

ISSUED: 3 February 2016

SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name: Alfaxan Anaesthetic 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

Email: jenq@jurox.com.au

Customer Centre: 1800 023 312

National Poisons Information Centre: 13 1126 (Australia-wide)

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

Section 2: HAZARDS IDENTIFICATION

This product has been assessed according to GHS 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%
Hydroxypropyl-beta-cyclodextrin	128446-35-5	< 10%
Ingredients not contributing to the hazards		to 100%

Section 4: FIRST AID MEASURES

General Information: 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 fumes, aerosols or combustion products are inhaled remove 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.

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

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: No data.

Hazardous Combustion Products: If involved in a fire, may emit noxious 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 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 30°C (room temperature). Protect from light.

Other Information: Avoid contact with incompatible substances as listed in Section 10. Always read the label before use.

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	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:	Not applicable
Melting Point:	Not applicable	Specific Gravity:	Approx. 1.02 – 1.03
Boiling Point:	Not available	Solubility in Water:	Miscible
Flash Point:	Not available	Partition coefficient:	Not available
Evaporation Rate:	Not available	Auto-ignition temperature:	Not available
Flammability:	Not flammable	Decomposition temperature:	Not available
Upper flammability limits:	Not available	Viscosity:	Not applicable

Section 10: STABILITY AND REACTIVITY

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

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 LD₅₀: 297 mg/kg (rat);

Hydroxypropyl-beta-cyclodextrin: Oral LD₅₀: > 5000 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 LD₅₀: 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 LD₅₀: 19 mg/kg (rat); Intraperitoneal LD₅₀: 116 mg/kg;

Subcutaneous LD₅₀: > 2,200 mg/kg.

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.

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.

STOT: Repeat 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.

Aspiration hazard: No data available.

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
Hydroxypropyl-beta-cyclodextrin	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: Crush or puncture and bury in an approved landfill if an approved recycling system is not available.

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

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 does 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.

Legend:

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.
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.
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
STOT – RE	Specific Target Organ Toxicity – Repeat Exposure
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: 3 February 2016 and is valid for 5 years from this date.

Supersedes: This SDS supersedes the version issued on 18 March 2014.

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.

END OF SDS