SAFETY DATA SHEETS

This SDS packet was issued with item:

078942686

N/A

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

DEXASED™ (DEXMEDETOMIDINE HYDROCHLORIDE) INJECTION 0.5MG/ML

SECTION 1: Identification

Product identifier

Product name: DEXASED™ (DEXMEDETOMIDINE HYDROCHLORIDE) INJECTION 0.5MG/ML

Product code: 21305014

Recommended use of the product and restriction on use

Relevant identified uses: For Animal Use Only. Dexmedetomidine Hydrochloride Injection is indicated for use as a sedative and analgesic in dogs and cats to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures. Dexmedetomidine Hydrochloride Injection is also indicated for use as a preanesthetic to general anesthesia in dogs and cats.

Uses advised against: Not determined or not applicable.

Reasons why uses advised against: Not determined or not applicable.

Manufacturer or supplier details

Supplier:

United States

Aspen Veterinary Resources, LTD.
3155 W. Heartland Drive
Liberty, MO 64068
1-800-792-1238

Emergency telephone number:

United States

CHEMTREC
Within USA and Canada: 1-800-424-9300 (24 hours)
Outside USA and Canada: +1-703-527-3887 (24 hours)

SECTION 2: Hazard(s) identification

GHS classification: Not a hazardous substance or mixture

Label elements

Hazard pictograms: None

Signal word: None

Hazard statements: None

Precautionary statements: None

Hazards not otherwise classified: None

SECTION 3: Composition/information on ingredients

Identification	Name	Weight %

CAS number: 7732-18-5	Water	>95
CAS number: 7647-14-5	Sodium chloride	0.9
CAS number: 99-76-3	Methylparaben	0.16
CAS number: 145108-58-3	Dexmedetomidine Hydrochloride	0.05
CAS number: 94-13-3	Propyparaben	0.02

Additional Information: None

SECTION 4: First aid measures

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

After inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. If respiratory symptoms develop or persist, seek medical advice/attention.

After skin contact:

Wash affected area with plenty of soap and water. Remove contaminated clothing and launder before reuse. If skin irritation develops or persists, seek medical advice/attention.

After eye contact:

Immediately rinse eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 15 minutes. If eye irritation develops or persists, seek medical advice/attention.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed

Acute symptoms and effects:

Not determined or not applicable.

Delayed symptoms and effects:

Not determined or not applicable.

Immediate medical attention and special treatment

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards during fire-fighting:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special protective equipment for firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA).

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage

Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

SECTION 8: Exposure controls/personal protection

Only those substances with limit values have been included below.

Occupational Exposure limit values:

No occupational exposure limits noted for the ingredient(s).

Biological limit values:

No biological exposure limits noted for the ingredient(s).

Information on monitoring procedures:

Not determined or not applicable.

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Clear, colorless solution
Odor	Not determined or not available.
Odor threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.

Dynamic viscosity	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

Other information

SECTION 10: Stability and reactivity

Reactivity:
Not reactive under recommended handling and storage conditions.
Chemical stability:
Stable under recommended handling and storage conditions.
Possibility of hazardous reactions:
Hazardous reactions are not anticipated under recommended conditions of handling and storage.
Conditions to avoid:
Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.
Incompatible materials:
Strong oxidizing agents.
Hazardous decomposition products:
Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
Dexmedetomidine Hydrochloride	Oral ATE	LD50 Rat: 500 mg/kg
Propyparaben	oral	LD50 Mouse: 6332 mg/kg
Methylparaben	oral	LD50 Rat: 2100 mg/kg
Sodium chloride	oral	LD50 Rat: 3000 mg/kg
	inhalation	LC50 Rat: 42,000 mg/m³ (1 hr (aerosol))
	dermal	LD50 Rabbit: >10,000 mg/kg

Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:
No data available.

Substance data:

Name	Result
Dexmedetomidine Hydrochloride	Causes skin irritation.
Propyparaben	Causes skin irritation.
Methylparaben	Causes skin irritation.

Serious eye damage/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data:

Name	Result
Dexmedetomidine Hydrochloride	Causes serious eye irritation.
Propyparaben	Causes serious eye irritation.
Methylparaben	Causes serious eye irritation.

Respiratory or skin sensitization

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

National Toxicology Program (NTP): None of the ingredients are listed.

OSHA Carcinogens: Not applicable

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Reproductive toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data:

Name	Result
Dexmedetomidine Hydrochloride	May cause respiratory irritation.
Propyparaben	May cause respiratory irritation.
Methylparaben	May cause respiratory irritation.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Information on likely routes of exposure:

No data available.

Symptoms related to the physical, chemical and toxicological characteristics:

No data available.

Other information:

No data available.

SECTION 12: Ecological information

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Methylparaben	LC50 Oryzias latipes: 59.5 mg/L (96 h - semi-static test (OECD) Test Guideline 203))
	EC50 Pseudokirchneriella subcapitata (algae): 91 mg/l mg/L (72 h - static test (ISO 8692) -)
	EC50 Daphnia magna (Water flea): 11.2 mg/L (48 h - static test)
	EC50 Pseudomonas fluorescens: 500 mg/L

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Persistence and degradability

Product data: No data available.

Substance data:

Name	Result
Propyparaben	Readily biodegradable in water (91.5% degradation after 28 days).
Methylparaben	Readily biodegradable (89% degradation after 28 days).

Bioaccumulative potential

Product data: No data available.

Substance data: No data available.

Mobility in soil

Product data: No data available.

Substance data: No data available.

Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment:

Sodium chloride	This substance is not PBT.

vPvB assessment:

Sodium chloride	This substance is not vPvB.

Other adverse effects: No data available.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities

Contaminated packages:

Not determined or not applicable.

SECTION 14: Transport information

United States Transportation of dangerous goods (49 CFR DOT)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

SECTION 15: Regulatory information

United States regulations

Inventory listing (TSCA): All ingredients are listed-active or exempt.

Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.

Export notification under TSCA Section 12(b): None of the ingredients are listed.

SARA Section 302 extremely hazardous substances: None of the ingredients are listed.

SARA Section 313 toxic chemicals: None of the ingredients are listed.

CERCLA: None of the ingredients are listed.
RCRA: None of the ingredients are listed.
Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.
Massachusetts Right to Know: None of the ingredients are listed.
New Jersey Right to Know: None of the ingredients are listed.
New York Right to Know: None of the ingredients are listed.
Pennsylvania Right to Know: None of the ingredients are listed.
California Proposition 65: None of the ingredients are listed.

SECTION 16: Other information

Abbreviations and Acronyms: None
Disclaimer:
This product has been classified in accordance with OSHA HCS 2012 guidelines. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.
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End of Safety Data Sheet