1. Identification

Product identifier Atipamezole hydrochloride sterile injectable solution

Other means of identification

Synonyms ANTISEDAN * ALZANE * ANTISEDAN® (atipamezole hydrochloride) injectable solution *
Dexmedetomidine and Medetomidine Reversing Agent

Recommended use Veterinary product used as anti-sedation agent

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)
1-866-531-8896

Rocky Mountain Poison and Drug Center 1-888-963-8471

Product Support/Technical Services CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone numbers International CHEMTREC (24 hours): +1-703-527-3887

Company Name (EU) Zoetis Belgium S.A.
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

Telephone: +32 10 808080

Emergency telephone number International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) 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, excitement, vomiting, diarrhea.

3. Composition/information on ingredients

Mixtures
Material name: Atipamezole hydrochloride sterile injectable solution

Version #: 07    Revision date: 11-01-2021    Issue date: 11-06-2013

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atipamezole hydrochloride</td>
<td>Imidazole derivative</td>
<td>104075-48-1</td>
<td>0.5</td>
</tr>
<tr>
<td>Methylparaben</td>
<td></td>
<td>99-76-3</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Water for injection</td>
<td></td>
<td>7732-18-5</td>
<td>*</td>
</tr>
</tbody>
</table>

Composition comments
*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation
Move to fresh air. For breathing difficulties, oxygen may be necessary. Call a physician if symptoms develop or persist.

Skin contact
Wash off with soap and water. Get medical attention if symptoms occur.

Eye contact
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.

Ingestion
Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed
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.

Indication of immediate medical attention and special treatment needed
alpha2-adrenergic receptor antagonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system.

General information
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed. May include hydrogen chloride. May emit toxic fumes of oxides of carbon and nitrogen.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Move containers from fire area if you can do so without risk.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe mist or vapor. 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.

Methods and materials for containment and cleaning up
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. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Environmental precautions
Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage

Precautions for safe handling: Wear appropriate personal protective equipment. Provide adequate ventilation. Avoid breathing mist or vapor. 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.

Conditions for safe storage, including any incompatibilities: Store locked up. Store in a well-ventilated place. @ 15-30°C (59-86°F). Protect from sunlight. Use care in handling/storage.

8. Exposure controls/personal protection

Occupational exposure limits: This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.

Biological limit values: No biological exposure limits noted for the ingredient(s).

Control banding approach: Atipamezole hydrochloride: Zoetis OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

Appropriate engineering controls: 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.

Individual protection measures, such as personal protective equipment

Eye/face protection: If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection: Wear appropriate chemical resistant gloves.

Other: Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection: 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.

General hygiene considerations: 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

Appearance: Liquid in multiple-dose vials

Physical state: Liquid.

Form: Liquid.

Color: Colorless.

Odor: Not available.

Odor threshold: Not available.

pH: Not available.

Melting point/freezing point: Not available.

Initial boiling point and boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid, gas): Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%): Not available.

Flammability limit - upper (%): Not available.

Explosive limit - lower (%): Not available.

Explosive limit - upper (%): Not available.
Vapor pressure: Not available.
Vapor density: Not available.
Relative density: Not available.
Solubility: Solubility (water): 100 %
Partition coefficient: Not available.
(n-octanol/water)
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.
Other information:
Explosive properties: Not explosive.
Oxidizing properties: Not oxidizing.

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

11. Toxicological information
Information on likely routes of exposure
Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact: No adverse effects due to skin contact are expected.
sodium;chloride
Species: Rabbit
Severity: Mild
Eye contact: Direct contact with eyes may cause temporary irritation.
sodium;chloride
Species: Rabbit
Severity: Moderate
Ingestion: May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics: 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.

Information on toxicological effects
Acute toxicity: Not acutely toxic

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atipamezole hydrochloride (CAS 104075-48-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
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<tr>
<td>Intramuscular</td>
<td></td>
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<tr>
<td>Minimum Lethal Dose Dog</td>
<td>&gt; 5 mg/m2</td>
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<tr>
<td>Subcutaneous</td>
<td></td>
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</tr>
<tr>
<td>LD50 Rat</td>
<td>44 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>
Components | Species | Test Results
--- | --- | ---
Methylparaben (CAS 99-76-3) | | 
**Acute**
Oral
LD50 | Guinea pig | 3 g/kg
sodium;chloride (CAS 7647-14-5) | | 
**Acute**
Oral
LD50 | Mouse | 4000 mg/kg
Rat | 3000 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.

Eye Contact
sodium;chloride | Species: Rabbit
Severity: Moderate

Respiratory or skin sensitization
Respiratory sensitization
Not a respiratory sensitizer.

Skin sensitization
This product is not expected to cause skin sensitization.

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

Carcinogenicity
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity
This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure
Not classified.

Specific target organ toxicity - repeated exposure
Not classified.

Aspiration hazard
Not an aspiration hazard.

Chronic effects
None expected under normal and foreseeable conditions of use

Further information
Caution - Pharmaceutical agent. alpha2-adrenergic receptor antagonist.

12. Ecological information
Ecotoxicity
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.

Components | Species | Test Results
--- | --- | ---
sodium;chloride (CAS 7647-14-5) | | 
**Aquatic**
**Acute**
Crustacea | EC50 | Water flea (Daphnia magna) | 340.7 - 469.2 mg/l, 48 hours
Fish | LC50 | Rainbow trout,donaldson trout (Oncorhynchus mykiss) | 4747 - 7824 mg/l, 96 hours

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.
Other adverse effects

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

Disposal instructions

Avoid release to the environment. 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.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

None known.

Waste from residues / unused products

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.

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not established.

15. Regulatory information

US federal regulations

This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

sodium;chloride (CAS 7647-14-5)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.
US state regulations

California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))
Methylparaben (CAS 99-76-3)

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Industrial Chemicals (AICIS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
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<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances</td>
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<td>(PICCS)</td>
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<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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, including date of preparation or last revision

Issue date: 11-06-2013
Revision date: 11-01-2021
Version #: 07
Further information: None known.

Disclaimer
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.

Revision information
Identification: Recommended restrictions
Composition / Information on Ingredients: Disclosure Overrides
Composition/information on ingredients: Component information
Accidental release measures: Methods and materials for containment and cleaning up
Handling and storage: Conditions for safe storage, including any incompatibilities
Exposure controls/personal protection: Respiratory protection
Exposure controls/personal protection: Thermal hazards
Physical and chemical properties: Color
Toxicological information: Acute toxicity
Disposal considerations: Disposal instructions
Regulatory information: California Proposition 65
Other information, including date of preparation or last revision: References
Other information, including date of preparation or last revision: Further information
GHS: Classification