

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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Publication: 07/10/2022

Revision: 03/07/2024

Version: 01



## DILTIAZEMI HYDROCHLORIDUM

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Diltiazem hydrochloride  
Diltiazemi hydrochloridum  
Diltiazem hydrochloride  
Diltiazem (chlorhydrate de)  
Diltiazemhydrochlorid

N° CAS: 33286-22-5

N° EC: 251-443-3

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV  
Neerlandweg 24  
2610 Wilrijk  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Acute Tox. 4 H302

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

P264 Wash thoroughly after handling.

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

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

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P330	Rinse mouth.
P501	Dispose of contents/container to hazardous or special waste collection point.
Additional applicable label elements:	Not applicable.

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Diltiazem hydrochloride
IUPAC name:	(2S,3S)-5-[2-(dimethylamino)ethyl]-2-(4-methoxyphenyl)-4-oxo-2,3,4,5-tetrahydro-1,5-benzothiazepin-3-yl acetate hydrochloride
Synonyms:	Aldizem Cardizem
N° CAS:	33286-22-5
N° EC:	251-443-3
Molecular Formula:	C <sub>22</sub> H <sub>27</sub> ClN <sub>2</sub> O <sub>4</sub> S
Content:	98.5 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

After inhalation:	If dust is inhaled, remove from contaminated area. Encourage patient to blow nose to ensure clear passage of breathing. If irritation or discomfort persists, seek medical attention.
After skin contact:	If skin or hair contact occurs: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
After eye contact:	If this product comes in contact with the eyes: 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.
After ingestion:	If swallowed, do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.

### 4.2 Most important symptoms and effects, both acute and delayed

Not available.

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### 4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: Treat symptomatically. 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

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media: Water spray or fog. Foam. Dry chemical powder. BCF (where regulations permit). Carbon dioxide.

Unsuitable extinguishing media: Not available.

### 5.2 Special hazards arising from the substance/mixture

Not available.

### 5.3 Advice for firefighters

Surrounding fires: Firefighting: Alert Fire Brigade and tell them location and nature of hazard. Wear full body protective clothing with breathing apparatus. Prevent, by any means available, spillage from entering drains or water course. Use firefighting procedures suitable for surrounding area. Do not approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

Fire incompatibility: Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Protection against fire: Breathing apparatus, chemical splash suit.

Hazardous combustion products: Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Personal protective equipment advice is contained in Section 8 of the MSDS

#### For emergency responders

Personal protective equipment advice is contained in Section 8 of the MSDS

### 6.2 Environmental precautions

Not available.

### 6.3 Methods and material for containment and cleaning up

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. Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). Dampen with water to prevent dusting before sweeping.

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### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Use good occupational work practice. Observe manufacturer's storing and handling recommendations. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source. Do NOT cut, drill, grind or weld such containers. In addition, ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorization or permit.

Personal protection:

Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs.

Technical protective measures:

Not available.

Handling:

When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Always wash hands with soap and water after handling. Observe manufacturer's storing and handling recommendations.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container. Glass container is suitable for laboratory quantities Polyethylene or polypropylene container. Check all containers are clearly labeled and free from leaks.

Conditions for safe storage, including any incompatibilities:

Avoid reaction with oxidizing agents. Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storing and handling recommendations.

Storage – away from:

Store protected from light. Store away from incompatible materials and foodstuff containers

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

OSHA – PEL / ACGIH – TLV / OEL: Not established.

#### 8.2 Exposure controls

##### Appropriate engineering control

Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. Unless written procedures, specific to the workplace are available, the following is intended as a guide: HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors. Supplied air respirator should be considered. High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system. Develop cleaning procedures and techniques that limit potential exposure.

##### Individual protection measures

Use good manufacturing practices (i.e., cGMPs).

Eye/face protection: Not determined.

Skin protection: Lab coat, coveralls or disposable Tyvek suit. Safety shoes and disposable booties.

Hand protection: Wear appropriate gloves

Respiratory protection: Not determined.

Thermal hazards: Not determined.

##### Environmental exposure control

Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder.

Odour: Odourless.

Odour threshold: Not available.

pH: 4.3 to 5.3

Melting/freezing point: About 213 °C, with decomposition

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

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Solubility:	Freely soluble in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Conditions contributing to instability: Presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.

### 10.2 Chemical stability

Not available.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

For incompatible materials - refer to Section 7 - Handling and Storage.

### 10.6 Hazardous decomposition products

Not available.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	No significant acute toxicological data identified in literature search.	
	LD <sub>50</sub> oral (rat):	560 mg/kg
	LD <sub>50</sub> subcutaneous (rat):	520 mg/kg
	LD <sub>50</sub> oral (mouse):	508 mg/kg
Skin corrosion/irritation:	Not available.	
Serious eye damage/irritation:	Not available.	
Respiratory/skin sensitisation:	Not available.	
Germ cell mutagenicity:	Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).	

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NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Not available.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Not available.

Skin contact: Not available.

Inhalation: Not available.

Ingestion: Harmful if swallowed.

Aspiration: Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

DO NOT discharge into sewer or waterways.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

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 authorized landfill. Where possible retain label warnings and MSDS 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.

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A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not regulated for transport of dangerous goods: UN, IATA, IMDG.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not regulated for transport of dangerous goods: UN, IATA, IMDG.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not regulated for transport of dangerous goods: UN, IATA, IMDG.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not regulated for transport of dangerous goods: UN, IATA, IMDG.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : Not regulated for transport of dangerous goods: UN, IATA, IMDG.

##### 14.6 Special precautions for user

Not available.

##### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

##### 14.8 Additional transport information

Not available.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R22 Harmful if swallowed.

Safety phrases:

S20/21 When using do not eat, drink or smoke.

S56 Dispose of this material and its container at hazardous or special waste collection point.

S64 If swallowed, rinse mouth with water (only if the person is conscious).



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### 15.2 Chemical safety assessment

Not available.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied

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### 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be