When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: <ul style="list-style-type: none"> ▸ Chemical goggles. ▸ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.
Skin protection	See Hand protection below
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care. <ul style="list-style-type: none"> ▸ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. ▸ Double gloving should be considered. ▸ PVC gloves. Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present. <ul style="list-style-type: none"> ▸ polychloroprene. ▸ nitrile rubber. ▸ butyl rubber.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▸ For quantities up to 500 grams a laboratory coat may be suitable. ▸ For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. ▸ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

Respiratory protection

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3 Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

SECTION 9 Physical and chemical properties**Information on basic physical and chemical properties**

Appearance	White to off-white odourless powder with bitter taste; mixes with water(50 mg/ml), alcohol, chloroform.
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DILTIAZEM HYDROCHLORIDE

Physical state	Divided Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	2.7
Odour threshold	Not Available	Auto-ignition temperature (°C)	380
pH (as supplied)	Not Applicable	Decomposition temperature	240
Melting point / freezing point (°C)	187-188; 207-215	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	451.00
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Negligible
Vapour pressure (kPa)	Negligible	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Applicable	VOC g/L	Not Applicable

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	<p>The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.</p> <p>Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.</p>
Ingestion	<p>Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.</p> <p>When given by mouth or by injection, in therapeutic doses, vasodilators may produce transient flushing of the face, a sensation of heat, a pounding in the head, peripheral oedema, headache, hypotension, palpitations, dizziness and fatigue. Most reactions are dose dependent and transient. High doses may cause flushing and dryness of the skin, skin lesions, abdominal cramps, diarrhoea, nausea, vomiting, malaise, anorexia, activation of peptic ulcer, jaundice and impairment of liver function, decrease in glucose tolerance, mild diabetes and hyperuricaemia. Most of these effects subside with withdrawal of the drug.</p> <p>Large doses of calcium channel blocking agents may produce nausea, weakness, dizziness, drowsiness, confusion and slurred speech. Marked and prolonged hypotension and bradycardia may result from second or third degree atrioventricular block, decreased cardiac output and junctional rhythms; death may ensue.</p> <p>May cause gastrointestinal disturbance, orthostatic hypotension, and bradycardia. Adverse effects of diltiazem may include headache, nausea, difficult breathing, coughing or wheezing, constipation, diarrhoea, dizziness or lightheadedness, swelling of feet ankles, or lower legs, flushing or feelings of warmth, skin rash, and unusual tiredness or weakness. Symptoms of diltiazem</p>

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	overdose may include a slow heart rate, low blood pressure, heart block and cardiac failure.
Skin Contact	<p>The material is not thought to be a skin irritant (as classified by EC Directives using animal models). Abrasive damage however, may result from prolonged exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.</p> <p>Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
Eye	<p>Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.</p> <p>The material may produce foreign body irritation in certain individuals.</p>
Chronic	<p>On the basis, primarily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment.</p> <p>Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, generally on the basis that results in appropriate animal studies provide strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.</p> <p>Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.</p> <p>Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.</p> <p>Therapeutic effects caused by long-term use of calcium channel blocking agents include cardiovascular effects such as peripheral oedema, rebound vasospasm, palpitation, congestive heart failure, tachycardia, hypertension, and abnormal ECG. Other effects may include neurological deficits, headache, vomiting, diarrhoea, abdominal discomfort, gastrointestinal haemorrhage, hepatitis and jaundice, dermatitis, acne, itching, anaemia, thrombocytopenia and a disseminated intravascular coagulation. Haematoma and deep vein thrombosis may occur.</p> <p>Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur. An individual may be predisposed to such antibody mediated reaction if other chemical agents have caused prior sensitisation (cross-sensitivity).</p> <p>Animal studies employing dose rates greater than 5 to 10 times the equivalent dose recommended for humans resulted in embryo and foetal deaths, reduced neonatal survival rates, and skeletal abnormalities. FDA Pregnancy Category C] A 24-month study in rats and a 21-month study in mice produced evidence of carcinogenic response.</p>

	TOXICITY	IRRITATION
diltiazem hydrochloride	21 mg/kg ^[2]	Not Available
	8.4 mg/kg ^[2]	
	Oral (mouse) LD50: 508 mg/kg ^[2]	
	Oral (rat) LD50: 560 mg/kg ^[2]	

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

DILTIAZEM HYDROCHLORIDE	Some reprotoxic effects have been observed in animals. Insufficient data in humans: discouraged during pregnancy. Breastfeeding contra-indicated. (Sanofi SDS)
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Acute Toxicity	✓	Carcinogenicity	✓
Skin Irritation/Corrosion	✗	Reproductivity	✓
Serious Eye Damage/Irritation	✗	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

Legend: ✗ – Data either not available or does not fill the criteria for classification
✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

DILTIAZEM HYDROCHLORIDE

	Endpoint	Test Duration (hr)	Species	Value	Source
diltiazem hydrochloride	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Harmful to aquatic organisms.

May cause long-term adverse effects in the aquatic environment.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

DO NOT discharge into sewer or waterways.

Biodegradability (28 d): 2% (OECD 301 F); not readily biodegradable according to OECD criteria Unlikely to bioaccumulated in living organisms (log Kow lt;4)

Daphnia magna EC50 (48 h): 22.4 mg/l (OECD 202) Algae EC50 (72 h): Desmodesmus subspicatus 33.5 mg/ (OECD 201)

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ Containers may still present a chemical hazard/ danger when empty. ▶ Return to supplier for reuse/ recycling if possible. Otherwise: <ul style="list-style-type: none"> ▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority.
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SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
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Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

DILTIAZEM HYDROCHLORIDE

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15 Regulatory information

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

diltiazem hydrochloride is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

National Inventory Status

National Inventory	Status
Australia - AIC	No (diltiazem hydrochloride)
Australia - Non-Industrial Use	Yes
Canada - DSL	No (diltiazem hydrochloride)
Canada - NDSL	No (diltiazem hydrochloride)
China - IECSC	No (diltiazem hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (diltiazem hydrochloride)
Korea - KECI	No (diltiazem hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (diltiazem hydrochloride)
USA - TSCA	No (diltiazem hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	No (diltiazem hydrochloride)
Russia - ARIPS	Yes
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 Other information

Revision Date	11/12/2016
Initial Date	Not Available

SDS Version Summary

Version	Issue Date	Sections Updated
5.1.1.1	01/05/2012	Appearance, Chronic Health, Classification, Environmental, Fire Fighter (fire/explosion hazard), Physical Properties, Spills (major), Spills (minor), Storage (storage requirement), Supplier Information, Transport, Transport Information
6.1.1.1	11/12/2016	Appearance, Chronic Health, Classification, Disposal, Engineering Control, Environmental, Fire Fighter (fire/explosion hazard), Physical Properties, Spills (major), Spills (minor), Toxicity and Irritation (Other), Transport, Transport Information

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit,
IDLH: Immediately Dangerous to Life or Health Concentrations
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index

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