SAFETY DATA SHEET

1. Identification

Product identifier Domitor Sedative and Analgesic for Dogs and Cats
Other means of identification
Synonyms Domitor Injectable Solution * Medetomidine hydrochloride sterile injectable solution

Recommended use of the chemical and restrictions on use
Recommended use Veterinary product used as sedative, analgesic
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)
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 Alpha2-adrenoreceptor agonist. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

3. Composition/information on ingredients

Mixture

<table>
<thead>
<tr>
<th>Identity of chemical ingredients</th>
<th>CAS number and other unique identifiers</th>
<th>Concentration of ingredients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medetomidine hydrochloride</td>
<td>86347-15-1</td>
<td>0.1</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>*</td>
</tr>
</tbody>
</table>

Material name: Domitor Sedative and Analgesic for Dogs and Cats
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**
Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. Rinse mouth.

**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. Symptoms reported after accidental human exposure have included decrease in blood pressure (hypotension), high blood pressure (hypertension), decreased heart rate (bradycardia), drowsiness, sleepiness (somnolence), dilated pupils, and vomiting.

**Medical attention and special treatment**
Alpha2-adrenoreceptor agonist. Treat symptomatically. Monitor respiratory, cardiac and central nervous system.

5. Fire-fighting measures

**Extinguishing media**
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

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

**Unsuitable extinguishing media**
During fire, gases hazardous to health may be formed.

**Specific hazards arising from the chemical**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Special protective equipment and precautions for fire fighters**
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 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. 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
Use this product with adequate ventilation. Keep away from heat, sparks and open flame. Wear personal protective equipment. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Wash thoroughly after handling. Avoid release to the environment. Use care in handling/storage. 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 heat and light. Protect from sunlight.

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
Medetomidine hydrochloride: Zoetis OEB 5 (control exposure to <1ug/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.

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. Impervious gloves. Suitable gloves can be recommended by the glove supplier.

Other
Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection
If airborne exposures are within or exceed the OEB, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB range. Respiratory protection should be worn to supplement engineering controls when handling this compound. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Professional use: In case of insufficient ventilation, wear suitable respiratory equipment. No personal respiratory protective equipment normally required.

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
Physical state
Liquid.
Form
Liquid.
Colour
Colorless
Odour
Odourless.
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)
  - Soluble

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. Exposure to light. High temperatures. Protect from sunlight.

Incompatible materials
- Strong oxidising agents.

Hazardous decomposition products
- No dangerous reaction known under conditions of normal use. At thermal decomposition temperatures, carbon monoxide and carbon dioxide. May include hydrogen chloride.

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
- Prolonged skin contact may cause temporary irritation.

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

Ingestion
- May cause discomfort if swallowed.

Symptoms related to exposure
- Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Symptoms reported after accidental human exposure have included decrease in blood pressure (hypotension), high blood pressure (hypertension), decreased heart rate (bradycardia), drowsiness, sleepiness (somnolence), dilated pupils, vomiting.

Acute toxicity
- Not acutely toxic

Components

<table>
<thead>
<tr>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medetomidine hydrochloride (CAS 86347-15-1)</td>
<td></td>
</tr>
<tr>
<td>Acute Oral LD50</td>
<td>31 mg/kg</td>
</tr>
<tr>
<td>Components</td>
<td>Species</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Methylparaben (CAS 99-76-3)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Guinea pig</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Mouse</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
</tr>
<tr>
<td>Oral LOAEL</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylparaben (CAS 94-13-3)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Mouse</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
</tr>
<tr>
<td>LD50 Mouse</td>
<td>Sub-tenon injection (eye)</td>
</tr>
</tbody>
</table>

**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**
  - Health injuries are not known or expected under normal use.
- **Other information**
  - Caution - Pharmaceutical agent. Alpha2-adrenoreceptor agonist. The active ingredient in this product produces sedation and analgesia. May be absorbed through mucous membranes and cause systemic effects.

**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**

**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

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. 40613

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
- 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 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
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 listed.

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>
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<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>

*“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 04-November-2016
Revision date 23-November-2021
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: Restrictions on use
Composition / Information on Ingredients: Disclosure Overrides
First-aid measures: Ingestion
Accidental release measures: Methods and materials for containment and cleaning up
Accidental release measures: For emergency responders
Accidental release measures: For non-emergency personnel
Handling and storage: Conditions for safe storage, including any incompatibilities
Toxicological information: Acute toxicity
Toxicological information: Ingestion
Ecological information: Bioaccumulative potential
Disposal considerations: Disposal methods
Regulatory information: National regulations
GHS: Classification