

Effective Date 18.04.2019
Revision 5.1

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

1.1. Product identifier

Trade name: Diltiazem hydrochloride
CAS-number: 33286-22-5

Reach registration number: NA

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

The uses of the chemical: Active pharmaceutical ingredients
Classification of the economic activities (NACE): 212
Use categories (UC62): 41

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

Manufacturer/importer: Fermion Oy
Street address: Koivu-Mankkaan tie 6 A
Post-office box: P.O. Box 28
Postcode: 02101 Espoo, Finland
Telephone number: +358 10 4261
Telefax: +358 9 452 1764
E-mail address: chemicalsafety@orion.fi
VAT Reg. No: FI18552129

1.4. Emergency telephone number

Poison Center: +358 9 471 977

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008	Acute Tox. 4	H302,
H Statements	Harmful if swallowed.	

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2.2. Label elements

Hazard Pictograms



Signal word Warning

H Statements

H302 Harmful if swallowed.

P Statements

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

P305+P351+P313, P501 IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

Dispose of contents according to national and local law.

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Diltiazem hydrochloride	33286-22-5	251-443-3	NA

Other information

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions

Helpers should ensure their own protection.

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Inhalation	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician.
Skin contact	Remove/Take off immediately all contaminated clothing. Wash with soap and water.
Eye contact	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
Ingestion	Rinse mouth. Induce vomiting. If the patient is conscious, give plenty of water (2 - 4 glasses), and let the charcoal (approximately 20 tablets), or give activated charcoal slurry (2 - 4 glasses). Get medical advice/attention.

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

See section 11 for symptoms of exposure.

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

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	Powder Carbon dioxide Foam Water
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5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of hydrogen chloride and oxides of carbon and nitrogen during heating or fire.
May emit toxic fumes of oxides of sulphur during heating or fire.

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

Other instructions Cool fire exposed containers with water jet.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.
Access of extra people to the spill area must be prevented.

6.2. Environmental precautions

Data not available.

6.3. Methods and material for containment and cleaning up

Collect spilled powder without dusting into tight closed container.

6.4. Reference to other sections

See Section 8 and 13

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed.
Protect from sunlight.
See incompatible materials in section 10.5.

7.3. Specific end use(s)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values	-
DNELs	-
PNECs	-

8.2. Exposure controls

Appropriate engineering controls

Handle in closed systems or use an efficient local exhaust if vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment. All exposure must be avoided.
Avoid dust formation.
Wash up thoroughly after handling (shower).

Respiratory protection

In open handling use respirator (P3) with a minimum protection factor of 20.
See standard working procedures/instructions or department's instructions for more detailed protection measures.

Hand protection

Use protective gloves (e.g. nitrile or neopren gloves).

Eye protection

Use protective goggles.

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Skin protection

Use normal working clothes.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**Appearance**

Physical state	Powder
Colour	White
Odour	Odourless
Odour threshold	-

9.1. Information on basic physical and chemical properties

pH Value 4,8 1 % w/V

Melting point 210 - 215 °C

Water solubility Freely soluble

Solubility Soluble in methanol

9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

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10.2. Chemical stability

Stable when stored and handled according to instructions of use.

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10.3. Possibility of hazardous reactions

Not expected to occur.

10.4. Conditions to avoid

Dust may form explosive mixtures with air.

10.5. Incompatible materials

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10.6 Hazardous decomposition products

May emit toxic fumes of hydrogen chloride and oxides of carbon and nitrogen during heating or fire.

May emit toxic fumes of oxides of sulphur during heating or fire.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity	Harmful if swallowed. LD50 = 560 mg/kg (rat, oral)
Skin irritation and corrosion	Data not available.
Skin sensitization	Data not available.
Serious eye damage and irritation	Data not available.
Respiratory irritation	Data not available.
Respiratory sensitization	Data not available.
Carcinogenicity	Data not available.
Germ cell mutagenicity	Data not available.
Reproductive toxicity	The substance has shown teratogenic effects in animal experiments. TDLO = 1200 mg/kg (rat, oral, 9-14D preg) -> maternal effects (parturition), effects on embryo or fetus TDLO = 60 mg/kg (rat, oral, 9-14D preg) ->

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specific developmental effects on newborn

STOT-single exposure Data not available.

STOT-repeated exposure Data not available.

Aspiration hazard Data not available.

Repeated dose toxicity Symptoms of exposure include gastrointestinal disturbances, dizziness and headache. Hypotension. Bradycardia. Possibly effects on the liver (elevations in liver enzyme values; occasionally hepatitis).

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Data not available.

Toxic effects on other organisms

Data not available.

12.2.Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Octanol-water partition coefficient Data not available.

Bioconcentration factor Data not available.

12.4. Mobility in soil

Data not available.

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12.5. Results of PBT and vPvB assessment

Data not available.

12.6. Other adverse effects

Data not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

-

14.2. UN Proper shipping name

-

14.3. Transport hazard class(es) (ADR/RID,IMDG,ICAO/IATA)

This product is not regulated under the transport regulations.

14.4. Packing group

-

14.5. Environmental hazard

-

14.6. Special precautions for user

-

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable

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SECTION 15: REGULATORY INFORMATION

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

The product has not been fully tested.

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Fermion Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Information provided by the supplier

Information which has been added, deleted or revised

Updated section / sections:

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