

SAFETY DATA SHEET

Creation Date 26-Jun-2012 Revision Date 25-Mar-2024 Revision Number 3

1. Identification

Product Name (+)-cis-Diltiazem hydrochloride

Cat No. : J63245

CAS No 33286-22-5

Synonyms 1,5-Benzothiazepin-4(5H)-one

Recommended Use Laboratory chemicals.

Uses advised against Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Thermo Fisher Scientific Chemicals, Inc. 30 Bond Street Ward Hill, MA 01835-8099

Tel: 800-343-0660 Fax: 800-322-4757

Emergency Telephone Number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute oral toxicity Category 4

Label Elements

Signal Word

Warning

Hazard Statements

Harmful if swallowed



Precautionary Statements

Prevention

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Rinse mouth

Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

WARNING. Reproductive Harm - https://www.p65warnings.ca.gov/.

3. Composition/Information on Ingredients

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

4. First-aid measures

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.

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.

Ingestion Do NOT induce vomiting. Get medical attention.

Most important symptoms and

effects

No information available.

Notes to Physician Treat symptomatically

5. Fire-fighting measures

Suitable Extinguishing Media Water spray. Carbon dioxide (CO 2). Dry chemical. Chemical foam.

Unsuitable Extinguishing Media No information available

Flash Point No information available Method - No information available

Autoignition Temperature

Explosion Limits

Upper Lower No information available

No data available No data available

Sensitivity to Mechanical Impact No information available Sensitivity to Static Discharge 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 (NOx). Carbon monoxide (CO). Carbon dioxide (CO2). Sulfur oxides. Hydrogen chloride gas.

Protective Equipment and Precautions for Firefighters

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

NFPA

Health 2		Flammability 1	Instability 1	Physical hazards N/A				
		6. Accidental re	ease measures					
Personal	Precautions	Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust formation.						
Environn	nental Precautions	See Section 12 for addition	al Ecological Information.					

Methods for Containment and Clean Sweep up and shovel into suitable containers for disposal. Avoid dust formation. **Up**

	7. Handling and storage
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.
Storage.	Keep container tightly closed in a dry and well-ventilated place. Keep refrigerated. Store under an inert atmosphere. Incompatible Materials. Strong oxidizing agents.

8. Exposure cor	itrols /	personal	protection
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Exposure Guidelines

This product does not contain any hazardous materials with occupational exposure limitsestablished by the region specific regulatory bodies.

Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations

and safety showers are close to the workstation location.

Personal Protective Equipment

Eye/face ProtectionWear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard

EN166.

Skin and body protection Wear appropriate protective gloves and clothing to prevent skin exposure.

Respiratory Protection Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard

EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

(+)-cis-Diltiazem hydrochloride

Physical StatePowder SolidAppearanceOff-white

Odor No information available
Odor Threshold No information available
pH No information available

Melting Point/Range 210 - 215 °C / 410 - 419 °F

Boiling Point/RangeNo information availableFlash PointNo information available

Evaporation Rate Not applicable

Flammability (solid,gas) No information available

Flammability or explosive limits

Upper

No data available

LowerNo data availableVapor PressureNo information available

Vapor Density Not applicable

Specific Gravity

No information available
Solubility

Soluble in water

Partition coefficient; n-octanol/water No data available

Autoignition TemperatureNo information availableDecomposition TemperatureNo information availableViscosityNot applicable

Molecular Formula C22 H26 N2 O4 S . H CI

Molecular Weight 450.99

10. Stability and reactivity

Reactive Hazard None known, based on information available

Stability Light sensitive, heat sensitive, Air sensitive.

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 (CO2), Sulfur oxides,

Hydrogen chloride gas

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

11. Toxicological information

Acute Toxicity

Product Information

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
(2S-cis)-3-Acetoxy-5-[2-(dimethylam	LD50 = 560 mg/kg (Rat)	LD50 = 271 mg/kg (Rat)	Not listed
ino)ethyl]-2,3-dihydro-2-(4-methoxy			
phenyl)-1,5-benzothiazepin-4(5H)-o			
ne monohydrochloride			

Toxicologically Synergistic No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation May cause skin, eye, and respiratory tract irritation

Sensitization No information available

CarcinogenicityThe table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
(2S-cis)-3-Acetoxy-5-[33286-22-5	Not listed				
2-(dimethylamino)ethyl						
]-2,3-dihydro-2-(4-met						
hoxyphenyl)-1,5-benzo						
thiazepin-4(5H)-one						
monohydrochloride						

No information available **Mutagenic Effects**

Reproductive Effects No information available.

Developmental Effects No information available.

Teratogenicity No information available.

STOT - single exposure None known STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects,both acute and No information available

delayed

Endocrine Disruptor Information No information available

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

been fully investigated.

12. Ecological information

Ecotoxicity

Do not empty into drains.

Persistence and Degradability Soluble in water Persistence is unlikely based on information available.

Bioaccumulation/ Accumulation No information available.

Will likely be mobile in the environment due to its water solubility. **Mobility**

13. Disposal considerations

Waste Disposal Methods Chemical waste generators must determine whether a discarded chemical is classified as a

hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

DOT Not regulated TDG Not regulated IATA Not regulated IMDG/IMO Not regulated

15. Regulatory information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
(2S-cis)-3-Acetoxy-5-[2-(dimethyla mino)ethyl]-2,3-dihydro-2-(4-metho xyphenyl)-1,5-benzothiazepin-4(5 H)-one monohydrochloride		-	<u>-</u>	-

(+)-cis-Diltiazem hydrochloride

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA - Per 40 CFR 751, Regulation of Certain Chemical Substances & Mixtures, Under TSCA Section 6(h) (PBT)

Not applicable

TSCA 12(b) - Notices of Export

Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
(2S-cis)-3-Acetoxy-5-[2-(dimethyla	33286-22-5	-	-	251-443-3	-	-		-	-	-
mino)ethyl]-2,3-dihydro-2-(4-metho										
xyphenyl)-1,5-benzothiazepin-4(5										
H)-one monohydrochloride										

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

U.S. Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and

Not applicable

Health Administration

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

California Proposition 65

This product contains the following Proposition 65 chemicals.

Component	CAS No	California Prop. 65	Prop 65 NSRL	Category
(2S-cis)-3-Acetoxy-5-[2-(33286-22-5	Developmental	-	Developmental
dimethylamino)ethyl]-2,3-				
dihydro-2-(4-methoxyphe				
nyl)-1,5-benzothiazepin-4				
(5H)-one				
monohydrochloride				

U.S. State Right-to-Know

Regulations

Not applicable

(+)-cis-Diltiazem hydrochloride

U.S. Department of Transportation

Reportable Quantity (RQ): N
DOT Marine Pollutant N
DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security

This product does not contain any DHS chemicals.

Other International Regulations

Mexico - Grade No information available

Authorisation/Restrictions according to EU REACH

Not applicable

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
(2S-cis)-3-Acetoxy-5-[2-(dimethylam ino)ethyl]-2,3-dihydro-2-(4-methoxy phenyl)-1,5-benzothiazepin-4(5H)-o ne monohydrochloride		-	-	<u>-</u>

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

Component	CAS No	OECD HPV	Persistent Organic Pollutant	Ozone Depletion Potential	Restriction of Hazardous Substances (RoHS)
(2S-cis)-3-Acetoxy-5-[2-(dimet hylamino)ethyl]-2,3-dihydro-2- (4-methoxyphenyl)-1,5-benzot hiazepin-4(5H)-one monohydrochloride		Listed	Not applicable	Not applicable	Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Other International Regulations

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements	Rotterdam Convention (PIC)	Basel Convention (Hazardous Waste)
(2S-cis)-3-Acetoxy-5-[2-(dimet hylamino)ethyl]-2,3-dihydro-2- (4-methoxyphenyl)-1,5-benzot hiazepin-4(5H)-one monohydrochloride		Not applicable	Not applicable	Not applicable	Not applicable

16. Other information

Prepared By Health, Safety and Environmental Department

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www.thermofisher.com

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 26-Jun-2012

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 25-Mar-2024

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 25-Mar-2024

Revision Summary New emergency telephone response service provider.

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 SDS