

An ISO 9001: 2015 & GMP Certified Company 101, Aarkay Ruby Industrial Estate (1B), Opp Shree Narayan Industrial Estate, Chinchpada, Vasai East, Waliv, Maharashtra 401208. Tel: + 91 98200 41841

Email: info@ottokemi.com Web: www.ottokemi.com

MATERIAL SAFETY DATA SHEET (MSDS)

SECTION 1. Product identifiers

Product name: Dexmedetomidine hydrochloride, 98%

Product Code: D 0425 CAS No: 145108-58-3

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

Use: Industrial. For professional use only.

1.3. Details of the supplier of the safety data sheet

Company identification OTTO CHEMIE PVT LTD

101, Aarkay Ruby Industrial Estate(1B), Opp Shree Narayan Industrial Estate,

Chinchpada, Vasai East, Waliv, Maharashtra 401208.

Email info@ottokemi.com

1.4. Emergency telephone number

Phone no.: + 91 22 2207 0099 (9:00am - 6:00 pm)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Acute toxicity, Oral (Category 4), H302

Specific target organ toxicity - single exposure (Category 3), Central nervous system, H336

Warning

Harmful if swallowed.

Avoid breathing dust.

May cause drowsiness or dizziness.

Wash skin thoroughly after handling.

Avoid release to the environment.

Toxic to aquatic life with long lasting effects.

Use only outdoors or in a well-ventilated area.

IF SWALLOWED: Call a POISON CENTER/ doctor if you feel

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

Long-term (chronic) aquatic hazard (Category 2), H411

For the full text of the H-Statements mentioned in this Section, see Section 16

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram

Signal Word

Hazard statement(s)

H302

H336 H411

Precautionary statement(s)

P261

P264

P271

P273

P301 + P312

P304 + P340 + P312

Supplemental Hazard

Statements

Reduced Labeling (<= 125 ml)

Pictogram

Signal Word Warning Hazard statement(s) none Precautionary none statement(s) Supplemental Hazard none

Statements 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

DISCI AIMER

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SECTION 3: Composition/information on ingredients

3.1 Substances

Synonyms: (+)-Medetomidine hydrochloride

(S)-Medetomidine hydrochloride

Formula : C13H16N2.HCl Molecular weight : 236,74 g/mol CAS-No. : 145108-58-3 EC-No. : 682-047-2

Component	Classification	Concentration
Dexmedetomidine hydrochloride		
CAS-No. 145108-58-3	Acute Tox. 4; STOT SE 3; Aquatic	<= 100 %
EC-No. 682-047-2	Chronic 2; H302, H336, H411	

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice

Show this material safety data sheet to the doctor in attendance.

If inhaled

After inhalation: fresh air. Call in physician.

In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with

water/ shower.

In case of eye contact

After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section

2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water Foam Carbon dioxide (CO2) Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Carbon oxides

Nitrogen oxides (NOx)

Hydrogen chloride gas

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

5.4 Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid inhalation of dusts. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures,

consult an expert.
For personal protection see section 8.

6.2 Environmental precautions

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Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Work under hood. Do not inhale substance/mixture.

Hygiene measures

Change contaminated clothing. Preventive skin protection recommended. Wash hands after working with substance.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Tightly closed. Dry.

Storage class

Storage class (TRGS 510): 11: Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses Skin protection

Skin protection

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell,

Internet: www.kcl.de).

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: KCL 741 Dermatril® L

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested:KCL 741 Dermatril® L

Body Protection

protective clothing

Respiratory protection

required when dusts are generated.

Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to

the used respiratory protection system.

Recommended Filter type: Filter type P2

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Control of environmental exposure

Do not let product enter drains.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical state solid
b) Color No data available
c) Odor No data available
d) Melting No data available

point/freezing point
e) Initial boiling point
No data available

and boiling range
f) Flammability (solid,

No data available

gas)
g) Upper/lower
No data available

g) Upper/lower No data available flammability or explosive limits

h) Flash point Not applicable
i) Autoignition No data available
temperature

j) Decomposition No data available temperature

k) pH No data available
l) Viscosity Viscosity

Viscosity, dynamic: No data available
m) Water solubility
No data available
n) Partition coefficient:
No data available

n-octanol/water
o) Vapor pressure
p) Density
Relative density
No data available
No data available
No data available
No data available

q) Relative vapor
No data available density

r) Particle
Characteristics

No data available

s) Explosive properties
No data available
t) Oxidizing properties
none

9.2 Other safety information No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidizing agents

10.4 Conditions to avoid no information available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Routes of Entry: Absorbed through skin. Dermal contact. Eye contact. Toxicity to Animals:

Oral LD50 Rat: 1500 mg/kg; Dermal LD50 Rabbit: 2000mg/kg

Inhalation LC50 Rat: > 50mg/L.

Chronic Effects on Humans: CARCINOGENIC EFFECTS: Classified None. by NTP, None. by OSHA, None. by NIOSH.

Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of inhalation (lung irritant).

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Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available. Special Remarks on other Toxic Effects on Humans: Not available.

SECTION 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available 12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components

considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 3077 IMDG: 3077 IATA: 3077

14.2 UN proper shipping name

ADR/RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(Dexmedetomidine hydrochloride)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

(Dexmedetomidine hydrochloride)

IATA : Environmentally hazardous substance, solid, n.o.s. (Dexmedetomidine

hydrochloride)

14.3 Transport hazard class(es)

ADR/RID: 9 IMDG: 9 IATA: 9

14.4 Packaging group

ADR/RID: III IMDG: III IATA: III

14.5 Environmental hazards

ADR/RID: yes IMDG Marine pollutant: yes IATA: yes

14.6 Special precautions for user Tunnel restriction code : (-)

Further information

EHS-Mark required (ADR 2.2.9.1.10, IMDG code 2.10.3) for single packagings and combination packagings containing inner packagings with Dangerous Goods > 5L for liquids or > 5kg for solids.Packages smaller than or equal to 5kg/L, not dangerous goods of

Class 9

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SECTION 15: Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

National legislation

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

: ENVIRONMENTAL HAZARDS

Other regulations

Observe work restrictions regarding maternity protection in accordance to Dir 92/85/EEC or stricter national regulations where applicable.

Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

Section 16: Other Information

This safety data sheet should be used in conjunction with technical sheets. It does not replace them. The information given is based on our knowledge of this product, at the time of publication. It is given in good faith. The attention of the user is drawn to the possible risks incurred by using the product for any other purpose other than that for which it was intended. This does not in any way excuse the user from knowing and applying all the regulations governing his activity. It is the sole responsibility of the user to take all precautions required in handling the product. The aim of the mandatory regulations mentioned is to help the user to fulfill his obligations regarding the use of hazardous products.

