

# SAFETY DATA SHEET



## 1. Identification

<b>Product identifier</b>	<b>Atipamezole hydrochloride sterile injectable solution</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	ANTISEDAN * ALZANE * ANTISEDAN® (atipamezole hydrochloride) injectable solution * Dexmedetomidine and Medetomidine Reversing Agent
<b>Recommended use</b>	Veterinary product used as anti-sedation agent
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (USA)</b>	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
<b>Rocky Mountain Poison and Drug Center</b>	1-866-531-8896
<b>Product Support/Technical Services</b>	1-800-366-5288
<b>Emergency telephone numbers</b>	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
<b>Company Name (CA)</b>	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
<b>Emergency telephone number</b>	International CHEMTREC (24 hours): +1-703-527-3887
<b>Contact E-Mail</b>	productsupport@zoetis.com
<b>Product Support</b>	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

**Supplier** Not available.

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.

### Label elements

<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Observe good industrial hygiene practices.
<b>Response</b>	Wash hands after handling.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.

**Other hazards** None known.

**Supplemental information** Administration of atipamezole causes transient changes in heart rate and blood pressure. alpha2-adrenergic receptor antagonist. Clinical use of this drug has caused nervousness, excitation, vomiting, diarrhea.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Atipamezole hydrochloride	Imidazole derivative	104075-48-1	0.5
Methylparaben		99-76-3	<1
Water for injection		7732-18-5	*

All concentrations are in percent by weight (kg) unless ingredient is a gas. Gas concentrations are in percent by volume (l).

**Composition comments** \*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if symptoms occur.
<b>Eye contact</b>	Do not rub eyes. Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention immediately.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control centre immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions.
<b>Most important symptoms/effects, acute and delayed</b>	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.
<b>Indication of immediate medical attention and special treatment needed</b>	alpha2-adrenergic receptor antagonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed. May include hydrogen chloride. May emit toxic fumes of oxides of carbon and nitrogen.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS. Local authorities should be advised if significant spillages cannot be contained.
<b>Methods and materials for containment and cleaning up</b>	Ensure adequate ventilation. Avoid release to the environment. Prevent entry into waterways, sewer, basements or confined areas.  Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.  Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Wash thoroughly after handling. When using, do not eat, drink or smoke. Avoid release to the environment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store locked up. Store in a well-ventilated place. @ 15-30°C (59-86°F). Protect from sunlight. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Control banding approach</b>	Atipamezole hydrochloride: Zoetis OEB 4 (control exposure to the range of 1ug/m3 to <10ug/m3)

<b>Appropriate engineering controls</b>	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. General ventilation normally adequate.
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### Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves.
<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

<b>Appearance</b>	Liquid in multiple-dose vials
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Colorless
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.

<b>Explosive limit – upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	100 %
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidising properties</b>	Not oxidising.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidising agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	No adverse effects due to skin contact are expected.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	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. Clinical use of this drug has caused nervousness, excitation, vomiting, diarrhea.
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### Information on toxicological effects

#### Acute toxicity

Components	Species	Test results
Atipamezole hydrochloride (CAS 104075-48-1)		
<b>Acute</b>		
<b>Intramuscular</b>		
Minimum Lethal Dose	Dog	> 5 mg/m2
<b>Subcutaneous</b>		
LD50	Rat	44 mg/kg

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.

#### Respiratory or skin sensitisation

**Respiratory sensitisation** Not a respiratory sensitizer.

**Skin sensitisation** This product is not expected to cause skin sensitisation.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.
<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not an aspiration hazard.
<b>Chronic effects</b>	None expected under normal and foreseeable conditions of use
<b>Further information</b>	Caution - Pharmaceutical agent. alpha2-adrenergic receptor antagonist.

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

<b>Disposal instructions</b>	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	None known.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

<b>TDG</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not established.

## 15. Regulatory information

<b>Canadian regulations</b>	This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.
<b>Controlled Drugs and Substances Act</b>	Not regulated.
<b>Export Control List (CEPA 1999, Schedule 3)</b>	Not listed.
<b>Greenhouse Gases</b>	Not listed.

## Precursor Control Regulations

Not regulated.

## International regulations

### Stockholm Convention

Not applicable.

### Rotterdam Convention

Not applicable.

### Kyoto protocol

Not applicable.

### Montreal Protocol

Not applicable.

### Basel Convention

Not applicable.

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information

<b>Issue date</b>	25-October-2016
<b>Revision date</b>	20-March-2017
<b>Version No.</b>	02
<b>Disclaimer</b>	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
<b>Revision information</b>	Composition / Information on Ingredients: Disclosure Overrides Disposal considerations: Disposal instructions Disposal considerations: Contaminated packaging Regulatory information: Canadian regulations