

SAFETY DATA SHEET

Zoetis New Zealand Limited



Section 1: Identification of the Substance and Supplier

Trade Name:	DEXDOMITOR®
ACVM Registration No.:	A010396
Classification:	Restricted Veterinary Medicine (RVM)
Recommended Use:	Injectable analgesic / sedative for non-invasive, mildly to moderately painful procedures and examinations which require restraint, sedation and analgesia in dogs and cats; deep sedation and analgesia in concomitant use with butorphanol for medical and minor surgical procedures, and premedication before induction and maintenance of general anaesthesia in dogs; and premedication before induction and maintenance of general anaesthesia with ketamine in cats.
Company Details:	Zoetis New Zealand Limited
Address:	Level 4, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
Telephone No.:	0800 963 847 (Business Hours)
Emergency Telephone No.:	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
Date of Preparation:	01 July 2019

Section 2: Hazards Identification

Hazard Classification:	6.9B
Priority Identifier(s):	WARNING - KEEP OUT OF REACH OF CHILDREN
Secondary Identifier(s):	6.9B May cause target organ damage from repeated oral exposure at high doses.

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Dexmedetomidine hydrochloride	86347-15-1	0.5 mg/mL
Methyl parahydroxybenzoate	99-76-3	Proprietary
Propyl parahydroxybenzoate	94-13-3	Proprietary
Other ingredients determined not to be hazardous.	-	-

This is a commercial product whose exact ratio of components may vary.
Trace quantities of impurities are also likely.

Section 4: First Aid Measures

Necessary First Aid Measures:	<p>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p>Self-Injection: Immediate medical advice should be sought on the management of all instances of accidental self-injection, particularly those near a joint or associated with bruising. Allow the wound to bleed freely and avoid squeezing the injection site to avoid spread of the product. Clean the wound thoroughly with soap and water, then keep it clean and dry.</p> <p>Ingestion: DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.</p> <p>Eye Contact: Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.</p> <p>Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.</p> <p>Inhalation: Move the patient to fresh air. If symptoms develop seek medical advice immediately.</p>
Poisoning Symptoms:	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.
Workplace Facilities:	No specific facilities required. Standard emergency equipment must be available.
Hygiene Practices:	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Notes for Medical Personnel:	Accidental self-injection may lead to an inflammatory response and deep injections, particularly those near a joint or associated with bruising, should be treated medically or surgically.

Section 5: Fire-Fighting Measures

Type of hazard:	This product is not flammable, however, irritating and possibly toxic gases may be generated by thermal decomposition or combustion.
Fire Hazard Properties:	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and other chlorine-containing compounds.
Regulatory Requirements:	Not applicable.
Extinguishing Media & Methods:	Use dry chemical, foam, carbon dioxide or water to extinguish fires involving this product.
Hazchem Code:	Not allocated.
Recommended Protective Clothing:	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear.

Section 6: Accidental Release Measures

Personal Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls.
Environmental Precautions:	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
Procedure for Spills:	<ol style="list-style-type: none">1. Non-essential personnel should be evacuated from the affected area.2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.3. Absorb the spill with an absorbent material (e.g. sand).4. Collect the spilled material into labelled containers for disposal, minimising dust generation.5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.
Procedure for Disposal:	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

Section 7: Handling and Storage

Handling

Precautions for Safe Handling:	No special technical protective measures required. No special handling advice required.
Regulatory Requirements:	Not required.
Handling Practices:	Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Approved Handlers:	Approved handlers are not required for this product.

Storage

Conditions for Safe Storage:	Store below 30°C (Room Temperature). Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
Store Site Requirements:	No additional requirements.
Packaging:	Store in the original container, away from foodstuffs.

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines

Workplace Exposure Standards:	A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m ³ for dusts or mists when limits have not otherwise been established.
Application in the Workplace:	The nature of this product makes it unlikely that this level will be approached during normal handling.
Exposure Standards Outside the Workplace:	None set.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protection:	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p>Hands: Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p>Eyes: It is always prudent to utilise protective eyewear.</p> <p>Skin: When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p>Respiratory: Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
General Hygiene:	Change work clothes regularly. Avoid self-injection, ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Section 9: Physical and Chemical Properties

Appearance:	Clear, colourless solution
Odour:	No data available
Specific Gravity / Density:	1.0058
Melting Point:	Not applicable. Liquid at normal temperatures
Boiling Point:	No data available
pH:	4.6 – 6.0
Solubility in Water:	Soluble in water
Flashpoint:	Not applicable. This product is not flammable.
Oxidising Properties:	Not applicable. This product is not an oxidiser.
Corrosive Properties:	Not applicable. This product is not corrosive.
Vapour Pressure:	No data available

Section 10: Stability and Reactivity

Stability of the Substance:	This product is stable under normal conditions of use.
Conditions to Avoid:	Store as recommended. Avoid excessive exposure to light.
Material to Avoid:	No particular incompatibilities.
Hazardous Decomposition Products:	This product is unlikely to spontaneously decompose. Carbon dioxide, and if combustion is incomplete, carbon monoxide, smoke and water. No significant quantities of decomposition products are expected at temperatures normally achieved in a fire.
Hazardous Polymerisation:	This product is unlikely to spontaneously polymerise.
Specific Data:	No specific data available.

Section 11: Toxicological Information

HSNO Classifications

6.9B May cause target organ damage from repeated oral exposure at high doses.

Acute Effects

Principle routes of exposure are expected to be by skin contact, accidental self-injection, ingestion and/or inhalation of syringe-expressed aerosols. As with any chemical product contact with unprotected bare skin; inhalation of vapour, mist or dust in the workplace atmosphere; or ingestion in any form should be avoided by observing good occupational work practices.

Acute Toxicity: (Species, Route, End Point, Dose)

Methylparaben:

- Mouse Oral LD50 > 8000 mg/kg
- Rat Oral LD50 2280 mg/kg

Propylparaben:

- Mouse Oral LD50 6332 mg/kg
- Mouse Intraperitoneal LD50 200 mg/kg

Dexmedetomidine hydrochloride:

- Dog IV LD50 = 2 mg/kg

Chronic / Long Term Effects

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Propylparaben:

- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
- 4 Week(s) Rat Oral 347.2 g/kg LOAEL Male reproductive system

Dexmedetomidine hydrochloride:

- 28 Day(s) Rat Intravenous Eyes, Adrenal gland, Lungs
- 28 Day(s) Rat Intramuscular Eyes, Adrenal gland, Lungs
- 28 Day(s) Dog Intravenous Liver, Central nervous system
- 28 Day(s) Dog Intramuscular Liver, Central nervous system

Genetic Toxicity: (Study Type, Cell Type / Organism, Result)

Dexmedetomidine hydrochloride:

- *In Vitro* Bacterial Mutagenicity (Ames) *Salmonella, E. coli* Negative
- *In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Negative
- *In Vitro* Chromosome Aberration Human Lymphocytes Positive with activation, Negative without activation
- *In Vivo* Micronucleus Mouse Positive

Carcinogenicity: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Section 12: Ecotoxicity Information

HSNO Classifications

Not applicable. This product is not classified as ecotoxic.

The environmental characteristics of this material have not been fully evaluated.
Avoid contamination of any water supply with product or empty container.

Ecotoxicity Effects

Toxicity to Birds:	Not applicable
Acute Toxicity to Fish:	Not applicable
Toxicity to Algae:	Not applicable
Toxicity to Aquatic Invertebrates:	Not applicable
Toxicity to Soil Dwelling Organisms:	Not applicable
Acute Toxicity to Bees:	Not applicable

Environmental Fate

No information available.

Section 13: Disposal Considerations

Product Disposal:	Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.
Container Disposal:	Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container. Used needles and syringes should immediately be placed in a designated and appropriately labelled "sharps" container.

Section 14: Transport Information

Dangerous Goods Classification

UN No.:	Not applicable. This product is not a dangerous good.
Class:	Not applicable. This product is not a dangerous good.
Packing Group:	Not applicable. This product is not a dangerous good.
Proper Shipping Name:	Not applicable. This product is not a dangerous good.

Section 15: Regulatory Information

HSNO Approval No.:	HSR10076
HSNO Controls:	See www.epa.govt.nz for controls
ACVM Registration No.:	A010396
ACVM Controls:	See www.foodsafety.govt.nz for registration conditions

Section 16: Other Information

Note: This product is a veterinary medicine and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

CONTACT POINT:	Zoetis New Zealand Limited:	0800 963 847 (Business Hours)
	National Poisons Centre:	0800 POISON (0800 764 766)
	Emergency Services:	Dial 111

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

If clarification of further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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