Section 1: Identification

Common Name/Trade Name	DILTIAZEM HYDROCHLORIDE USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	**IN CASE OF EMERGENCY:** Chemtrec 1 (800) 424-9300 **(24 hours)** NSW Poisons Information Centre: 131 126 (24 hours)
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	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	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	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	
Signal Word	Warning	
Hazard Statement(s)	H302 H313 H333 H351 H361 H362 H412	Harmful if swallowed May be harmful in contact with skin May be harmful if inhaled Suspected of causing cancer Suspected of damaging fertility or the unborn child May cause harm to breast-fed children Harmful to aquatic life with long-lasting effects
Pictogram(s)		
Precautionary Statement(s)	P201 P202 P260 P263 P264 P270 P273 P280 P281 P301+P312 P304+P312 P308+P313 P312 P330 P405 P501	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact during pregnancy/while nursing. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. Use personal protective equipment as required. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. IF INHALED Call a POISON CENTER or doctor/physician if you feel unwell. IF exposed or concerned Get medical advice/attention. Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Store locked up. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	CRD-401 (2S,3S)-(+)-cis-3-Acetoxy-5-(2-dimethylaminoethyl)-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-onehydrochloride
Common Name	Diltiazem hydrochloride
CAS Number	33286-22-5
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.
If Inhaled	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.
In Case of Skin Contact	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.
In Case of Eye Contact	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.
If Swallowed	For advice, contact a Poisons Information Centre or a doctor. Urgent hospital treatment is likely to be needed. In the meantime, 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. Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise: 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. NOTE: Wear a protective glove when inducing vomiting by mechanical means.
Most Important Symptoms and Effects	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 make haemodialyis, 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 plasmaphersis of charcoal haemoperfusion may hasten elimination but peritoneal or haemodialysis is NOT effective. PDR 55 th ed. 2001 USP MSDS

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Water spray or fog. Foam. Dry chemical powder. BCF (where regulations permit).
Special Hazards Arising From the Substance/Mixture	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result. 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. Combustion products include: carbon monoxide (CO) carbon dioxide (CO_2) hydrogen chloride phosgene nitrogen oxides (NOx) sulfur oxides (SOx) other pyrolysis products typical of burning organic material. May emit poisonous fumes.
Special PPE and/or Precautions for Firefighters	Wear breathing apparatus plus protective gloves. Alert Fire Brigade and tell them location and nature of hazard. 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.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Minor Spills: Wear protective clothing, gloves, safety glasses, and dust respirator. Major Spills: Control personal contact by wearing protective clothing.
Methods and Materials Used for Containment	Use dry clean up procedures and avoid generating dust.
Cleanup Procedures	Minor Spills: 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: CAUTION: Advise personnel in area. Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid all personal contact, including inhalation. 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.
Conditions for Safe Storage	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. Avoid reaction with oxidizing agents

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Occupational Exposure Banding: Rating E, Exposure Band Limit: < / = 0.01 mg/m3. 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.
Appropriate Engineering Controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. 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.
PPE - Eye/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: Chemical goggles. Face shield. Full-face shield may be required for supplementary but never for primary protection of eyes.
PPE - Skin 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. 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. polychloroprene. nitrile rubber. butyl rubber.
PPE - Body Protection	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.
PPE - Respiratory Protection	Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:001, ANSI Z 88 or national equivalent). 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

Appearance	White to off-white odourless powder with bitter taste; mixes with water (50 mg/ml), alcohol, chloroform.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	Melting/freezing point (C): 187-188; 207-215
Solubility	Miscible in water.
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	Not applicable
Flammability (Solid, Gas)	No data available
Partition Coefficient	n-octanol / water: 2.7
Auto-Ignition Temperature	380°C
Decomposition Temperature	240°C
Viscosity	Not Applicable

Section 10: Stability and Reactivity

Reactivity	No data available
Chemical Stability	Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of Hazardous Reactions	No data available
Conditions to Avoid	No data available
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	No data available

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	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]. Harmful if swallowed. 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.
Acute Toxicity - Inhalation	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. 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. May be harmful if inhaled. 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.
Acute Toxicity - Dermal	May be harmful in contact with skin. 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. Skin contact with the material may damage the health of the individual.
Acute Toxicity - Eye	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. The material may produce foreign body irritation in certain individuals.
Skin Corrosion/Irritation	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. Skin contact with the material may damage the health of the individual
Serious Eye Damage/Irritation	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. The material may produce foreign body irritation in certain individuals.
Respiratory or Skin Sensitization	No data available
Germ Cell Mutagenicity	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.
Carcinogenicity IARC	No data available. Suspected of causing cancer.
Carcinogenicity ACGIH	No data available. Suspected of causing cancer.
Carcinogenicity NTP	No data available. Suspected of causing cancer.
Carcinogenicity OSHA	No data available. Suspected of causing cancer.
Reproductive Toxicity	Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.
Specific Target Organ Toxicity - Single Exposure	No data available
Specific Target Organ Toxicity - Repeated Exposure	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.
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	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	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. Otherwise: If container cannot 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: 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. 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.
Waste Treatment Methods Packaging	See Waste Product.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

diltiazem hydrochloride is found on the following regulatory lists Chemical Footprint Project - Chemicals of High Concern List National Inventory Status National Inventory Status Australia - AIIC 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 - NZIo C 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

Section 16: Other Information

Additional Information	N/A
Prepared By	Scarlotte Smith
Revision Date	08/02/2023 12:11