

SAFETY DATA SHEETS

This SDS packet was issued with item:

078949389

N/A



Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 03.22.2024

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Revertased (atipamezole) Injection 5.0 mg/mL | 10mL (RX)

SECTION 1: Identification

Product Identifier

Product Name: Revertased (atipamezole) Injection 5.0 mg/mL | 10mL (RX)

Product code: 78949389

Recommended Use of the Product and Restriction on Use

Relevant Identified Uses: ANTISEDAN * ALZANE * ANTISEDAN® (atipamezole hydrochloride) injectable solution * Dexmedetomidine and Medetomidine Reversing Agent

Uses Advised Against: Veterinary product used as anti-sedation agent
Not for human use.

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	96.55

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CAS Number: 7647-01-0	Hydrochloric acid	1
CAS Number: 1310-73-2	Sodium hydroxide	1
CAS Number: 7647-14-5	Sodium chloride	0.85
CAS Number: 104075-48-1	Atipamezole hydrochloride	0.5
CAS Number: 99-76-3	Methylparaben	0.1

Additional Information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200).

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:

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Administration of atipamezole causes transient changes in heart rate and blood pressure.

Delayed Symptoms and Effects:

Not determined or not applicable.

Immediate Medical Attention and Special Treatment

Specific Treatment:

Alpha2-adrenergic receptor antagonist. Monitor respiratory, cardiac, and central nervous system.

Notes for the Doctor:

Treat symptomatically.

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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). Recommended storage condition: 15 - 30°C (59 - 86°F).

SECTION 8: Exposure Controls/Personal Protection

Only those substances with limit values have been included below.

Occupational Exposure Limit Values:

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Country (Legal Basis)	Substance	Identifier	Permissible concentration
ACGIH	Hydrochloric acid	7647-01-0	Ceiling Limit: 2 ppm (TLV)
	Sodium hydroxide	1310-73-2	Ceiling Limit: 2 mg/m ³
NIOSH	Hydrochloric acid	7647-01-0	IDLH: 50 ppm
	Hydrochloric acid	7647-01-0	Ceiling Limit: 5 ppm (7 mg/m ³)
	Sodium hydroxide	1310-73-2	IDLH: 10 mg/m ³
	Sodium hydroxide	1310-73-2	Ceiling Limit: 2 mg/m ³
OSHA	Hydrochloric acid	7647-01-0	Ceiling Limit: 5 ppm (7 mg/m ³)
	Hydrochloric acid	7647-01-0	PEL: 5 ppm (7 mg/m ³)
	Sodium hydroxide	1310-73-2	8-Hour TWA-PEL: 2 mg/m ³
United States(California)	Hydrochloric acid	7647-01-0	PEL: 0.3 ppm (0.45 mg/m ³)
	Hydrochloric acid	7647-01-0	Ceiling Limit: 2 ppm
	Sodium hydroxide	1310-73-2	Ceiling Limit: 2 mg/m ³

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

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Appearance	Liquid in multiple-dose vials
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 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	100 % (In water)
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 explosive
Oxidizing properties	Not oxidizing

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:

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Name	Route	Result
Atipamezole hydrochloride	Oral ATE	LD50 Rat: 500 mg/kg
	Dermal ATE	LD50 Rabbit: 1100 mg/kg
	Inhalation ATE	LC50 Rat: 1.5 mg/L (4 hr [Dust/mist])
Methylparaben	oral	LD50 Rat: 2100 mg/kg
Sodium chloride	oral	LD50 Rat: >3980 mg/kg
	inhalation	LC50 Rat: >10.5 mg/L (4 hr [aerosol])
	dermal	LD50 Rabbit: >10,000 mg/kg
Hydrochloric acid	Inhalation ATE	LC50 Rat: 700 ppmV (4 hr [gas])
Sodium hydroxide	Oral ATE	LD50 Rat: 325 mg/kg
	dermal	LD50 Rabbit: 1350 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
Hydrochloric acid	Causes severe skin burns.
Sodium hydroxide	Causes severe skin burns.

Serious Eye Damage/Irritation

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

Product Data:

No data available.

Substance Data:

Name	Result
Hydrochloric acid	Causes serious eye damage.
Sodium hydroxide	Causes serious eye damage.

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):

Name	Classification
Hydrochloric acid	Group 3

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.

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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
Hydrochloric acid	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	Fish LC50 <i>Oryzias latipes</i> : 59.5 mg/L (96 hr)
	Aquatic Plants EC50 <i>Pseudokirchneriella subcapitata</i> (algae): 91 mg/L (72 hr [growth rate])
	Aquatic Invertebrates EC50 <i>Daphnia magna</i> : 11.2 mg/L (48 hr [mobility])
Sodium chloride	Fish LC50 <i>Lepomis macrochirus</i> : 5840 mg/L (96 hr)
	Aquatic Invertebrates EC50 <i>Daphnia magna</i> : 874 mg/L (48 hr [immobilisation])

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Name	Result
Sodium hydroxide	Aquatic Invertebrates EC50 Ceriodaphnia sp.: 40.4 mg/L (48 hr [immobilization])
	Fish LC50 Fish: 35 - 189 mg/L (96 hr)

Chronic (Long-Term) Toxicity

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

Product Data: No data available.

Substance Data:

Name	Result
Methylparaben	Aquatic Invertebrates EC50 Daphnia magna: 0.89 mg/L (21 d [mortality])
Sodium chloride	Fish NOEC Pimephales promelas: 252 mg/L (33 d [mortality])
	Aquatic Invertebrates NOEC Daphnia pulex: 314 mg/L (21 d [reproduction])

Persistence and Degradability

Product Data: No data available.

Substance Data:

Name	Result
Methylparaben	The substance is readily biodegradable. 89% degradation, measured by CO2 evolution, after 28 days.
Sodium chloride	Persistence assessment based on biodegradability is not relevant for inorganic compounds such as this substance.
Hydrochloric acid	Persistence assessment based on biodegradability is not relevant for inorganic compounds such as this substance.
Sodium hydroxide	Persistence assessment based on biodegradability is not relevant for inorganic compounds such as this substance.

Bioaccumulative Potential

Product Data: No data available.

Substance Data:

Name	Result
Methylparaben	The substance has a low potential for bioaccumulation. Estimated BCF: 6.4 [QSAR]
Sodium chloride	Bioaccumulation assessment using a classic BCF assessment is not considered relevant for inorganic compounds such as this substance.
Hydrochloric acid	Bioaccumulation assessment using a classic BCF assessment is not considered relevant for inorganic compounds such as this substance.
Sodium hydroxide	Bioaccumulation assessment using a classic BCF assessment is not considered relevant for inorganic compounds such as this substance.

Mobility in Soil

Product Data: No data available.

Substance Data:

Name	Result
Methylparaben	The substance has a low potential for adsorption to soil and sediment. Koc at 20 °C: 280
Sodium chloride	Mobility in soil assessment based on KOC/Kd values are not relevant for inorganic compounds such as this substance.
Hydrochloric acid	Mobility in soil assessment based on KOC/Kd values are not relevant for inorganic compounds such as this substance.

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Name	Result
Sodium hydroxide	Mobility in soil assessment based on KOC/Kd values are not relevant for inorganic compounds such as this substance.

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:

Methylparaben	The substance is not PBT.
Sodium chloride	PBT assessment does not apply to inorganic compounds such as this substance.
Hydrochloric acid	PBT assessment does not apply to inorganic compounds such as this substance.
Sodium hydroxide	PBT assessment does not apply to inorganic compounds such as this substance.

vPvB assessment:

Methylparaben	The substance is not vPvB.
Sodium chloride	vPvB assessment does not apply to inorganic compounds such as this substance.
Hydrochloric acid	vPvB assessment does not apply to inorganic compounds such as this substance.
Sodium hydroxide	vPvB assessment does not apply to inorganic compounds such as this substance.

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 agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

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

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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):

104075-48-1	Atipamezole hydrochloride	Not Listed
99-76-3	Methylparaben	Listed - Active
7647-14-5	Sodium chloride	Listed - Active
7647-01-0	Hydrochloric acid	Listed - Active
1310-73-2	Sodium hydroxide	Listed - Active
7732-18-5	Water	Listed - Active

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:

7647-01-0	Hydrochloric acid	Listed
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SARA Section 313 Toxic Chemicals:

7647-01-0	Hydrochloric acid	Listed
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CERCLA:

7647-01-0	Hydrochloric acid	Listed	5000 lbs
1310-73-2	Sodium hydroxide	Listed	1000 lb

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:

7647-01-0	Hydrochloric acid	Listed
1310-73-2	Sodium hydroxide	Listed

New Jersey Right to Know:

7647-01-0	Hydrochloric acid	Listed
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1310-73-2	Sodium hydroxide	Listed
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New York Right to Know:

7647-01-0	Hydrochloric acid	Listed
1310-73-2	Sodium hydroxide	Listed

Pennsylvania Right to Know:

7647-01-0	Hydrochloric acid	Listed
1310-73-2	Sodium hydroxide	Listed

California Proposition 65: None of the ingredients are listed.

Additional information: Not determined.

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