

SAFETY DATA SHEET**Section 1: IDENTIFICATION**

Product Name:	ALFAXAN (alfaxalone 10 mg/mL)
Common name / synonyms:	ALFAXAN, Alfaxan Anesthetic Injection
Product Code:	505310 (10 mL), 504345 (10 mL samples, not for sale)
Importer:	Jurox Inc.
Address:	American Century Tower II, 4520 Main Street, Kansas City, MO 64111, USA
Emergency Telephone Number:	1-844-ALFAXAN or 1-844-253-2926
Customer Centre:	1-844-ALFAXAN or 1-844-253-2926
Recommended Use:	An intravenous injectable anesthetic for use in cats and dogs.
Restrictions on use:	For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Poison Help Line:	1-800-222-1222 (AAPCC 24 hour hotline)

Section 2: HAZARDS IDENTIFICATION

GHS hazard classification(s):	Not hazardous
Signal word:	Controlled drug (CIV)
GHS hazard statement(s):	None
GHS pictograms:	None
GHS precautionary statement(s):	None
Description of any hazards not otherwise classified identified during the classification process:	Possible sedation or anaesthesia on self-injection.
Ingredient(s) with unknown toxicity;	None

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

CHEMICAL NAME*	COMMON NAME & SYNONYMS	CAS No. (and / or other unique identifiers)	CONTENT (% by weight)
Alfaxalone		23930-19-0	1 %
2-Hydroxypropyl-beta-cyclodextrin	Hydroxypropylbetadex	128446-35-5	8 %
Sodium chloride		7647-14-5	< 1 %
Sodium phosphate dibasic	Sodium phosphate	7558-79-4	< 1 %
Potassium phosphate monobasic	Potassium phosphate	7778-77-0	<1 %
Hydrochloric acid (added to adjust pH)		7647-01-0	< 1 %
Water	Water for Injection		to 100 %

- There are no impurities or stabilizing additives which are themselves classified and which contribute to the classification of the substance.

Section 4: FIRST AID MEASURES

First Aid Measures:	Consult the Poisons Help Line on 1-800-222-1222 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 product container or label at hand.
Inhalation:	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. For advice, contact the Poisons Help Line on 1-800-222-1222. Seek medical assistance immediately.
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. Remove and wash / dispose of contaminated clothing promptly.
Eye:	If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.
Injected:	Treat as for needle-stick injury. Wash area well and disinfect. If other symptoms become evident, seek medical advice.
Advice to Doctor:	Alfaxalone is a steroid anesthetic. Treat symptomatically.
Important symptoms:	Sedation or anesthesia. Possible apnea.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media:	There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
Hazardous Combustion Products:	If involved in a fire, may emit noxious fumes. Non-combustible – not considered to be a significant fire risk.
Flash Point:	Not flammable (aqueous product).
Protective Equipment:	For individual 10 mL bottles: None – no fire risk anticipated. For the bulk product: Gas-tight chemical resistant suit, protective gloves and breathing apparatus

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal:	Wear appropriate protective clothing. Exclude non-essential people from the area. Contain spill and sweep up / 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 according to the applicable federal, state or local regulations.
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:	<p>This is a Controlled Drug (Schedule IV) with federal law restricting this drug to use by or on the order of a licensed veterinarian. Prescribing practitioners must adhere to the laws and regulations of the FDA, DEA, the States in which they are practising and their licencing boards. In the event that discrepancies between Federal and State laws exist the more stringent of the two must be followed.</p> <p>Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.</p> <p>Avoid accidental injection, ingestion, inhalation and contact with skin and eyes. Use personal protective equipment as required</p>
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Storage: Keep out of reach of children. Store individual vials of product at controlled room temperature 20 to 25 °C (68 to 77 °F) with excursions between 15 and 30 °C (59 to 86 °F), under secure conditions appropriate to local requirements for this class of drug. Protect from freezing.

No known incompatibilities for storage.

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

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits: No exposure limits have been assigned for the manufactured product. Use with adequate ventilation. Follow standard veterinary product handling procedures.

Do not handle until all safety precautions have been read and understood. Due to the small volumes involved, and the methods of administration, exposure under normal conditions of use would likely be limited to splashing on to skin or in to eyes, or accidental self-injection.

Exposure limits for the major components are as follows:-

Component	Exposure limits				
	Type	mg/m ³	ppm	µg/m ³	Note
Alfaxalone	OSHA-PEL	NE	NE	NE	-
Alfaxalone	ACGIH-TLV	NE	NE	NE	-
2-Hydroxypropyl-beta-cyclodextrin	OSHA-PEL	NE	NE	NE	-
2-Hydroxypropyl-beta-cyclodextrin	ACGIH-TLV	NE	NE	NE	-
Water	OSHA-PEL	NE	NE	NE	-
Water	ACGIH-TLV	NE	NE	NE	-

NE = Not established

Engineering Controls: Additional controls not normally required

Protective Equipment: Protective gloves and eyewear

Hygiene Precautions: As for good veterinary practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear colorless solution	Upper / lower flammability or explosive limits	Not applicable
Odor	Odorless	Vapor pressure	Not available
Odor threshold	Not applicable	Relative vapor density (air = 1)	Not available
pH	6.5 – 7.0	Relative density / specific gravity	S.G. = 1.02 – 1.03
Melting point / freezing point	Not available	Solubility(ies)	Water: Miscible
Initial boiling point and boiling range	Not available	Partition co-efficient: n-octanol / water	Not available
Flash point	Not applicable	Auto-ignition temperature	Not applicable
Evaporation rate	Not available	Decomposition temperature	Not available
Flammability (solid, gas)	Not applicable	Viscosity	Not available

Section 10: STABILITY AND REACTIVITY

Reactivity:	Hazardous polymerization will not occur.
Chemical stability:	Stable under normal conditions of storage and handling. When stored appropriately this product should show no significant degradation before the expiry date indicated on the packaging.
Possibility of hazardous reactions:	Not known to occur.
Conditions to avoid (e.g. static discharge, shock or vibration):	Avoid freezing.
Incompatible material:	This product is generally compatible with other common materials in a veterinary facility.
Hazardous decomposition products:	None known.

Section 11: TOXICOLOGICAL INFORMATION

Inhalation:	Unlikely to present an inhalation hazard under normal conditions of use, due to the non-volatile nature of the product.
Ingestion:	Alfaxalone: Oral LD ₅₀ ; > 300 mg/kg (rat) Hydroxypropyl beta cyclodextrin: Oral LD ₅₀ ; >5,000 mg/kg (rat) Unlikely to present a hazard, due to the low oral bioavailability of alfaxalone.
Skin:	Not a skin irritant. Not a skin sensitiser. Alfaxalone: Skin LD ₅₀ ; 2,200 mg/kg (rat)
Eye:	Not classified as an eye irritant, but may cause transient discomfort and redness following eye contact.
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)
Chronic Effects:	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.
Reproductive Toxicity:	Not known to affect reproduction. Studies using alfaxalone in pregnant mice, rats and rabbits have demonstrated no deleterious effects on gestation of the treated animals or on the reproductive performance of their offspring.
Mutagenicity:	Alfaxalone is not considered to be mutagenic.
Carcinogenicity:	There are no reports of the carcinogenicity of Alfaxan in animals in published literature or pharmacovigilance data, and no pre-neoplastic lesions were observed in repeat dose toxicity or target species safety studies. Alfaxalone is classified in Group 3 (Not classifiable as to its carcinogenicity to humans) in the IARC Monographs. Alfaxalone has not been reviewed in NTP Reports on Carcinogens.

Section 12: ECOLOGICAL INFORMATION

Aquatic toxicity:	Not determined for product.
Persistence / Biodegradability:	Not determined for product.
Bioaccumulation:	Not determined for product.
Mobility in soil:	Not determined for product.

Section 13: DISPOSAL INFORMATION

- Product Disposal:** All waste materials must be properly characterized. Further, disposal should be performed in accordance with federal, state and local regulatory requirements.
- Container Disposal:** Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14: TRANSPORT INFORMATION

This material is not hazardous as defined by 49 CFR 172.101 by the U.S. Department of Transportation.

- ADR/ADG/DOT STATUS:** Not regulated
- IMDG STATUS:** Not regulated.
- ICAO/IATA STATUS:** Not regulated.
- UN number:** Not applicable. Not classed as a Dangerous Good for transport purposes by road, sea or air.
- UN proper shipping name:** Not applicable. Not classed as a Dangerous Good for transport purposes by road, sea or air.
- Transport hazard class(es):** Not applicable.
- Packing group:** Not applicable.
- DOT Label(s) Required:** Not applicable.
- North American Emergency Response Guidebook Number (1996):** Not applicable.
- Environmental Hazards:** Not a Marine Pollutant.
- Transport in bulk:** Not regulated according to Annex II of MARPOL 73/78 and the IBC code.
- Transport Canada Transportation of Dangerous Goods Regulations:** Not regulated.
- Special precautions:** Not applicable.

Section 15: REGULATORY INFORMATION

- FDA Approval:** NADA 141-342
- Harmonised Tariff Code:** 304.90.9103
- TSCA Inventory Status:** Exempt
- CERCLA Status:** Not determined
- RCRA Status:** Not an RCRA Hazardous Waste
- Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.
- USA Regulations:**

Substance	SARA 302 Status	SARA 304	SARA 313 Status	PROP 65 Status
Alfaxalone	Not listed	Not listed	Not listed	Not listed

Canadian Regulations:**Canadian Inventory:** Not determined.**Canadian NDSL:** Not determined.**WHMIS Hazard Class:** Not determined.**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.

This SDS supersedes the SDS dated 18 June 2014. The format follows that prescribed in the Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)) revised in 2012.

Legend

AAPCC	American Association of Poison Control Centers
ACGIH	American Conference of Governmental Industrial Hygienists
ADG	Australian Dangerous Goods Code
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation and Liability Act
DOT	US Department of Transport regulations
EPA	US Environmental Protection Agency
FDA	Food and Drug Administration, US Dept. of Health and Human Services
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC Code	International Bulk chemical Code
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
LD50	Dosage providing 50% mortality
MARPOL 73/78	International Convention for the Prevention of Pollution from Ships, 1973 as modified by the Protocol of 1978
NADA	New Animal Drug Application
NDSL	Non-Domestic Substances List
NTP	National Toxicology Program
OSHA	Occupational Safety & Health Administration (United States Department of Labor)
PEL	Permissible Exposure Limit
RCRA	US EPA, Resource Conservation and Recovery Act
SARA	Superfund Amendments and Reauthorization Act
Prop 65	California Proposition 65
SDS	Safety Data Sheet
TSCA	Toxic Substance Control Act
TLV	Threshold Limit Value
UN	United Nations
VMD	United Kingdom Veterinary Medicines Directorate
VSD	Veterinary Substances Database
WHMIS	Canadian Workplace Hazardous Materials Information System

References

VMD Assessment Report for Alfaxan 10 mg/mL Solution for Injection for Dogs and Cats
VSDB entry on Alphaxalone (<http://item.herts.ac.uk/aeru/vsdb/Reports/1759.htm>)