# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

**Contact information**

| | |
|---|---|
| **General** | Dechra Veterinary Products<br>7015 College Blvd, Suite 525, Overland Park, KS 66211<br><br>Technical Support: (866) 933-2472<br>Fax: (913) 327-0016<br>E-mail: support@dechra.com |
| **Emergency telephone number** | +1 (866) 683-0660 *(General inquiries)*<br>+1 (866) 933-2472 *(Veterinary support & adverse event reporting)* |

| | |
|---|---|
| **Product identifier** | Dexmedesed™ (dexmedetomidine hydrochloride) |
| **Synonyms** | Sterile Injectable Solution-0.5 mg/mL |
| **Trade names** | For dexmedetomidine hydrochloride: 1H-Imidazole, 4-(1-(2,3-dimethylphenyl)ethyl)-, monohydrochloride, (S)-; 4-((S)-alpha,2,3-trimethylbenzyl)imidazole monohydrochloride |
| **Chemical family** | Mixture |
| **Relevant identified uses of the substance or mixture and uses advised against** | None identified<br><br>Bulk formulated pharmaceutical mixture/formulated pharmaceutical product packaged in final form for veterinary use; indicated as a sedative and analgesic for cats and dogs. |
| **Note** | The physical, chemical, toxicological and ecological properties of this product/ mixture have not been fully characterized. This SDS will be revisited as more data become available. |
| **Issue Date** | June 8, 2017 |

## SECTION 2 - HAZARDS IDENTIFICATION

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| **Classification of the substance or mixture** | **Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada.** Please consult the prescribing/packaging information. **The classification and labelling listed below is for bulk Dexmedetomidine Hydrocholoride Sterile Injectable Solution** |
| **Regulation (EC) 1272/ 2008 [GHS]** | Not classified |

| | |
|---|---|
| **Directive 67/548/EEC or 1999/45/EC** | Not classified |

**Label elements**

| | |
|---|---|
| **CLP/GHS hazard pictogram** | None required |
| **CLP/GHS signal word** | None required |
| **CLP/GHS hazard statements** | None required |
| **CLP/GHS precautionary statements** | None required |
| **EU symbol/indication of danger** | None required |
| **Risk (R) Phrase(s)** | None required |
| **Safety Advice** | None required |

**Other hazards**

Dexmedetomidine hydrochloride is an $\alpha_2$-adrenergic agonist with potent sedative properties. The most common adverse effects reported with clinical use of mixtures containing dexmedetomidine are hypotension, bradycardia, and dry mouth. Other adverse effects include transient hypertension, fever, hypoxia, and anemia, and tachycardia episodes. Symptoms of withdrawal (*e.g.,* nausea, vomiting, and agitation) have been reported following discontinuation after 7 days of repeated administration.

**US Signal word**

Attention

**US Hazard overview**

None required

**Note**

This mixture is not classified as dangerous/hazardous according to directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP), and applicable US regulations. See Section 16 for full text of EU and GHS classifications. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC or 1999/45/EC. The GHS classifications are based on Regulation (EC) 1272/2008. See Section 16 for full text of EU and GHS classifications.

## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

| Ingredient | CAS # | EINECS/ ELINCS# | Amount | EU Classification | GHS Classification |
|---|---|---|---|---|---|
| Dexmedetomidine hydrochloride | 145108-58-3 | N/A | <0.01% | Harmful - Xn: R63 | STOT-S3: H336; RT2: H361d |
| Sodium chloride | 7647-14-5 | 231-598-3 | <1% | Not classified | Not classified |

**Note** The ingredient(s) listed above are considered dangerous/hazardous. Sodium chloride is included because it has an OEL. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

## SECTION 4 - FIRST AID MEASURES

**Description of first aid measures**

**Immediate Medical Attention Needed** Yes

**Eye Contact** If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

**Skin Contact** Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

**Inhalation** Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

**Ingestion** Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

**Protection of first aid responders** See Section 8 for Exposure Controls/Personal Protection recommendations.

**Most important symptoms and effects, both acute and delayed** See Sections 2 and 11.

**Indication of immediate medical attention and special treatment needed, if necessary** Contains dexmedetomidine, a potent sedative. Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. Refer to current prescribing information or to local poison control information centers.

## SECTION 5 - FIREFIGHTING MEASURES

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| **Extinguishing media** | Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials. |
| **Specific hazards arising from the substance or mixture** | No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen or chloride and sodium-containing compounds. |
| **Flammability/ Explosivity** | No specific information identified for the product/mixture. No explosivity or flammability data identified. As product is in an aqueous solution, it is not expected to be flammable or explosive. |
| **Advice for firefighters** | Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use. |

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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| **Personal precautions, protective equipment and emergency procedures** | If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust/mist/vapors/spray. |
| **Environmental precautions** | Do not empty into drains. Avoid release to the environment. |
| **Methods and material for containment and cleaning up** | DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice. |
| **Reference to other sections** | See Sections 8 and 13 for more information. |

## SECTION 7 - HANDLING AND STORAGE

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| **Precautions for safe handling** | When handling, use proper personal protective equipment as specified in Section 8. Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). |
| **Conditions for safe storage including any incompatibilities** | Store at controlled room temperatures 68-77° F(20-25°C). Protect from freezing.. |
| **Specific end use(s)** | No information identified. |

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

**Note**

Wash hands, face and other potentially exposed areas immediately in the event of physical contact.

**Control Parameters/ Occupational Exposure Limit Values**

| Compound | Issuer | Type | OEL |
|---|---|---|---|
| Sodium chloride | Latvia, Lithuania, Russia | TWA-8 HR | 5 mg/m³ |

**Exposure/Engineering controls**

None required for normal handling of packaged product. If vials are crushed or broken: control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at mist/aerosol/spray-generating points.

**Respiratory protection**

None required for normal handling of packaged product. If vials are crushed or broken: choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with appropriate HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.

**Hand protection**

None required for the normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

**Skin protection**

Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

**Eye/face protection**

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Environmental Exposure Controls**

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

**Other protective measures**

Wash hands in the event of contact with this mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

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|---|---|
| **Appearance** | Liquid |
| **Color** | Clear, colorless |
| **Odor** | Odorless |
| **Odor threshold** | No information identified. |
| **pH** | No information identified. |
| **Melting point/ freezing point** | No information identified. |
| **Initial boiling point and boiling range** | No information identified. |
| **Flash point** | No information identified. |
| **Evaporation rate** | No information identified. |
| **Flammability (solid, gas)** | No information identified. |
| **Upper/lower flammability or explosive limits** | No information identified. |
| **Vapor pressure** | No information identified |
| **Vapor density** | No information identified. |
| **Relative density** | No information identified. |
| **Water solubility** | Freely soluble in water |
| **Solvent solubility** | No information identified. |
| **Partition coefficient (*n-octanol/water*)** | No information identified. |
| **Auto-ignition temperature** | No information identified. |
| **Decomposition temperature** | No information identified. |
| **Viscosity** | No information identified. |
| **Explosive properties** | No information identified. |
| **Oxidizing properties** | No information identified. |

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

**Other information**

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|---|---|
| **Molecular weight** | Not applicable (Mixture) |
| **Molecular formula** | Not applicable (Mixture) |

## SECTION 10 - STABILITY AND REACTIVITY

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|---|---|
| **Reactivity** | No information identified. |
| **Chemical stability** | No information identified. |
| **Possibility of hazardous reactions** | No information identified. |
| **Conditions to avoid** | Avoid extreme temperatures. |
| **Incompatible materials** | No information identified. |
| **Hazardous decomposition products** | No information identified. |

## SECTION 11 - TOXICOLOGICAL INFORMATION

**Note** **No toxicology data for the product/mixture were identified. The following data describe the active ingredient and/or the individual ingredients where applicable.**

**Information on toxicological effects**

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

**Acute toxicity**

| Compound | Type | Route | Species | Dose |
|---|---|---|---|---|
| Dexmedetomidine hydrochloride | Highest non-lethal dose | IV | mice, rats, and dogs | 1 mg/kg |
| | $LD_{50}$ | IV | Dog | 2 mg/kg |
| Sodium chloride | $LD_{50}$ | Oral | Rat | 3000 mg/kg |
| | $LD_{50}$ | Dermal | Rabbit | >10,000 mg/kg |
| | $LC_{50}$ | Inhalation | Rat | >42 g/m³ (1-hr) |
| | $LD_{50}$ | Oral | Mouse | 4000 mg/kg |

**Irritation/Corrosion** No information identified.

**Sensitization** No information identified.

**STOT-single exposure** No information identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION …continued

**STOT-repeated exposure/Repeat-dose toxicity**

Dexmedetomidine given IV to rats caused sedation, piloerection (hair standing up), and exophthalmos (abnormal eyeball protrusion) at 160 mg/kg/day. Small changes in thymus and body weights were reported at lower doses. A NOAEL of 40 mg/kg/day was identified.

**Reproductive toxicity**

No effects on fertility were reported in rats given subcutaneous (SC) dexmedetomidine at doses up to 54 mg/kg/day. The NOAEL for systemic toxicity was 6 mg/kg/day.

**Developmental toxicity**

Dexmedetomidine was administered SC to rats and IV to rabbits during gestation at doses up to 200 and 96 mg/kg/day, respectively. Increased post-implantation loss and a reduced number of live pups were noted in rats (NOAEL = 20 mg/kg/day). No developmental/maternal toxicity was seen in rabbits (NOAEL = 96 mg/kg/day).

In a multi-generational study, SC dexmedetomidine was administered to pregnant rats from gestational day 16 through nursing. Decreased pup weights were noted at doses ≥ 8 mg/kg/day. When pups born to mothers treated with 32 mg/kg/day were allowed to mature and mate, elevated embryo-fetal toxicity and delayed motor development was noted in their offspring. The NOAEL was 2 mg/kg/day.

**Genotoxicity**

Dexmedetomidine was negative for mutagenicity in the Ames assay, an *in vitro* forward mutation assay with mouse lymphoma cells, and was negative for chromosomal abberations (in human lymphocytes). However, it was positive for chromosomal aberrations with rat S9 metabolic activation, and was positive *in vivo* in the mouse micronucleus test with NMRI mice, but not with CD-1 mice. Overall, the mutagenicity data are difficult to interpret.

**Carcinogenicity**

No studies identified. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Aspiration hazard**

No data available.

**Human health data**

See Section 2 - "Other hazards"

## SECTION 12 - ECOLOGICAL INFORMATION

**Toxicity**

| Compound | Type | Species | Concentration |
|---|---|---|---|
| Dexmedetomidine hydrochloride | -- | -- | -- |
| Sodium chloride | $EC_{50}$/96h | Fish (various species) | >4,700 mg/L |
| | $EC_{50}$/48h | Daphnia magna | 340-1000 mg/L |

**Persistence and Degradability**

No data identified.

**Bioaccumulative potential**

No data identified.

## SECTION 12 - ECOLOGICAL INFORMATION …continued

| | |
|---|---|
| **Mobility in soil** | No data identified. |
| **Results of PBT and vPvB assessment** | Not performed. |
| **Other adverse effects** | No data identified. |
| **Note** | Ecological characteristics of this product/mixture were not available. Releases to the environment should be avoided. |

## SECTION 13 - DISPOSAL CONSIDERATIONS

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|---|---|
| **Waste treatment methods** | Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility. |

## SECTION 14 - TRANSPORT INFORMATION

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|---|---|
| **Transport** | Based on the available data, this mixture is not regulated as a hazardous material/ dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG. |
| **UN number** | None assigned. |
| **UN proper shipping name** | None assigned. |
| **Transport hazard classes and packing group** | None assigned. |
| **Environmental hazards** | Based on the available data, this mixture is not regulated as an environmental hazard or a marine pollutant. |
| **Special precautions for users** | Avoid release to the environment. |
| **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | Not applicable. |

## SECTION 15 - REGULATORY INFORMATION

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|---|---|
| **Safety, health and environmental regulations/legislation specific for the substance or mixture** | This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information. |
| **Chemical safety assessment** | Not conducted. |
| **OSHA Hazardous** | No |
| **WHMIS classification** | Not required. Drugs are not subject to WHMIS. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations. |
| **TSCA status** | Drugs are exempt from TSCA. |
| **SARA section 313** | Not listed. |
| **California proposition 65** | Not listed. |
| **Additional information** | No other information identified. |

## SECTION 16 - OTHER INFORMATION

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|---|---|
| **Full text of R phrases and EU Classifications** | Xn - Harmful. Repr. Cat. 3 - Toxic for Reproduction Category 3. R63 - Possible risk of harm to the unborn child. |
| **Full text of H phrases, P phrases and GHS classification** | STOT-S3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H336 - May cause drowsiness or dizziness. RT2 - Reproductive toxicity Category 2. H361d - Suspected of damaging the unborn child. |
| **Sources of data** | Information from published literature and internal company data. |
| **Abbreviations** | ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - |

## SECTION 16 - OTHER INFORMATION …continued

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|---|---|
| **Abbreviations …continued** | Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System |
| **Revisions** | This is the first version of this SDS. |
| **Disclaimer** | The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.<br><br>No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel. |