ISSUED: **13 February 2018**

SAFETY DATA SHEET

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

Product Code: 520370 (10 mL)

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

Address: 85 Gardiner Street,
Rutherford, NSW 2320,
Australia

Customer Centre: 1800 023 312

Email: customerservice@jurox.com.au

National Poisons Information Centre: 13 1126 (24 hours)

Emergency Telephone Number: 1800 023 312 (9am – 5pm, Monday to Friday)

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 α2 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%
Ingredients not contributing to the hazards	-	> 90%

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 1126 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 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. Seek medical assistance immediately.

Ingestion: If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. 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 1126 immediately.

Injection: Treat as for needle stick injury. Wash area well and disinfect. If other symptoms become evident, seek medical advice.

Skin: If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.

Eye: If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. 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. If eye irritation persists, get medical advice/attention.

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

Advice to Doctor: Dexdomitor is an α2-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 α2 –adrenoreceptor antagonist, atipamezole, which is approved for use in animals, has been used in humans only experimentally to antagonize dexmedetomidine-induced effects.

Section 5: FIRE FIGHTING MEASURES

Flash Point: No data available on the mixture. Product is predominantly water and non-combustible.

Hazardous Combustion Products: Non combustible, not considered a significant fire risk, however if involved in a fire may emit toxic and corrosive fumes.

Extinguishing Media: Water spray or fog, Foam, Dry chemical powder, Carbon dioxide.

Protective Equipment: Protective gloves and boots and breathing apparatus.

Hazchem Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: No special protective clothing is normally necessary. For small spills, wash area well with excess water. For large spills, exclude non-essential people from the area. Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. 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 contact with skin, eyes and inhalation of vapours. Take care to avoid accidental self-injection. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children. Store below 25ºC (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.

Personal Protective Equipment (PPE):

Eye Protection: Protective glasses or 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.

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, fine particles (such as dust and mists) may fuel fires / explosions.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Thermal decomposition products may include carbon monoxide, Carbon dioxide, oxides of nitrogen and hydrogen chloride.

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 α2-adrenoreceptor agonist and as such may be harmful if swallowed.

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 α2-adrenoreceptor agonist and as such may be may be harmful if inhaled.

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 α2-adrenoreceptor agonist and as such may be may be harmful if absorbed through the skin.

Injection: Dexmedetomidine hydrochloride: IV LD_{50}: 2 mg/kg (Dog).

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 µg / kg NOAEL Not teratogenic, Fetotoxicity.
Peri-/Postnatal Development: Rat: Subcutaneous 2 µg / 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.

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 α2 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

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16: OTHER INFORMATION

Legend:

APVMA	Australian Pesticides and Veterinary Medicines Authority.
AICS	Australian Inventory of Chemical Substances.
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.
LD_{50}	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

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 13 February 2018 and is valid for 5 years from this date.

Supercedes: This is the first SDS for this product.

Revision History:

Date of Revision	Reason

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