

Classified as hazardous in accordance with the criteria of EPA New Zealand

Section 1 - Identification

Product Identifier

Product Name	<u>Dilthiazem hydrochloride</u>
CAS No	33286-22-5
Synonyms	1,5-Benzothiazepin-4(5H)-one
Molecular Formula	C22 H26 N2 O4 S . H Cl
Molecular Weight	450.99
Recommended Use	Laboratory chemicals.
Uses advised against	No Information available

Product Code	329080000; 329080010; 329080050; 329080250
Address	Thermo Fisher Scientific New Zealand Ltd 244 Bush Road, Albany, Auckland, New Zealand
Emergency Tel.	CHEMTREC® 09 980 6780 or +64 9 980 6780
Telephone / Fax Numbers	Tel: 09 980 6700 Fax: 09 980 6788
E-mail address	<u>ANZinfo@thermofisher.com</u>

Section 2 - Hazard(s) Identification

Classification under Work Safe New Zealand

Classified as hazardous in accordance with the criteria of EPA New Zealand

HSNO Approval Number **HSR100425**

GHS Classification

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Acute Oral Toxicity	Category 4
Skin Sensitization	Category 1
Carcinogenicity	Category 2
Reproductive Toxicity	Category 2

Environmental hazards

Based on available data, the classification criteria are not met

Label Elements**Signal Word****Warning****Hazard Statements**

H302 - Harmful if swallowed

H317 - May cause an allergic skin reaction

H351 - Suspected of causing cancer

H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements**Prevention**

P270 - Do not eat, drink or smoke when using this product

P264 - Wash face, hands and any exposed skin thoroughly after handling

Response

P330 - Rinse mouth

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Storage

P403 - Store in a well-ventilated place

Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

Other hazards which do not result in classification

Toxic to terrestrial vertebrates

Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %
(2S-cis)-3-Acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride	33286-22-5	>95

Section 4 - First Aid Measures

Description of first aid measures**New Zealand Emergency Tel.**CHEMTREC®
09 980 6780 or +64 9 980 6780**Inhalation**

Remove from exposure, lie down. Remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention.

Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

Skin Contact

Get medical attention. Wash off immediately with plenty of water for at least 15 minutes.

Ingestion

Do NOT induce vomiting. Get medical attention.

Self-Protection of the First Aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

First Aid Facilities Eyewash, safety shower and washroom.

Most important symptoms and effects No information available.

Notes to Physician Treat symptomatically.

Section 5 - Fire Fighting Measures

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Chemical foam.

Extinguishing media which must not be used for safety reasons

No information available.

Specific Hazards Arising from the Chemical

Keep product and empty container away from heat and sources of ignition. Thermal decomposition can lead to release of irritating gases and vapors.

Hazardous Combustion Products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂), Sulfur oxides, Hydrogen chloride gas.

Special protective equipment and precautions for fire fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Emergency procedures

Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust formation.

Environmental Precautions

See Section 12 for additional Ecological Information.

Methods for Containment and Clean Up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

Precautions to prevent secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

Section 7 - Handling and Storage

Precautions for Safe Handling

Advice on safe handling

Avoid contact with skin and eyes. Do not breathe dust. Avoid dust formation. Avoid breathing dust/fume/gas/mist/vapors/spray. Ensure adequate ventilation. Wear personal protective equipment/face protection.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions

Keep container tightly closed in a dry and well-ventilated place. Keep refrigerated. Store under an inert atmosphere.

Incompatible Materials

Strong oxidizing agents.

AS/NZS 2243.10:2004, Safety in laboratories - Storage of chemicals

Section 8 - Exposure Controls and Personal Protection

Control parameters**Exposure limits**

The product does not contain any hazardous materials with occupational exposure limits established.

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Appropriate engineering controls**Engineering Measures**

Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location. Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Individual protection measures, such as personal protective equipment**Eye Protection**

Wear safety glasses with side shields (or goggles) (Australian/New Zealand Standard AS/NZS 1337 - Eye protectors for Industrial applications)

Hand Protection

Protective gloves

Glove material	Breakthrough time	Glove thickness	AUS/NZ Standard	Glove comments
Nitrile rubber, Neoprene, Natural rubber, PVC.	See manufacturers recommendations	-	AS/NZS 2161	(minimum requirement)

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

Skin and body protection

Wear appropriate protective gloves and clothing to prevent skin exposure

Respiratory Protection

Use an AS/NZS 1716 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained in line with AS/NZS 1715 on the use and maintenance of respiratory protective devices (or AUS/NZ equivalent)

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls

No information available.

Section 9 - Physical and Chemical Properties

Information on basic physical and chemical properties

Physical State	Powder Solid	
Appearance	Off-white	
Odor	No information available	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	210 - 215 °C / 410 - 419 °F	
Softening Point	No data available	
Boiling Point/Range	No information available	
Flammability (liquid)	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
Flash Point	No information available	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
Viscosity	Not applicable	Solid
Water Solubility	Soluble	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	No data available	
Vapor Density	Not applicable	Solid
Particle characteristics	No data available	

Other information

Molecular Formula	C22 H26 N2 O4 S . H Cl
Molecular Weight	450.99
Evaporation Rate	Not applicable - Solid

Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	Light sensitive, heat sensitive, Air sensitive.
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available
Hazardous Polymerization	No information available.
Hazardous Reactions	No information available.
Conditions to Avoid	Exposure to light, Avoid dust formation, Exposure to air, Heat.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO ₂). Sulfur oxides. Hydrogen chloride gas.

Section 11 - Toxicological Information**Acute Effects****Information on likely routes of exposure**

Product Information

Inhalation	May cause irritation. May be harmful if inhaled.
Eyes	May cause irritation.
Skin	May cause irritation. May be harmful in contact with skin.
Ingestion	Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Numerical measures of toxicity**(a) acute toxicity;**

Oral	Category 4
Dermal	No data available
Inhalation	No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
(2S-cis)-3-Acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride	LD50 = 560 mg/kg (Rat)	LD50 = 271 mg/kg (Rat)	

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

Respiratory	No data available
Skin	No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available
There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available
Target Organs No information available.

(j) aspiration hazard; Not applicable
Solid

Other Adverse Effects See actual entry in RTECS for complete information The toxicological properties have not been fully investigated.

Symptoms / effects, both acute and delayed
No information available.

Section 12 - Ecological Information

Ecotoxicity

Aquatic ecotoxicity	Do not empty into drains.
Terrestrial ecotoxicity	There is no data for this product
Persistence and Degradability	
Persistence	Soluble in water, Persistence is unlikely, based on information available.
Bioaccumulative Potential	Bioaccumulation is unlikely
Mobility	The product is water soluble, and may spread in water systems. Will likely be mobile in the environment due to its water solubility. Highly mobile in soils
<u>Other adverse effects</u>	
Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors
Persistent Organic Pollutant	This product does not contain any known or suspected substance
Ozone Depletion Potential	This product does not contain any known or suspected substance

Section 13 - Disposal Considerations

Waste treatment methods

Waste from Residues/Unused Products	Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes, including emptied containers, are controlled wastes and should be disposed of in accordance with all federal, E.P.A., state and local regulations. Assure conformity with all applicable regulations.
Contaminated Packaging	Dispose of this container to hazardous or special waste collection point.
Other Information	Disposal agencies or waste contractors must comply with the New Zealand Hazardous Substances (Disposal) Regulations . Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains.

Section 14 - Transport Information

<u>NZS 5433:2020</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG/IMO</u>	Not regulated
Environmental hazards	No hazards identified
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable, packaged goods
Special Precautions	No special precautions required. Please refer to the applicable dangerous goods regulations for additional information.

Additional information None known

Section 15 - Regulatory Information

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

HSNO Approval Number	HSR100425
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National Regulations

There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

Certified handlers, tracking and controlled substance license requirements

Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information. Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information.

Prohibition or notification/licensing requirements

Shown below are details of specific prohibition/notifications or licencing requirements when they apply.

International Regulations

Ozone Depletion Potential This product does not contain any known or suspected substance

Persistent Organic Pollutant This product does not contain any known or suspected substance

Rotterdam Convention (PIC) Not applicable

Authorisation/Restrictions according to EU REACH Not applicable

International Inventories

New Zealand (NZIoC), Australia (AICS), Europe (EINECS/ELINCS/NLP), Korea (KECL), China (IECSC), Taiwan (TCSI), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	NZIoC	AICS	EINECS	ELINCS	NLP	KECL	IECSC	TCSI
(2S-cis)-3-Acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride	33286-22-5	X	-	251-443-3	-	-	-	-	X

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	PICCS	ISHL	ENCS
(2S-cis)-3-Acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride	33286-22-5	-	-	-	-	-	-	-

Legend: X - Listed '-' - Not Listed

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

Section 16 - Other Information

This safety data sheet complies with the requirements of the EPA Hazardous Substances (Hazard Classification) Notice 2020 and WorkSafe New Zealand Regulations

Legend

NZIoC - New Zealand Inventory of Chemicals
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

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

IECSC - Chinese Inventory of Existing Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

NZS 5433:2020 - Transport of Dangerous Goods on Land

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from Ships

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

WEL - Workplace Exposure Limit

DNEL - Derived No Effect Level

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

VOC - (Volatile Organic Compound)

AICS - Australian Inventory of Chemical Substances

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

ENCS - Japanese Existing and New Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

CAS - Chemical Abstracts Service

ACGIH - American Conference of Governmental Industrial Hygienists

PNEC - Predicted No Effect Concentration

OECD - Organisation for Economic Co-operation and Development

IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code

ADG - Australian Code for the Transport of Dangerous Goods by Road and Rail

LC50 - Lethal Concentration 50%

ATE - Acute Toxicity Estimate

RPE - Respiratory Protective Equipment

NOEC - No Observed Effect Concentration

BCF - Bioconcentration factor

PBT - Persistent, Bioaccumulative, Toxic

Key literature references and sources for data

HSNO classifications provided in the New Zealand Chemical Classification Information Database (CCID).

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

EPA Guide to classifying hazardous substances in New Zealand

EPA - Assigning a product to an existing HSNO approval guide

Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

Revision Date 10-Mar-2023
Revision Summary Not applicable

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet