

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

## M0019820-DILTIAZEM HYDROCHLORIDE Ph.Eur



Version 1 Date of compilation: 8/10/2018  
Version 3 (replaces version 2)

Revision date: 31/07/2023

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

#### 1.1 Product identifier.

Product Name: DILTIAZEM HYDROCHLORIDE Ph.Eur  
Product Code: M0019820  
Chemical Name: (2S-cis)-3-acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride  
CAS No: 33286-22-5  
EC No: 251-443-3

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

Raw material for master formulation

#### Uses advised against:

Uses other than those recommended.

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

Company: **ACOFARMA DISTRIBUCIÓN S.A.**  
Address: C/ Llobregat, 20, Pol. Ind. Santa Margarita  
City: Terrassa  
Province: Barcelona  
Telephone: 902362203  
Fax: 937360090  
E-mail: [atencioncliente@acofarma.com](mailto:atencioncliente@acofarma.com)  
Web: [www.acofarma.es](http://www.acofarma.es)

**1.4 Emergency telephone number:** 902362203 (Only available during office hours; Monday-Friday; 09:00-18:00)

### SECTION 2: HAZARDS IDENTIFICATION.

#### 2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:  
Acute Tox. 4 : Harmful if swallowed.

#### 2.2 Label elements.

##### Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

**Warning**

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container according to national regulations.

#### 2.3 Other hazards.

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The substance is not PBT  
The substance is not vPvB  
Substance does not have endocrine disrupting properties.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

#### 3.1 Substances. Mono-constituent.

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 33286-22-5 EC No: 251-443-3	(2S-cis)-3-acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride	25 - 100 %	Acute Tox. 4, H302	-

#### 3.2 Mixtures. Not Applicable.

### SECTION 4: FIRST AID MEASURES.

#### 4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

#### Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

#### Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Dont let the person to rub the affected eye.

#### Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

#### Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract.

### SECTION 5: FIREFIGHTING MEASURES.

The product does not present any particular risk in case of fire.

#### 5.1 Extinguishing media.

##### Suitable extinguishing media:

Extinguisher powder or CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

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#### Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

#### **5.2 Special hazards arising from the substance or mixture.**

##### Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

#### **5.3 Advice for firefighters.**

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

#### Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

### SECTION 6: ACCIDENTAL RELEASE MEASURES.

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

For exposure control and individual protection measures, see section 8.

#### **6.2 Environmental precautions.**

Product not classified as hazardous for the environment, avoid spillage as much as possible.

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

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

#### **6.4 Reference to other sections.**

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

### SECTION 7: HANDLING AND STORAGE.

#### **7.1 Precautions for safe handling.**

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

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

Store according to local legislation. Observe indications on the label. Store the containers between 5 and 25 ° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

#### **7.3 Specific end use(s).**

Raw material for compounding

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

#### **8.1 Control parameters.**

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The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

#### 8.2 Exposure controls.

##### Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

<b>Concentration:</b>	<b>100 %</b>				
<b>Uses:</b>	<b>Raw material for master formulation</b>				
<b>Breathing protection:</b>					
PPE:	Particle filter mask				
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.				
CEN standards:	EN 149				
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.				
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.				
Filter Type needed:	P2				
<b>Hand protection:</b>					
PPE:	Protective gloves against chemicals.				
Characteristics:	«CE» marking, category III.				
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420				
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.				
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.				
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480	Material thickness (mm):	0,35
<b>Eye protection:</b>					
PPE:	Protective goggles against particle impacts.				
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.				
CEN standards:	EN 165, EN 166, EN 167, EN 168				
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.				
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.				
<b>Skin protection:</b>					
PPE:	Protective clothing.				
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.				
CEN standards:	EN 340				
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.				
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.				
PPE:	Work footwear.				
Characteristics:	«CE» marking, category II.				
CEN standards:	EN ISO 13287, EN 20347				
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.				
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident				

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

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

Physical state: Solid - Dust

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Colour: White  
Odour: Odourless  
Odour threshold: Not available  
Melting point: 210-215 °C  
Freezing point: Not available  
Boiling point or initial boiling point and boiling range: 594.4 °C (Estimations in base on the Regulation (CE) N°1272 / 2008 indications.)  
Flammability: Not available  
Lower explosion limit: Not available  
Upper explosion limit: Not available  
Flash point: 313.3 °C (Estimations in base on the Regulation (CE) N°1272 / 2008 indications.)  
Auto-ignition temperature: Not available  
Decomposition temperature: Not available  
pH: 4.8 (1%) (pH Meter/potentiometric/electrometric method)  
Kinematic viscosity: Not available  
Solubility: Soluble in methanol  
Hydrosolubility: Freely soluble in water  
Liposolubility: Not available  
Partition coefficient n-octanol/water (log value): Not available  
Vapour pressure: Not available  
Absolute density: Not available  
Relative density: Not available  
Relative vapour density: Not applicable  
Particle characteristics: Not available

#### 9.2 Other information

Not applicable/Not available due to the nature/properties of the product

### SECTION 10: STABILITY AND REACTIVITY.

#### 10.1 Reactivity.

The product does not present hazards by their reactivity.

#### 10.2 Chemical stability.

Unstable in contact with:

- Bases.

#### 10.3 Possibility of hazardous reactions.

Neutralization can occur on contact with bases.

#### 10.4 Conditions to avoid.

- Avoid contact with bases.

#### 10.5 Incompatible materials.

Avoid the following materials:

- Bases.

#### 10.6 Hazardous decomposition products.

Depending on conditions of use, can be generated the following products:

- COx (carbon oxides).
- Organic compounds.
- Corrosive vapors or gases.
- Aromatics compounds.

### SECTION 11: TOXICOLOGICAL INFORMATION.

#### 11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

a) acute toxicity;

Product classified:

Acute toxicity (Oral), Category 4: Harmful if swallowed.

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Acute Toxicity Estimate (ATE):

Substances:

ATE (Oral) = 500 mg/kg

b) skin corrosion/irritation;  
Not conclusive data for classification.

c) serious eye damage/irritation;  
Not conclusive data for classification.

d) respiratory or skin sensitisation;  
Not conclusive data for classification.

e) germ cell mutagenicity;  
Not conclusive data for classification.

f) carcinogenicity;  
Not conclusive data for classification.

g) reproductive toxicity;  
Not conclusive data for classification.

h) STOT-single exposure;  
Not conclusive data for classification.

i) STOT-repeated exposure;  
Not conclusive data for classification.

j) aspiration hazard;  
Not conclusive data for classification.

#### 11.2 Information on other hazards.

##### Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

##### Other information

There is no information available on other adverse health effects.

## SECTION 12: ECOLOGICAL INFORMATION.

#### 12.1 Toxicity.

No information is available regarding the ecotoxicity.

#### 12.2 Persistence and degradability.

No information is available regarding the biodegradability

No information is available on the degradability

No information is available about persistence and degradability of the product.

#### 12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation.

#### 12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

#### 12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

#### 12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

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#### 12.7 Other adverse effects.

No information is available about other adverse effects for the environment.

### SECTION 13: DISPOSAL CONSIDERATIONS.

#### 13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

### SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

#### 14.1 UN number or ID number.

Transportation is not dangerous.

#### 14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

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

Transportation is not dangerous.

#### 14.4 Packing group.

Transportation is not dangerous.

#### 14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

#### 14.6 Special precautions for user.

Transportation is not dangerous.

#### 14.7 Maritime transport in bulk according to IMO instruments.

Transportation is not dangerous.

### SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

#### 15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

### SECTION 16: OTHER INFORMATION.

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Classification codes:

Acute Tox. 4 : Acute toxicity (Oral), Category 4

Changes regarding to the previous version:

- Modification in the values of the physical and chemical properties (SECTION 9).

#### **Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:**

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

PPE: Personal protection equipment.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.