

Dexmedetomidine hydrochloride

Version: 4.2

Revision Date: 10.01.2025

SDS Number: 100000000101

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

1.1 Product identifier

Trade name : Dexmedetomidine hydrochloride

REACH Registration Number : NA

CAS-No. : 145108-58-3

Unique Formula Identifier : -

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

Use of the Sub-
stance/Mixture : Active pharmaceutical ingredients

Recommended restrictions
on use : No data available

1.3 Details of the supplier of the safety data sheet

Company : Fermion Oy

Street address : Koivu-Mankkaan tie 6 A

Post-office box: : P.O. Box 28

Postcode : 02101 Espoo, Finland

Telephone : +358 10 4261

E-mail address of person
responsible for the SDS : chemicalsafety@orion.fi

VAT Reg. No: : FI18552129

1.4 Emergency telephone number

Poison Center : +358 800 147111
+358 9 471 977

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 1	H300: Fatal if swallowed.
Acute toxicity, Category 2	H330: Fatal if inhaled.
Specific target organ toxicity - single exposure, Category 1, Eyes	H370: Causes damage to organs.
Specific target organ toxicity - single exposure, Category 3, Central nervous system	H336: May cause drowsiness or dizziness.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 2	H410: Very toxic to aquatic life with long lasting effects.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.

For explanation of abbreviations see section 16.

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2.2 Label elements

Labeling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal Word : Danger

Hazard Statements

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.
H300 Fatal if swallowed.
H330 Fatal if inhaled.
H370 Causes damage to organs.

Precautionary Statements

General:

P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

2.3 Other hazards

Other hazards : No data available
PBT : No data available
vPvB : No data available
Endocrine disrupting properties : Ecological information: No data available
Toxicological information: No data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Dexmedetomidine hydrochloride	145108-58-3		M-Factor (Acute aquatic toxicity): 1

Other information : No data available

3.2 Mixtures

Not applicable

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SECTION 4: First aid measures

4.1 Description of first-aid measures

- | | | |
|-------------------------|---|---|
| General advice | : | IF exposed: Call a POISON CENTER or doctor/ physician.
Helpers should ensure their own protection. |
| If inhaled | : | IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
Get medical advice/attention. |
| In case of skin contact | : | Remove/ Take off immediately all contaminated clothing.
IF ON SKIN: Wash with soap and water.
If skin irritation occurs: Get medical advice/ attention.
Rinse continuously with water for several minutes. |
| In case of eye contact | : | IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention. |
| If swallowed | : | Get immediate medical advice/ attention. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|----------|---|--|
| Symptoms | : | See section 11 for symptoms of exposure. |
| Risks | : | No data available |

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|-------------------|
| Treatment | : | No data available |
|-----------|---|-------------------|

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|--------------------------------|---|--|
| Suitable extinguishing media | : | Carbon dioxide (CO ₂)
Foam
Water
Powder |
| Unsuitable extinguishing media | : | No data available |

5.2 Special hazards arising from the substance or mixture

- | | | |
|---------------------------------------|---|---|
| Specific hazards during fire fighting | : | May emit toxic fumes of hydrogen chloride and oxides of carbon and nitrogen during heating or fire. |
| Hazardous combustion products | : | No data available |

5.3 Advice for firefighters

- | | | |
|--|---|---|
| Special protective equipment for fire-fighters | : | Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing. |
| Specific extinguishing methods | : | No data available |
| Further information | : | No data available |

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment as required.

6.2 Environmental precautions

Environmental precautions : Do not put into water system, drain or soil.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Collect spilled powder without dusting into tight closed container.

6.4 Reference to other sections

See Section 8 and 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Handle in well-ventilated space.
Avoid dust formation.
All exposure must be avoided.

7.2 Conditions for safe storage, including any incompatibilities

Packaging material : Suitable material: No data available
Unsuitable material: No data available

Further information on storage conditions : 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)

Specific use(s) : No information identified.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures : 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.

Personal protective equipment

Respiratory protection : In open handling use respirator (P3) with a minimum protec-

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		tion factor of 200. See standard working procedures/instructions or department's instructions for more detailed protection measures.
Eye/face protection	:	Use protective goggles.
Hand protection	:	
Remarks	:	Use protective gloves (e.g. nitrile or neopren gloves).
Skin and body protection	:	In dust making work use disposal overalls and extra throwaway sleeves.
Protective measures	:	No data available

Environmental exposure controls

Air	:	Avoid release to the environment.
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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	:	powder
Physical state	:	solid
Color	:	white
Odor	:	odorless
Odor Threshold	:	No data available
Melting point/range	:	156 - 158 °C
Boiling point/boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, dynamic	:	No data available

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Viscosity, kinematic	:	No data available
Flow time	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Dissolution Rate	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Dispersion Stability	:	No data available
Vapor pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	No data available
Relative vapor density	:	No data available
Dissociation constant	:	No data available
Particle characteristics	:	No data available

9.2 Other information

Self-ignition	:	No data available
Hygroscopic properties	:	No data available
Henry's Constant	:	No data available
Further information	:	No data available

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.

10.3 Possibility of hazardous reactions

Hazardous reactions : Not expected to occur.

10.4 Conditions to avoid

Conditions to avoid : moisture

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Light

10.5 Incompatible materials

Materials to avoid : 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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Health hazard information : Fatal if swallowed.
Fatal if inhaled.

Acute oral toxicity : Dexmedetomidine tartrate: LD50: < 5 mg/kg (rat, oral)

Acute inhalation toxicity : Medetomidine:
LC50: 0,14 mg/l (rat, inhalation, 4 h)

Acute dermal toxicity : Medetomidine:
LD50: > 2000 mg/kg (rat, dermal)

Acute toxicity (other routes of administration) : No data available

Skin corrosion/irritation

Remarks : Medetomidine: Non-irritant (rabbit)

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Genotoxicity in vitro : No data available

Genotoxicity in vivo : No data available

Carcinogenicity

No data available

Reproductive toxicity

Effects on fertility : No data available

Effects on fetal development : No data available

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STOT-single exposure

Target Organs : Eyes

Assessment : May cause drowsiness or dizziness.
Causes damage to organs.

STOT-repeated exposure

Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

11.2 Information on other hazards

Endocrine disrupting properties

No data available

Experience with human exposure

General Information : No data available

Inhalation : No data available

Skin contact : No data available

Eye contact : No data available

Ingestion : No data available

Toxicology, Metabolism, Distribution

Remarks : No data available

Neurological effects

Remarks : No data available

Further information

No data available

Other Health Hazards

No data available

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish	:	Medetomidine: LC50 (Danio rerio (zebra fish)): 30 mg/l Exposure time: 96 h NOEC (Cyprinodon variegatus (sheepshead minnow)): 0,001 mg/l Exposure time: 28 Days
Toxicity to daphnia and other aquatic invertebrates	:	Medetomidine: EC50 (Daphnia magna (Water flea)): 4,5 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	Medetomidine: ErC50 (Scenedesmus subspicatus, algae): 0,65 mg/l Exposure time: 72 h NOEC (Scenedesmus subspicatus, algae): 0,12 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	No data available
Toxicity to microorganisms	:	No data available
Toxicity to soil dwelling organisms	:	No data available
Plant toxicity	:	No data available
Sediment toxicity	:	No data available
Toxicity to terrestrial organisms	:	No data available

Ecotoxicology Assessment

Acute aquatic toxicity	:	Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.
Chronic aquatic toxicity	:	No data available
Toxicity Data on Soil	:	No data available
Other organisms relevant to the environment	:	No data available

12.2 Persistence and degradability

Biodegradability	:	No data available
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Biochemical Oxygen Demand (BOD) : No data available

Chemical Oxygen Demand (COD) : No data available

BOD/COD : No data available

ThOD : No data available

BOD/ThOD : No data available

Dissolved organic carbon (DOC) : No data available

Physico-chemical removability : No data available

Stability in water : No data available

Impact on Sewage Treatment : No data available

Photodegradation : No data available

12.3 Bioaccumulative potential

Bioaccumulation : No data available

Partition coefficient: n-octanol/water : No data available

12.4 Mobility in soil

Mobility : No data available

Distribution among environmental compartments : No data available

Stability in soil : No data available

12.5 Results of PBT and vPvB assessment

Assessment : No data available

12.6 Endocrine disrupting properties

No data available

12.7 Other adverse effects

Environmental fate and pathways : No data available

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Adsorbed organic bound halogens (AOX) : No data available

Ozone-Depletion Potential : No data available

Additional ecological information : No data 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

ADR/RID: UN 2811

IMDG: UN 2811

IATA: 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)

ADR/RID: 6.1

IMDG: 6.1

IATA: 6.1

14.4 Packing group

ADR/RID: I

IMDG: I

IATA: I

14.5 Environmental hazards

ADR/RID: Marine pollutant: yes

IMDG: Marine pollutant: yes

IATA: Marine pollutant: yes

14.6 Special precautions for user

Tunnel restriction code : No data available

Further information for transport : No data available

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

Not applicable

SECTION 15: Regulatory information

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

The product has not been fully tested.

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15.2 Chemical Safety Assessment

No

SECTION 16: Other information

Full text of H-Statements

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.
H300	Fatal if swallowed.
H330	Fatal if inhaled.
H370	Causes damage to organs.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Acute Tox.	: Acute toxicity
STOT SE	: Specific target organ toxicity - single exposure
STOT SE	: Specific target organ toxicity - single exposure
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
STOT RE	: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

AIIC - Australian Inventory of Industrial Chemicals

ASTM - American Society for the Testing of Materials

bw - Body weight

CLP - Classification Labelling Packaging Regulation

Regulation (EC) No 1272/2008

CMR - Carcinogen, Mutagen or Reproductive Toxicant

DIN - Standard of the German Institute for Standardisation

DSL - Domestic Substances List (Canada)

ECHA - European Chemicals Agency

EC-Number - European Community number

ECx - Concentration associated with x% response

ELx - Loading rate associated with x% response

EmS - Emergency Schedule

ENCS - Existing and New Chemical Substances (Japan)

ErCx - Concentration associated with x% growth rate response

GHS - Globally Harmonized System

GLP - Good Laboratory Practice

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

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IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC50 - Half maximal inhibitory concentration

ICAO - International Civil Aviation Organization

IECSC - Inventory of Existing Chemical Substances in China

IMDG - International Maritime Dangerous Goods

IMO - International Maritime Organization

ISHL - Industrial Safety and Health Law (Japan)

ISO - International Organisation for Standardization

KECI - Korea Existing Chemicals Inventory

LC50 - Lethal Concentration to 50 % of a test population

LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)

MARPOL - International Convention for the Prevention of Pollution from Ships

n.o.s. - Not Otherwise Specified

NO(A)EC - No Observed (Adverse) Effect Concentration

NO(A)EL - No Observed (Adverse) Effect Level

NOELR - No Observable Effect Loading Rate

NZIoC - New Zealand Inventory of Chemicals

OECD - Organization for Economic Co-operation and Development

OPPTS - Office of Chemical Safety and Pollution Prevention

PBT - Persistent, Bioaccumulative and Toxic substance

PICCS - Philippines Inventory of Chemicals and Chemical Substances (Q)SAR - (Quantitative) Structure Activity Relationship

REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

RID - Regulations concerning the International Carriage of Dangerous Goods by Rail

SADT - Self-Accelerating Decomposition Temperature

SDS - Safety Data Sheet

SVHC - substance of very high concern

TCSI - Taiwan Chemical Substance Inventory

TECI - Thailand Existing Chemicals Inventory

TRGS - Technical Rule for Hazardous Substances

TSCA - Toxic Substances Control Act (United States)

UN - United Nations

vPvB - Very Persistent and Very Bioaccumulative

Further information

Other information : No data available

Sources of key data used to : Information provided by the supplier

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compile the Material Safety
Data Sheet

Information which has been : Updated section / sections:
added, deleted or revised 8

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