

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)
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 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

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Medetomidine hydrochloride	86347-15-1	0.1
Methylparaben	99-76-3	*

Propylparaben	94-13-3	*
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	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

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.
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 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	Species	Test Results
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Medetomidine hydrochloride (CAS 86347-15-1)

Acute

Oral

LD50

Rat

31 mg/kg

Components	Species	Test Results
Methylparaben (CAS 99-76-3)		
<u>Acute</u>		
Oral		
LD50	Guinea pig	3 g/kg
Propylparaben (CAS 94-13-3)		
<u>Acute</u>		
Oral		
LD50	Mouse	6332 mg/kg 6 g/kg
Other		
LD50	Mouse	200 mg/kg Sub-tenon injection (eye)
<u>Chronic</u>		
Oral		
LOAEL	Rat	347.2 mg/kg, 4 weeks Male reproductive system 27.1 g/kg, 3 weeks Endocrine system
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.
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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 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 Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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** 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