

Effective Date 29.10.2019
Revision 4.1

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

1.1. Product identifier

Trade name: Dexmedetomidine hydrochloride
CAS-number: 145108-58-3

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. 1 Acute Tox. 2 STOT SE 1 STOT SE 3 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H300, H330, H370, H336, H372, H400, H410,
H Statements	Fatal if swallowed.	

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	<p>Fatal if inhaled. Causes damage to organs. May cause drowsiness or dizziness. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.</p>
M-Factor	<p>M(Acute): 1 M(Chronic): 100</p>

2.2. Label elements

Hazard Pictograms



Signal word

Danger

H Statements

- H300 Fatal if swallowed.
- H330 Fatal if inhaled.
- H370 Causes damage to organs.
- H336 May cause drowsiness or dizziness.
- H372 Causes damage to organs through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

P Statements

- P260 Do not breath dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves/protective clothing/eye protection.
- P273 Avoid release to the environment.

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

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Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Dexmedetomidine hydrochloride	145108-58-3	-	NA

Other information -

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions

IF exposed: Call a POISON CENTER or doctor/physician.
Helpers should ensure their own protection.

Inhalation

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Get medical advice/attention.

Skin contact

Remove/Take off immediately all contaminated clothing.
IF ON SKIN: Wash with soap and water.
Rinse continuously with water for several minutes.
If skin irritation occurs: Get medical advice/attention.

Eye contact

IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

Ingestion

Get immediate 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.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

- Carbon dioxide
- Foam
- Water
- Powder

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.

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters

Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.

6.2. Environmental precautions

Do not put into water system, drain or soil.

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.
Avoid dust formation.
All exposure must be avoided.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry place.
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

Provide sufficient ventilation.
Avoid dust formation.
All exposure must be avoided.
Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment.

Respiratory protection

In open handling use respirator (P3) with a minimum protection factor of 200.
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).

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Eye protection

Use protective goggles.

Skin protection

In dust making work use disposal overalls and extra throwaway sleeves.

Environmental exposure controls

Avoid release to the environment.

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

Melting point 156 - 158 °C

Water solubility Soluble

9.2. Other information

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

Stable in normal conditions.

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

Moisture
Light

10.5. Incompatible materials

Alkalis

10.6 Hazardous decomposition products

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

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity	Fatal if swallowed. Fatal if inhaled. Dexmedetomidine tartrate: LD50: < 5 mg/kg (rat, oral) Medetomidine: LC50: 0,14 mg/l (rat, inhalation, 4 h) LD50: > 2000 mg/kg (rat, dermal)
Skin irritation and corrosion	Medetomidine: Non-irritant (rabbit)
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.

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Reproductive toxicity

Data not available.

STOT-single exposure

May cause drowsiness or dizziness.
Causes damage to organs.
Target organs:
Eyes

STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard

Data not available.

Repeated dose toxicity

Data not available.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Very toxic to aquatic life.

Very toxic to aquatic life with long lasting effects.

Medetomidine:

Toxicity to fish:

LC50(96 h): 30 mg/l, Danio rerio

NOEC(28 d): 0,001 mg/l, Cypridon variegatus

Toxicity to daphnia:

EC50(48 h): 4,5 mg/l, Daphnia magna

Toxicity to algae:

ErC50(72 h): 0,65 mg/l, Scenedesmus subspicatus

NOEC(72 h): 0,12 mg/l, Scenedesmus subspicatus

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

UN 2811

14.2. UN Proper shipping name

TOXIC SOLID, ORGANIC, N.O.S. (Dexmedetomidine hydrochloride)

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

6.1

14.4. Packing group

I

14.5. Environmental hazard

Marine pollutant: yes

14.6. Special precautions for user

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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:
1, 8