

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

Manufacturer

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 australia.animalhealth@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 |
| Imidazole derivative | | |

| | | |
|---------------------|-----------|---|
| Methylparaben | 99-76-3 | * |
| Water for injection | 7732-18-5 | * |

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 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 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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders 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. 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. 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.

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. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits No exposure limits noted for ingredient(s).

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. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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 Colorless

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. |
| Eye contact | Direct contact with eyes may cause temporary irritation. |
| 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. |
|-------------------------------------|--|

| Components | Species | Test results |
|---|----------------|---------------------|
| Atipamezole hydrochloride (CAS 104075-48-1) | | |
| Acute | | |
| Intramuscular | | |
| Minimum Lethal Dose | Dog | > 5 mg/m2 |

| Components | Species | Test results |
|---|--|--------------|
| Subcutaneous | | |
| LD50 | Rat | 44 mg/kg |
| Methylparaben (CAS 99-76-3) | | |
| Acute | | |
| Oral | | |
| LD50 | Dog | 3000 mg/kg |
| | Guinea pig | 3 g/kg |
| | Mouse | 8 g/kg |
| | Rabbit | 6 g/kg |
| Skin corrosion/irritation | Prolonged skin contact may cause temporary irritation. | |
| Serious eye damage/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. | |
| Carcinogenicity | Due to partial or complete lack of data the classification is not possible. | |
| 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 | |
| Other 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. |
| Persistence and degradability | No data is available on the degradability of this product. |
| Bioaccumulative potential | no data available. |
| Mobility in soil | No data available for this product. |
| 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

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|-------------------------------|--|
| Disposal methods | 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. Contract with a disposal operator licensed by the Law on Disposal and Cleaning. |
| 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 (see: Disposal instructions). |
| Contaminated packaging | Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal |

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

National regulations

This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011).

APVMA No. 40612

Poison Schedule (Product) - Schedule 4

This SDS replaces version: Issued October 2015

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Methylparaben (CAS 99-76-3)

Low toxicity. General: Preservative

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

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 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

Poisons schedule number not allocated.

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)

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

| 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**Issue date**

25-October-2016

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

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties