SAFETY DATA SHEET

1. Identification

Product identifier: Antisedan® Specific Reverser of Medetomidine and Dexmedetomidine for Dogs and Cats

Other means of identification:

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

Recommended use of the chemical and restrictions on use:

Recommended use: Veterinary product used as anti-sedation agent

Restrictions on use: Not for human use

Details of manufacturer or importer:

Company Name (AU): Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard
Rhodes NSW 2138 AUSTRALIA

Tel: 1800 814 883
Fax: (02) 8876 0444
Email: productsupport.au@zoetis.com
Emergency Phone: 1800 814 883 (all hours)
Police and Fire Brigade: Dial 000
If ineffective: Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical:

Physical hazards: Not classified.
Health hazards: Not classified.
Environmental hazards: Not classified.

Label elements, including precautionary statements:

Hazard symbol(s): None.
Signal word: None.
Hazard statement(s): The mixture does not meet the criteria for classification.
Precautionary statement(s):

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.

Other hazards which do not result in classification: 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

Mixture

Identity of chemical ingredients | CAS number and other unique identifiers | Concentration of ingredients (%)
--- | --- | ---
Atipamezole hydrochloride | 104075-48-1 | 0.5
Methylparaben | 99-76-3 | <1

Material name: Antisedan® Specific Reverser of Medetomidine and Dexmedetomidine for Dogs and Cats
SDS AUSTRALIA
Composition comments

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

4. First-aid measures

**Description of necessary 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 centre immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions.

**Personal protection for first-aid responders**

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

**Symptoms caused by exposure**

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.

**Medical attention and special treatment**

alpha2-adrenergic receptor antagonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system.

5. Fire-fighting measures

**Extinguishing media**

- **Suitable extinguishing media**

- **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 fire fighters**

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.

**Hazchem code**

None.

**General fire hazards**

No unusual fire or explosion hazards noted.

**Specific methods**

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

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel

- Keep unnecessary personnel away.

For emergency responders

- Ensure adequate ventilation. Ventilate the contaminated area. Do not breathe the mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.

**Environmental precautions**

- Avoid discharge into drains, water courses or onto the ground.

**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.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
7. Handling and storage

Precautions for safe handling
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.

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 and personal protection

Control parameters
Follow standard monitoring procedures.

Occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>sodium;chloride (CAS 7647-14-5)</td>
<td>TWA 5 mg/m3</td>
</tr>
</tbody>
</table>

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

Exposure guidelines
No exposure standards allocated.

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, for example personal protective equipment (PPE)

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.

Thermal hazards
Not applicable.

Hygiene measures
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.

Colour
Colourless.

Odour
Not available.

Odour 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.

Vapour pressure
Not available.

Vapour density
Not available.

Relative density
Not available.

Solubility(ies)
Solubility (water) 100 %

Partition coefficient (n-octanol/water)
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other physical and chemical parameters

Explosive properties Not explosive.

Oxidising properties Not oxidising.

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 oxidising agents.

Hazardous decomposition products
No hazardous decomposition products are known.

11. Toxicological information

Information on possible 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 exposure
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.

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><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intramuscular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum Lethal Dose</td>
<td>Dog</td>
<td>&gt; 5 mg/m²</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>44 mg/kg</td>
</tr>
<tr>
<td>Methylparaben (CAS 99-76-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Guinea pig</td>
<td>3 g/kg</td>
</tr>
<tr>
<td>sodium;chloride (CAS 7647-14-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>4000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>3000 mg/kg</td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td></td>
<td>Prolonged skin contact may cause temporary irritation.</td>
</tr>
<tr>
<td><strong>Serious eye damage/irritation</strong></td>
<td></td>
<td>Direct contact with eyes may cause temporary irritation.</td>
</tr>
<tr>
<td><strong>Eye contact</strong></td>
<td>sodium;chloride</td>
<td>Species: Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severity: Moderate</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory sensitisation</strong></td>
<td></td>
<td>Not a respiratory sensitizer.</td>
</tr>
<tr>
<td><strong>Skin sensitisation</strong></td>
<td></td>
<td>This product is not expected to cause skin sensitisation.</td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td></td>
<td>No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td></td>
<td>Due to partial or complete lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Reproductive toxicity</strong></td>
<td></td>
<td>This product is not expected to cause reproductive or developmental effects.</td>
</tr>
<tr>
<td><strong>Specific target organ toxicity - single exposure</strong></td>
<td></td>
<td>Not classified.</td>
</tr>
<tr>
<td><strong>Specific target organ toxicity - repeated exposure</strong></td>
<td></td>
<td>Not classified.</td>
</tr>
<tr>
<td><strong>Aspiration hazard</strong></td>
<td></td>
<td>Not an aspiration hazard.</td>
</tr>
<tr>
<td><strong>Chronic effects</strong></td>
<td></td>
<td>None expected under normal and foreseeable conditions of use</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td></td>
<td>Caution - Pharmaceutical agent. alpha2-adrenergic receptor antagonist.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
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</thead>
<tbody>
<tr>
<td>sodium;chloride (CAS 7647-14-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td></td>
<td>340.7 - 469.2 mg/l, 48 hours</td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Rainbow trout, donaldson trout</td>
</tr>
<tr>
<td></td>
<td>4747 - 7824 mg/l, 96 hours</td>
<td>(Oncorhynchus mykiss)</td>
</tr>
<tr>
<td><strong>Persistence and degradability</strong></td>
<td></td>
<td>No data is available on the degradability of this product.</td>
</tr>
<tr>
<td><strong>Bioaccumulative potential</strong></td>
<td></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Mobility in soil</strong></td>
<td></td>
<td>No data available for this product.</td>
</tr>
</tbody>
</table>
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 methods  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.

Residual waste  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

ADG  Not regulated as dangerous goods.

RID  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

Safety, health and environmental regulations  This Safety Data Sheet was prepared in accordance with the Australia Model Code of Practice for the preparation of safety data sheets for hazardous chemicals.

APVMA No. 40612

Poison Schedule (Product) - Schedule 4

Australia Medicines & Poisons Appendix A  Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B  Methylparaben (CAS 99-76-3)

Australia Medicines & Poisons Appendix D  Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E  sodium;chloride (CAS 7647-14-5)

Australia Medicines & Poisons Appendix F  Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G  Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H  Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I  Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J  Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K  Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 10  Poisons schedule number not allocated.
Australia Medicines & Poisons Schedule 2
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7
sodium;chloride (CAS 7647-14-5)

Australia Medicines & Poisons Schedule 8
Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9
Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)
sodium;chloride (CAS 7647-14-5)
100000 - 999999 TONNES See the regulation for additional information.

Water for injection (CAS 7732-18-5)
1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)
Not listed.

National Pollutant Inventory (NPI) substance reporting list
Not listed.

Prohibited Carcinogenic Substances
Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)
Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)
Not listed.

Restricted Carcinogenic Substances
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

<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>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
</tbody>
</table>

Material name: Antisedan® Specific Reverser of Medetomidine and Dexmedetomidine for Dogs and Cats
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>No</td>
</tr>
<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

**Issue date** 25-October-2016  
**Revision date** 01-November-2021  
**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** This document has undergone significant changes and should be reviewed in its entirety.