



SAFETY DATA SHEET

Title: DEXDOMITOR 0.5 mg/mL INJECTION		Document: SDS-AU028	
		Rev: 2.0	PAGE 1 OF 7
Status: Current	Issue Date: 28-Mar-2023	Effective Date: 28-Mar-2023	Review Date: 27-Mar-2028

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	Dexdomitor 0.5 mg/mL Injectable Sedative and Analgesic for Dogs and Cats
Product Identifier:	0.5 mg/mL Dexmedetomidine hydrochloride
Recommended Use:	Sedative, analgesic for use in the restraint of dogs and cats.
Restrictions on Use:	For animal treatment only.
Company Identification:	Jurox Pty Limited (part of Zoetis)
Address:	85 Gardiner Street, Rutherford, NSW 2320, Australia
Email:	customerservice@jurox.com.au
Customer Service:	1800 022 442 (Mon-Fri, 8:00am – 6:00pm AEST)
National Poisons Information Centre:	13 11 26 (all hours)
Emergency Telephone Number:	1800 814 883 (all hours)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as non-hazardous.

GHS Label Elements:

Signal Word: None.

Pictograms: None.

Precautionary Statements: None.

Other hazards: Dexmedetomidine is a potent α_2 adrenoreceptor agonist. May cause decrease in blood pressure (hypotension), sedation, slow breathing, fainting (syncope) and decreased salivation.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Dexmedetomidine hydrochloride	145108-58-3	0.5%
Other ingredients not contributing to the hazards	-	99.5%



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Section 4: FIRST AID MEASURES

General Information: Persons with known hypersensitivity to the active substance or any of the excipients should administer the product with caution. Consult the National Poisons Centre on 13 11 26 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand. **In case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the physician but DO NOT DRIVE as sedation and changes in blood pressure may occur.**

Symptoms and Effects of Exposure: May cause decrease in blood pressure (hypotension), sedation, slow breathing, fainting (syncope) and decreased salivation.

Inhalation: If fumes, aerosols or combustion products are inhaled remove patient from contaminated area. Other measures are usually not necessary. If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.

Ingestion: If swallowed, DO NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Contact a doctor or the National Poisons Centre on 13 11 26 immediately.

Skin: If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of rash or irritation.

Eye: If eye contact occurs: Immediately flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing for at least 20 minutes. If eye irritation persists, get medical advice/attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Injection: Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleaner or antiseptic if water is unavailable. Apply a dressing as necessary, and apply pressure through the dressing if bleeding is occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention immediately.

Advice to Doctor: Dexdomitor is an α_2 -adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically. The specific α_2 -adrenoreceptor antagonist, atipamezole, which is approved for use in animals, has been used in humans only experimentally to antagonize dexmedetomidine-induced effects.



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Section 5: FIRE FIGHTING MEASURES

Flash Point: No data.

Hazardous Combustion Products: If involved in a fire, may emit poisonous and irritant fumes.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Protective gloves and boots and breathing apparatus.

Hazchem Code: Not specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear gloves and appropriate protective clothing. Avoid breathing vapours and contact with skin and eyes. Clean up all spills immediately. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, exclude non-essential people from the area. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent spillage from entering drains or water courses and call emergency services. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Handling: This is a Schedule 4 (Prescription Animal Remedy) product and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid accidental self-injection and contact with skin, eyes and inhalation of vapours. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children. Store below 25°C (air conditioning). Do not freeze. Protect from light. Store away from foodstuffs.

Other Information: Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: No exposure limits have been assigned for this product nor for any ingredients.

Engineering Controls: Use only in a well ventilated area. Ensure that the work environment remains clean.



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Personal Protective Equipment (PPE):

Eye Protection: Safety glasses with side shields or chemical goggles are recommended when handling bulk quantities of this product.

Skin Protection: When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory Protection: Not required for the normal use of this product.

Other: When handling bulk quantities of this product, overalls, PVC apron, barrier cream, skin cleansing cream and eye wash unit may be required.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	A clear, colourless liquid	Upper / Lower Flammability Limits:	Not available.
Odour:	Not available.	Vapour Pressure:	Not available.
Odour Threshold:	Not available.	Vapour Density:	Not available.
pH:	4.0 – 6.0.	Relative Density / Specific Gravity:	Not available.
Melting Point / Freezing Point:	Not available.	Solubility:	Soluble in water.
Boiling Point and Boiling Range:	Not available.	Partition Coefficient (n-octanol/water):	Not available.
Flash Point:	Not available.	Auto-Ignition Temperature:	Not available.
Evaporation Rate:	Not available.	Decomposition Temperature:	Not available.
Flammability:	Not available.	Viscosity:	Not available.

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Chemical Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Combustion products include carbon dioxide, nitrogen oxides, silicon dioxide and other pyrolysis products typical of burning organic material.



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Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route. However, dexmedetomidine is a potent α 2-adrenoreceptor agonist and as such may be harmful if swallowed.

Dexmedetomidine hydrochloride: Oral (Dog) LD₅₀: 30 mg/kg.

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route. However, dexmedetomidine is a potent α 2-adrenoreceptor agonist and as such may be may be harmful if inhaled.

Dexmedetomidine hydrochloride: Inhalation (Rat) LC₅₀: 0.02 mg/L4h.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route. However, dexmedetomidine is a potent α 2-adrenoreceptor agonist and as such may be may be harmful if absorbed through the skin.

Injection: Dexmedetomidine hydrochloride: IV (Dog) LD₅₀: 2 mg/kg.

Aspiration Hazard: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

Respiratory Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a respiratory irritant.

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin irritant.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as a skin sensitiser or a respiratory sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant. However dexmedetomidine hydrochloride may have the potential to produce effects on the developing foetus.

Dexmedetomidine hydrochloride:

Not specified: Rat: Subcutaneous 20 μ g / kg NOAEL Not teratogenic, Fetotoxicity.

Peri-/Postnatal Development: Rat: Subcutaneous 2 μ g / kg / day NOAEL Fetotoxicity,

Developmental toxicity.

Specific Target Organ Toxicity (STOT): Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.



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Specific Target Organ Toxicity (STOT): Repeated exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeat exposure. However, repeated exposure may cause effects on eyes, liver, thymus, endocrine system, and blood forming organs and may have the potential to produce effects on the developing foetus.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have narcotic effects. However, Dexmedetomidine is a potent α_2 adrenoreceptor agonist and as such may cause decrease in blood pressure (hypotension), sedation, slow breathing, fainting (syncope) and decreased salivation.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be toxic to the environment.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Dexmedetomidine hydrochloride	No data available	No data available	No data available	No data available

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not considered a Dangerous Good for land, sea and air transport.

Hazchem Code: None specified.

Section 15: REGULATORY INFORMATION

Poisons Schedule (SUSMP): S4

APVMA Registration No: 64563



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Section 16: OTHER INFORMATION

Legend:

APVMA	Australian Pesticides and Veterinary Medicines Authority.
CAS No.	Chemical Abstracts Service Registry Number.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
IV	Intravenous.
LC₅₀	The median lethal concentration, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
NOAEL	No Observed Adverse Effect Level.
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
TGA	Therapeutic Goods Administration

References:

ChemID Plus
ChemwatchEPA New Zealand Chemical Classification and Information Database (CCID)
HSDB (Hazardous Substances Data Bank)

Revision History:

Date of Revision	Reason
01 March 2023	Updates to Customer Service and emergency contact telephone numbers to Zoetis numbers.
28 March 2023	Five year review. Addition of acute toxicology data in Section 11 and editorial changes throughout document.

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein do so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

END OF SDS