

SAFETY DATA SHEET



Atipamezole hydrochloride sterile injectable solution

Section 1. Identification

GHS product identifier : Atipamezole hydrochloride sterile injectable solution

Other means of identification : ☒ ALZANE
ANTISEDAN
ANTISEDAN® (atipamezole hydrochloride) injectable solution
Dexmedetomidine and Medetomidine Reversing Agent

Product type : Liquid.

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

Identified uses

☒ Veterinary product used as anti-sedation agent

Uses advised against

Not for human use

Supplier's details : Zoetis Inc.
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1-888-963-8471

Emergency telephone number (with hours of operation) : CHEMTREC (24 hours): 1-800-424-9300
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Product Support/Technical Services: 1-888-963-8471

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Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.


Section 2. Hazards identification

Disposal : Not applicable.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	Identifiers
 H-Imidazole, 4-(2-ethyl-2,3-dihydro-1H-inden-2-yl)-, monohydrochloride	≤1	CAS: 104075-48-1

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

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

Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled. No specific treatment.

- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

- Hazardous thermal decomposition products** : No specific data.

Section 5. Fire-fighting measures

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : Keep unnecessary personnel away.
- For emergency responders** : Keep unnecessary personnel away. If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Biological exposure indices

No exposure indices known.

Control Banding Approach

Section 8. Exposure controls/personal protection

1H-Imidazole, 4-(2-ethyl-2,3-dihydro-1H-inden-2-yl)-, monohydrochloride: OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)

- Appropriate engineering controls** : Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
- Individual protection measures**
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : 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.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid. [Liquid in multiple-dose vials]
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Boiling point or initial boiling point and boiling range** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.

Section 9. Physical and chemical properties and safety characteristics

Flammability	: Not available.
Lower and upper explosion limit/flammability limit	: Not available.
Vapor pressure	: Not available.
Relative vapor density	: Not available.
Relative density	: Not available.
Solubility in water	: Not available.
Miscible with water	: <input checked="" type="checkbox"/> Yes.
Partition coefficient: n-octanol/water	: Not applicable.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C (104°F)): Not available.

Particle characteristics

Pmax	: Not available.
Kst	: Not available.
Min. Ignition Temperature (Dust)	: Not available.
Minimum ignition energy (MIE) - dust cloud	: Not available.
Median particle size	: Not applicable.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Remarks	: Strong oxidizing agents
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name

☒ H-Imidazole, 4-(2-ethyl-2,3-dihydro-1H-inden-2-yl)-, monohydrochloride

Result

Rat - Subcutaneous - LD50

44 mg/kg

Dog - Intramuscular - LDLo

>5 mg/kg

Section 11. Toxicological information

Conclusion/Summary [Product] : Not applicable.

Skin corrosion/irritation

Not available.

Conclusion/Summary [Product] : Not applicable.

Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product] : Not applicable.

Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product] : Not applicable.

Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product] : Not applicable.

Respiratory

Conclusion/Summary [Product] : Not applicable.

Specific target organ toxicity (single exposure)

Not applicable.

Specific target organ toxicity (repeated exposure)

Not applicable.

Aspiration hazard

Not applicable.

Information on the likely routes of exposure

Not available.

Potential acute health effects

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

Potential chronic health effects

Not available.

Section 11. Toxicological information

General : No known significant effects or critical hazards.

Germ cell mutagenicity

Not available.

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Carcinogenicity

Not available.

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Reproductive toxicity

Not available.

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

N/A

Section 12. Ecological information

Toxicity

Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/Water partition coefficient : Not available.

Other adverse effects

No known significant effects or critical hazards.

Conclusion/Summary [Product] : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name			
Transport hazard class(es)			
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

TSCA 12(b) - Chemical export notification

Not applicable.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

Section 15. Regulatory information

DEA List I Chemicals : Not listed
(Precursor Chemicals)

DEA List II Chemicals : Not listed
(Essential Chemicals)

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia	: Not determined.
Canada	: Not determined.
China	: Not determined.
Eurasian Economic Union	: Russian Federation inventory : Not determined.
Japan	: Japan inventory (CSCL) : Not determined. Japan inventory (ISHL) : Not determined.
New Zealand	: All components are listed or exempted.
Philippines	: Not determined.
Republic of Korea	: Not determined.
Taiwan	: Not determined.
Thailand	: Not determined.
Turkey	: Not determined.
United States	: Not determined.

Section 15. Regulatory information

Viet Nam : Not determined.

Section 16. Other information

Procedure used to derive the classification

Not classified.

History

Date of issue/Date of revision : 6/24/2025

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Version : 1

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
DOT = Department of Transportation
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
IMO = International Maritime Organization
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
TDG = Transportation of Dangerous Goods
UN = United Nations

References : Not available.

Notice to reader

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