

SAFETY DATA SHEET



Section 1 - Identification

Product identifier Dormosedan® Injection

Other means of identification

Synonyms Dormosedan® * Domosedan * Detomidine hydrochloride sterile solution * Dormosedan Sedative/Analgesic for Horses

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product used as analgesic, sedative

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)

Section 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.

Supplemental information May be absorbed through mucous membranes and cause systemic effects. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Alpha2-adrenoreceptor agonist. May cause nervous system and cardiovascular system effects.

Other hazards which do not result in classification None known.

Section 3 - Composition and information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Detomidine Hydrochloride	90038-01-0	1
Methylparaben	99-76-3	<1

Sodium chloride	7647-14-5	<1
Water for Injection	7732-18-5	

Section 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	In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
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. Never give anything by mouth to a victim who is unconscious or is having convulsions. If ingestion of a large amount does occur, call a poison control centre immediately.
Personal protection for first-aid responders	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse. You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.
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	Treat symptomatically. Monitor respiratory, cardiac and central nervous system. Alpha2-adrenoreceptor agonist. Symptoms may be delayed.

Section 5 - Firefighting measures

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.
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.

Section 6 - Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away.
For emergency responders	Keep unnecessary personnel away. Ventilate the contaminated area. Ensure adequate ventilation. Do not breathe mist or vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. 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

Avoid release to the environment. Ensure adequate ventilation. Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. 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.

Section 7 - Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Use this product with adequate ventilation. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. Use care in handling/storage. Avoid accidental injection.

Conditions for safe storage, including any incompatibilities

Store locked up. Protect from sunlight. Store in a well-ventilated place. Keep out of the reach of children. Storage Temperature: 15-30°C (59-86°F). Protect from heat and light. Store away from incompatible materials (see Section 10 of the SDS).

Section 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).

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. 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

Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

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.

Section 9 - Physical and chemical properties

Appearance

Physical state

Liquid.

Form

Liquid.

Colour

Clear, 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	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.

Section 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	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Carbon oxides. Nitrogen oxides (NOx). May include hydrogen chloride.

Section 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.

Sodium chloride Species: Rabbit
Severity: Mild

Eye contact Direct contact with eyes may cause temporary irritation.

Sodium chloride Species: Rabbit
Severity: Moderate

Ingestion Health injuries are not known or expected under normal use.

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, and vomiting.

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Product	Species	Test Results
Dormosedan® Injection		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg (Calculated ATE)
Components	Species	Test Results
Detomidine Hydrochloride (CAS 90038-01-0)		
<u>Acute</u>		
Intravenous		
LD50	Mouse	35 mg/kg
Oral		
LD50	Rat	60 mg/kg
<u>Subacute</u>		
Oral		
LOAEL	Rat	1 mg/kg/day, 3.5 weeks [Target organ(s): Adrenal gland]
Methylparaben (CAS 99-76-3)		
<u>Acute</u>		
Oral		
LD50	Rat	2100 mg/kg
Sodium chloride (CAS 7647-14-5)		
<u>Acute</u>		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/irritation	Direct contact with eyes may cause temporary irritation.	
Eye contact		
Sodium chloride	Species: Rabbit	Severity: Moderate
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitiser.	
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	Not classifiable as to carcinogenicity to humans.	
Reproductive toxicity	Due to partial or complete lack of data the classification is not possible.	
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. May cause decreases in blood pressure and other cardiac effects. May cause central nervous system effects. drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance.	

Section 12 - Ecological information

Ecotoxicity Avoid release to the environment. 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.

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

Persistence and degradability No data available for 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.

Section 13 - Disposal considerations

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. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.

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. 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.

Section 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.

Section 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.

APVMA No. 37945

Poison Schedule (Product) - Schedule 4

Australia Medicines & Poisons Appendix B

Methylparaben (CAS 99-76-3)

Australia National Pollutant Inventory (NPI): Threshold quantity

Sodium chloride (CAS 7647-14-5) 10 tonnes/yr Threshold Category: 1

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 Depleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10, as amended)

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 Carcinogenic Substances

Not regulated.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

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).

Section 16 - Any other relevant information

Issue date	03-November-2016
Revision date	28-February-2025
Key abbreviations or acronyms used	AICIS: Australian Inventory of Industrial Chemicals. ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).
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Revision information	Product and Company Identification: Synonyms Toxicological Information: Toxicological Data