

Diltiazem hydrochlorid

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 23/05/2013 Revision date: 13/03/2017

840335

Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Diltiazem hydrochlorid
EC No : 251-443-3
CAS No : 33286-22-5
Product code : 840335
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Industrial/Professional use spec : Industrial
For professional use only
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302
Acute toxicity (dermal), Category 3 H311
Reproductive toxicity, Additional category, Effects on or via lactation H362

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Reproductive toxicity, Category 2 H361d
Hazardous to the aquatic environment — Chronic Hazard, Category 3 H412



Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :  
GHS06 GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H302 - Harmful if swallowed
H311 - Toxic in contact with skin
H361d - Suspected of damaging the unborn child
H362 - May cause harm to breast-fed children
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements (CLP) : P260 - Do not breathe dust, fume, gas, mist, spray, vapours
P263 - Avoid contact during pregnancy/while nursing
P273 - Avoid release to the environment
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes

Extra phrases : Do not handle until all safety precautions have been read and understood
Use personal protective equipment as required

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Diltiazem hydrochlorid	(CAS No) 33286-22-5 (EC No) 251-443-3	100	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Lact., H362 Repr. 2, H361d Aquatic Chronic 3, H412

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). Suspected of causing cancer (Oral).
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Get medical advice/attention.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

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

Symptoms/injuries after ingestion	: Swallowing a small quantity of this material will result in serious health hazard.
Chronic symptoms	: Dizziness, headaches, drop in blood pressure, nausea.

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

No additional information available

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: In case of fire it can release. Hydrogen chloride. Sulphur oxides. Nitrogen oxides.
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5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with skin and eyes. Do not breathe dust.
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6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not handle until all safety precautions have been read and understood.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Keep only in the original container in a cool, well-ventilated place.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Personal protective equipment:**

Avoid all unnecessary exposure.

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Approved dust respirator. Dustmask with filtertype P3

Consumer exposure controls:

Do not breathe dust. Avoid contact with skin and eyes.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4.3 - 5.3
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 213 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Moderately soluble in water. Water: < 100 mg/l
Log Pow	: 2.7
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Store separately from oxidising agents and strongly alkaline and strongly acidic materials.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity : Oral: Harmful if swallowed. Dermal: Toxic in contact with skin.

Diltiazem hydrochlorid (33286-22-5)	
LD50 oral rat	560 mg/kg
LD50 dermal rabbit	271 mg/kg
LC50 inhalation rat	271 mg/kg

Skin corrosion/irritation : Not classified
pH: 4.3 - 5.3

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified
pH: 4.3 - 5.3

Additional information : Slight eye irritant

Respiratory or skin sensitisation : Not classified

Additional information : Slight irritant

Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Reproductive toxicity : May cause harm to breast-fed children. Suspected of damaging the unborn child.

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : May cause sensitization by inhalation

Potential adverse human health effects and symptoms : Harmful if swallowed.

Other information : Information on Effects: refer to section 4.

SECTION 12: Ecological information**12.1. Toxicity**

Diltiazem hydrochlorid (33286-22-5)	
EC50 Daphnia 1	22.4 mg/l 48 hour

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12.2. Persistence and degradability

Diltiazem hydrochlorid (33286-22-5)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Diltiazem hydrochlorid (33286-22-5)	
Log Pow	2.7
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations


13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of this material and its container at hazardous or special waste collection point.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
	Not applicable
14.4. Packing group	
III	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : T2
Special provisions (ADR) : 274, 614
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Vehicle for tank carriage : AT
Transport category (ADR) : 2

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Hazard identification number (Kemler No.) : 60

Orange plates :



Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Diltiazem hydrochlorid is not on the REACH Candidate List

Diltiazem hydrochlorid is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

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Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Other information	: DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. REACH Disclaimer: This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number).

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 2	Reproductive toxicity, Category 2
H302	Harmful if swallowed
H311	Toxic in contact with skin
H361d	Suspected of damaging the unborn child
H362	May cause harm to breast-fed children
H412	Harmful to aquatic life with long lasting effects

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