ISSUED: **04 May 2018**

SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	**Alfaxan Anaesthetic Injection**
Product Identifier:	10 mg/mL Alfaxalone solution for injection.
Product Code:	502135 (10 mL); 503320 (20 mL)
Recommended Use:	An injectable anaesthetic for 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

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

Signal word: None.

GHS Pictograms: None.

Precautionary statements: None.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Alfaxalone	23930-19-0	1%
Ingredients not contributing to the hazards	-	> 90%

Section 4: FIRST AID MEASURES

General Information: 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.

Symptoms and Effects of Exposure: Sedation, anaesthesia, CNS effects.

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 and seek medical assistance immediately.

Ingestion: If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact a doctor or the National Poisons Centre on 13 1126.

Skin: If skin contact occurs: Immediately remove all contaminated clothing, including footwear, 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: 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.

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

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

Advice to Doctor: Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Flash Point: Not flammable.

Hazardous Combustion Products: If involved in a fire, may emit noxious and irritant fumes.
Non-combustible – not considered to be a significant fire risk.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area. Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances. In such an event consider: foam, dry chemical powder and carbon dioxide.

Protective Equipment: Gas-tight chemical resistant suit, protective gloves and breathing apparatus.

HAZCHEM Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Exclude non-essential people from the area. Wear gloves and appropriate protective clothing. For small spills, clean up spilled product then wipe area and put empty container in garbage. For large spills, 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. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

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

Environmental Precautions: Prevent from entering drains, waterways or sewers. If spill does enter waterways contact 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 30ºC (room temperature). Protect from light.

Other Information: Avoid contact with incompatible substances as listed in Section 10. 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 or its ingredients.

Engineering Controls: Use only in a well-ventilated area. Make sure that the work environment remains clean and that vapours and mists are minimised.

Personal Protective Equipment (PPE):

Eye protection: Protective glasses or goggles are recommended when this product is being used.

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:	Clear colourless solution.	**Upper / Lower Flammability Limits:**	Not available.
Odour:	Not available.	**Vapour Pressure:**	Not available.
Odour Threshold:	Not available.	**Vapour Density:**	Not available.
pH:	6.5-7.0.	**Relative Density / Specific Gravity:**	Approx. 1.02 – 1.03.
Melting Point / Freezing Point:	Not available.	**Solubility:**	Miscible with water.
Boiling Point and Boiling Range:	Not available.	**Partition Coefficient (n-octanol/water):**	Not available.
Flash Point:	Not Applicable.	**Auto-Ignition Temperature:**	Not applicable.
Evaporation Rate:	Not available.	**Decomposition Temperature:**	Not available.
Flammability:	Not flammable.	**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: Protect this product from light.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: No data available.

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. Alfaxalone is known to have low oral bioavailability.

Alfaxalone: Oral LD_{50}: 297 mg/kg (rat);

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.

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.

Alfaxalone: Dermal LD_{50}: 2,200 mg/kg (rat).

Injection: Effects may vary in severity according to the quantity involved, from localised site reaction (pain, redness, swelling) to a more acute systemic reaction. Significant CNS effects are expected only from the intravenous route, and this is unlikely from accidental self-injection.

Alfaxalone: Intravenous LD_{50}: 19 mg/kg (rat); Intraperitoneal LD_{50}: 116 mg/kg;
Subcutaneous LD_{50}: > 2,200 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 considered to be a skin sensitiser or 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. Not considered to affect reproduction, based on data for the ingredients.

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. No adverse effects were reported from intraperitoneal administration of alfaxalone to rats of up to 50 mg/kg/day for one month, or up to 20 mg/kg/day for 3 months.

Narcotic Effects: Anaesthetic agent: May cause central nervous system and cardiovascular system effects. May cause drowsiness, dizziness, respiratory depression and unconsciousness.

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
Alfaxalone	No data	No data	No data	No data

Section 13: DISPOSAL INFORMATION

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

Container Disposal: Dispose of empty container by wrapping with paper and placing in garbage.

Section 14: TRANSPORT INFORMATION

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

Section 15: REGULATORY INFORMATION

Poison Schedule (SUSMP): S4

APVMA No.: 52881

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

Section 16: OTHER INFORMATION

Legend:

AICS	Australian Inventory of Chemical Substances.
APVMA	Australian Pesticides and Veterinary Medicines Authority
CAS No.	Chemical Abstracts Service Registry Number.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
CNS	Central Nervous System.
EPA	Environmental Protection Authority.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
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.
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
SWA	Safe Work Australia.

References:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 04 May 2018 and is valid for 5 years from this date.

Supercedes: This SDS supercedes the version issued on 3 February 2016.

Revision History:

Date of Revision	Reason
3 February 2016	Reclassification of substance to GHS classification and update of SDS to comply with SWA Code of Practice.
04 May 2018	Updates to Section 1.0, Email address and minor updates to all sections.

END OF SDS