SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Dexmedesed™ (dexmedetomidine hydrochloride) Sterile Injectable Solution
Synonyms:	Not Available
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Bulk formulated pharmaceutical mixture/formulated pharmaceutical product packaged in final form for veterinary use; indicated as a sedative and analgesic for cats and dogs.
Uses advised against:	Not for human use.
1.3 Name, Address, and Telephone of the Responsible Party	
Address:	Dechra Veterinary Products 7015 College Boulevard Suite 525 Overland Park KS 66211
Telephone:	1-866-933-2472 (Monday-Friday: 8:00 AM-5:00 PM EST)
Distributor name (Canada):	Dechra Veterinary Products
Address:	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada
Telephone:	(855) 332-9334
Website:	www.dechra.ca
Email:	Not Available
1.4 Emergency Telephone Numbers	
Emergency phone (CA)	(855) 332-9334
	1-866-933-2472 (Monday-Friday: 8:00 AM-5:00 PM EST)

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture 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. 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 Dexmedesed™ Sterile Injectable Solution.	
Classification according to regulation (EC) No 1272/2008 [GHS]:	Not classified
Classification according to Directive 67/548/EEC or 1999/45/EC:	Not classified
2.2 Label Elements	
CLP/GHS hazard pictogram:	None required
CLP/GHS signal word:	None required
US signal word:	Attention
US Hazard overview:	None required
CLP/GHS hazard statement(s):	
None required	
CLP/GHS Precautionary Statement(s) Prevention:	
None required	
CLP/GHS Precautionary Statement(s) Response:	
None required	
CLP/GHS Precautionary Statement(s) Storage:	
None required	
CLP/GHS Precautionary Statement(s) Disposal:	
None required	
EU symbol/indication of danger:	
None required	
Risk (R) Phrase(s):	
None required	
Safety advice:	
None required	

2.3 Other Hazard Information

Dexmedetomidine hydrochloride is an α2-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.

Note: 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: INFORMATION ON THE INGREDIENTS

3.1 Substances

See section below for composition of mixtures

3.2 Mixtures

1. CAS # 2. EINECS/ELINCS No.	% weight	Name	EU Classification	GHS Classification
1. 145108-58-3 2. N/a	<0.1%	Dexmedetomidine hydrochloride	Harmful – Xn: R63	STOT-S3: H336; RT2: H361d
1. 7647-14-5 2. 231-598-3	<1%	Sodium chloride	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

4.1 Description of first aid measures

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 and show the package leaflet or the label to the medical practitioner.
Skin contact:	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor and show the package leaflet or the label to the medical practitioner.

Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. 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 and show the package leaflet or the label to the medical practitioner.
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 and show the package leaflet or the label to the medical practitioner.
Self-injection:	In case of accidental self-injection, seek medical advice and show the package leaflet to the medical practitioner.

4.2 Most important symptoms and effects, both acute and delayed

See Sections 2 and 11

4.3 Indication of immediate medical attention and special treatment needed

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: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable:	Select extinguishing media suitable for surrounding area.
Unsuitable:	There is no restriction on the type of extinguisher which may be used.

5.2 Special hazards arising from the substance or mixture

Fire incompatibility:	None known

5.3 Special protective actions for fire-fighters:

Firefighting:	Alert Fire Brigade and tell them location and nature of hazard. Wear full protective clothing and a self-contained breathing apparatus with a full face-piece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use. Prevent, by any means available, spillage from entering drains or water courses.
Fire / explosion hazard:	No explosivity or flammability data identified. As product is in an aqueous solution, it is not expected to be flammable or explosive. May emit carbon monoxide, carbon dioxide, oxides of nitrogen or chloride and sodium-containing compounds.

SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 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.	
6.2 Environmental Precautions	
Do not empty into drains. Avoid release to the environment.	
6.3 Methods and material for containment and cleaning up	
Spills are unlikely due to the nature of the product and how it is packaged	
Minor Spills:	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Soak up material with absorbent, e.g., paper towels. Control personal contact with the substance, by using protective equipment.
Major 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. Prevent, by any means available, spillage from entering drains or water course.
SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Wear suitable protective clothing when handling the product. When handling, **DO NOT** eat, drink or smoke. Always wash hands with water after handling. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Check that containers are clearly labelled. Store at controlled room temperatures 68-77°F (20-25°C). Protect from freezing.
Storage incompatibility:	None known.
7.3 Specific end uses	
Not available	

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION
8.1 Control parameters
DERIVED NO EFFECT LEVEL - DNEL (EU)
Not Available
PREDICTED NO EFFECT LEVEL - PNEC (EU)
Not Available
OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:		
Not Available		
EMERGENCY LIMITS:		
Not Available		
Ingredient	**Original IDLH**	**Revised IDLH**
Not Available		
8.2 Exposure controls		
Appropriate 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.	
Personal protection:		
Eye and 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.	
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.	

Hands/ feet 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.
Body protection:	Wear appropriate clothing.
Other protection:	No special equipment needed when handling small quantities. 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).
Thermal hazards:	Not applicable
Respiratory protection:	Not applicable

8.3 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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Dexmedesed™: Clear, colorless liquid
Container:
Physical state: Liquid
Odor: Odorless
Odor Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Not available
Initial boiling point and boiling range: Not available
Flash Point: In water – no flash point
Evaporation rate: Not available
Flammability: Not available
Upper/lower flammability or explosive limits: Not available
Vapor pressure: Not available
Relative Density (at degrees C): Not available
Solubility in water and solvents (mg/l): Freely soluble in water
Vapour density: Not available
Auto ignition temperature (degrees C): Not available
Decomposition temperature (degrees C): Not available
Viscosity: (degrees C): Not available
Explosive properties: Not available
Oxidising properties: Not available
Partition Coefficient: Not available
Molecular weight: Not available
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Not available

9.2 Other information

Not Available

10: REACTIVITY AND STABILITITY

10.1 Reactivity:	See Section 7.
10.2 Chemical stability:	Product is considered stable.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions.
10.4 Conditions to avoid:	Avoid extreme temperatures. Do not freeze.
10.5 Incompatible materials:	See section 7.

10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

Dexmedesed™:	**Acute toxicity**	**Irritation**
	Not Available	Not Available
Dexmedetomidine hydrochloride:	**Acute toxicity**	**Irritation**
	IV (mice/rats/dogs) highest non-lethal dose: 1mg/kg IV (dog) LD_{50}: 2mg/kg	Not available
Sodium chloride:	**Acute toxicity**	**Irritation**
	Oral (rat) LD_{50}: 3000 mg/kg Dermal (rabbit) LD_{50}: >10,000 mg/kg Inhalation (rat) LC_{50}: >42 g/m^3 (1-hr) Oral (mouse) LD_{50}: 4000 mg/kg	Not available

Skin corrosion / irritation:
No information identified.
Serious eye damage / irritation:
No information identified.
Respiratory or skin sensitization:
No information identified.
Germ cell mutagenicity:
No information identified.
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.
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.
STOT – single exposure:
No information identified.
STOT–repeated exposure:
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.
Aspiration hazard:
No information identified.

SECTION 12: ECOLOGICAL INFORMATION
12.1 Toxicity
Not Available
DO NOT discharge into sewer or waterways.
12.2 Persistence and degradability
Not Available
12.3 Bioaccumulative potential
Not Available
12.4 Mobility in Soil
Not Available

12.5 Results of PBT and vPvB assessment
Not Available

12.6 Other adverse effects
Not data identified

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / packaging disposal:	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 clean-ups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or onsite wastewater treatment facility. Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations (Canada 2015).
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available

SECTION 14: TRANSPORT INFORMATION

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.

Labels required:

Marine pollutant:	NO
Hazchem:	Not Applicable

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Limited quantity	N/a

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	

14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
14.6 Special precautions for user	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION
This SDS complies with the requirements under US, EU, Canada and GHS (EU CLP - Regulation EC No 1272/2008, WHMIS, 2015) guidelines. Consult your local/regional authorities for more information.
Safety, health and environmental regulations/legislation specific for the substance or mixture
This SDS complies with the requirements under US, EU, Canada and GHS (EU CLP - Regulation EC No 1272/2008, WHMIS, 2015) 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
Warning: This packaging contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.
SECTION 16: OTHER INFORMATION
Revision date 07/12/2017 **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 - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

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.

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.