SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name: Alfaxan Multidose (alfaxalone 10mg/mL)
Product Identifier: 10 mg/mL Alfaxalone solution for injection.
Common name / synonyms: Alfaxan Multidose
Product Code: 520510 (10 mL); 520520 (20 mL)
Recommended Use: 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.
Importer: Jurox Inc.
Address: 1321 Burlington Road, Suite D, North Kansas City, MO, 64116, USA
Emergency telephone number: 1-844-253-2926
Customer Centre: 1-844-253-2926
Poison help line: 1-800-222-1222 (AAPCC 24 hour hotline)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as follows:

<table>
<thead>
<tr>
<th>GHS Category</th>
<th>Hazard code</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable Liquid Category 3</td>
<td>H226</td>
<td>Flammable liquid and vapor</td>
</tr>
<tr>
<td>Eye Irritant Category 2A</td>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
</tbody>
</table>

Signal Word: WARNING

GHS Pictograms:

- Flame
- Exclamation Mark

GHS Precautionary Statements:

Prevention
- P210 Keep away from heat / sparks / open flames / hot surfaces – No smoking.
- P233 Keep container tightly closed.
- P240 Ground and bond container and receiving equipment.
- P241 Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P264 Wash hands thoroughly after handling.
- P280 Wear protective gloves / eye protection / face protection.
Response
P370 + P378 In case of fire: Use water spray / fog for extinction.
P303 + P361 + P353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/attention

Storage
P403 + P235 Store in a well-ventilated place. Keep cool.

Disposal
P501 Dispose of unused product in accordance with local regulations. Dispose of empty container by wrapping with paper and placing in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled ‘sharps’ container.

Description of any hazards not otherwise classified identified during the classification process:
Possible sedation or anaesthesia on self-injection.

Short term: May cause drowsiness, dizziness, respiratory depression and unconsciousness. May cause eye irritation.
Long term: May cause damage to the liver and cause scarring (based on ingredients).

Ingredient(s) with unknown Toxicity:
None.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

<table>
<thead>
<tr>
<th>INGREDIENT</th>
<th>CAS No.</th>
<th>GHS Classification</th>
<th>CONTENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfaxalone</td>
<td>23930-19-0</td>
<td>Non-hazardous</td>
<td>1%</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>Eye Irritant Category 2A, Flammable Liquid Category 2</td>
<td>10 – 30%</td>
</tr>
<tr>
<td>Chlorocresol</td>
<td>59-50-7</td>
<td>Skin Sensitizer Category 1</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Ingredients not contributing to hazards</td>
<td>-</td>
<td>-</td>
<td>&gt; 60%</td>
</tr>
</tbody>
</table>

- There are no impurities or stabilizing additives which are themselves classified and which contribute to the classification of the substance.
- Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200 – Hazard Communication, the exact percentage composition of this mixture has been withheld as a trade secret.

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 this SDS, product container or label at hand.

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. For advice, contact the Poisons Help Line on 1-800-222-1222.

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

**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

**Extinguishing Media:** Foam, dry chemical powder, BCF (where regulations permit), carbon dioxide, water spray or fog (Large fires only).

**Hazardous Combustion Products:** Flammable liquid. Moderate fire hazard when exposed to heat or flame. Combustion products include carbon monoxide, carbon dioxide and other pyrolysis products typical of burning organic material.

**Flash Point:** 43.5 °C.

**Protective Equipment:** For bulk product: Safety glasses with side shields / chemical goggles. Chemical protective gloves e.g. PVC. Safety footwear or safety gumboots e.g. rubber. Overalls / PVC apron – PVC protective suit may be required if exposure severe. Respiratory protection – Type A filter of sufficient capacity. Eyewash unit. Ready access to a safety shower.

### Section 6: ACCIDENTAL RELEASE MEASURES

**Spills and Disposal:** Wear appropriate protective clothing. For small spills (i.e. those associated with normal use of the product), wipe up spill with paper towels or other suitable materials. Rinse area with 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 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.

Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Avoid accidental injection, ingestion, inhalation and contact with skin and eyes. Use personal protective equipment as required.

**Storage:** Store at controlled room temperature 20°C - 25°C (68° to 77°F) with excursions between 15° and 30°C (59° and 86°F). ALFAXAN MULTIDOSE contains preservatives. The product can be used for 28 days after broaching the vial. Any unused ALFAXAN MULTIDOSE remaining after 28 days should be discarded.

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:- Occupational Exposure Limits (OEL)

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Type</th>
<th>TWA mg/m³</th>
<th>STEL ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfaxalone</td>
<td>US NIOSH Recommended Exposure Limits (RELs)</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Alfaxalone</td>
<td>US ACGIH Threshold Limit Values (TLV)</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Alfaxalone</td>
<td>US OSHA Permissible Exposure Levels (PELs)</td>
<td>NE</td>
<td>NE</td>
</tr>
<tr>
<td>Ethanol</td>
<td>US NIOSH Recommended Exposure Limits (RELs)</td>
<td>1000 ppm / 1900 mg/m³</td>
<td>NE</td>
</tr>
<tr>
<td>Ethanol</td>
<td>US ACGIH Threshold Limit Values (TLV)</td>
<td>NE</td>
<td>1000 ppm</td>
</tr>
<tr>
<td>Ethanol</td>
<td>US OSHA Permissible Exposure Levels (PELs)</td>
<td>1000 ppm / 1900 mg/m³</td>
<td>NE</td>
</tr>
<tr>
<td>Chlorocresol</td>
<td>US NIOSH Recommended Exposure Limits (RELs)</td>
<td>0.5 mg/m³</td>
<td>NE</td>
</tr>
<tr>
<td>Chlorocresol</td>
<td>US ACGIH Threshold Limit Values (TLV)</td>
<td>0.5 mg/m³</td>
<td>NE</td>
</tr>
<tr>
<td>Chlorocresol</td>
<td>US OSHA Permissible Exposure Levels (PELs)</td>
<td>0.5 mg/m³</td>
<td>NE</td>
</tr>
</tbody>
</table>

NE – Not established.

Emergency Limits:

<table>
<thead>
<tr>
<th>Component</th>
<th>TEEL-1</th>
<th>TEEL-2</th>
<th>TEEL-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorocresol</td>
<td>5.5 mg/m³</td>
<td>60 mg/m³</td>
<td>360 mg/m³</td>
</tr>
</tbody>
</table>

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

Protective Equipment (PPE):
- Hands: Chemical protective gloves
- Eyes: Wear safety glasses or goggles if eye contact is possible.
- Skin: Wear protective clothing when working with large quantities.

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

Hygiene precautions: As for good veterinary practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear, colourless liquid</td>
</tr>
<tr>
<td>Odour</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
<td>Approx. 7</td>
</tr>
<tr>
<td>Melting Point / Freezing Point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Boiling Point and Boiling Range</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flash Point</td>
<td>43.5°C</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability</td>
<td>Flammable</td>
</tr>
<tr>
<td>Upper / Lower Flammability Limits</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour Pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour Density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative Density / Specific Gravity</td>
<td>1.01</td>
</tr>
<tr>
<td>Solubility</td>
<td>Miscible in water.</td>
</tr>
<tr>
<td>Partition Coefficient (n-octanol/water)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Auto-Ignition Temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
</tbody>
</table>
Section 10: STABILITY AND REACTIVITY

Reactivity: May react with oxidizing agents.

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. Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.

Possibility of hazardous reactions: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition. Avoid prolonged exposure to higher temperatures and/or direct sunlight.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Heating may cause expansion or decomposition leading to violent rupture of containers. Combustion products include carbon monoxide, carbon dioxide, other pyrolysis products typical of burning organic material.

Section 11: TOXICOLOGICAL INFORMATION

General Information: Toxicological properties of the formulation have not been investigated. The information in this Section describes the potential hazards of the individual ingredients and the formulation.

Inhalation: Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo. Animal testing shows that the most common signs of inhalation overdose are incoordination and drowsiness.

Ethanol: Inhalation (rat) LC$_{50}$: 63926.976 mg/L/4h

Ingestion: Ingestion of ethanol (ethyl alcohol, "alcohol") may produce nausea, vomiting, bleeding from the digestive tract, abdominal pain, and diarrhoea.

Ethanol: Oral (rat) LD$_{50}$: 7060 mg/kg

Alfaxalone: Oral (rat) LD$_{50}$: 297 mg/kg

Skin: Not a skin irritant. However, open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Alfaxalone: Skin (rat) LD$_{50}$: 2,200 mg/kg

Serious Eye Damage / Irritation: Based on available data for the ingredients, the mixture is considered to be an Eye Irritant Category 2A.

Ethanol: Eye (rabbit): 500 mg - Severe irritation, 100 mg / 24 hr - Moderate irritation

Injection: Alfaxalone is an anaesthetic. Avoid needle stick injury. The product will cause drowsiness, dizziness or anaesthesia.

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. However, prolonged exposure to ethanol may cause damage to the liver and cause scarring. It may also worsen damage caused by other agents.

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.
- Alfaxalone: No data available.
- Ethanol: LC50 (96 hr) (fish): 42 mg/L
  EC50 (48 hr) (crustacea): 2 mg/L
  EC50 (96 hr) (algae / aquatic plants): 17.921 mg/L
  NOEC (2016 hr) (fish): 0.000375 mg/L
- Chlorocresol: LC50 (96 hr) (fish): 0.971 mg/L
  EC50 (48 hr) (crustacea): 1.5 mg/L

Persistence / Biodegradability: Not determined for product.
- Alfaxalone: No data available.
- Ethanol: Water/soil: LOW (Half-life = 2.17 days)
  Air: LOW (Half-life = 5.08 days)
- Chlorocresol: Water/soil: LOW (Half-life = 49 days)
  Air: LOW (Half-life = 0.67 days)

Bioaccumulation: Not determined for product.
- Alfaxalone: No data available.
- Ethanol: LOW (LogKOW = -0.31)
- Chlorocresol: LOW (BCF = 13)

Mobility in soil: Not determined for product.
- Alfaxalone: No data available.
- Ethanol: HIGH (KOC = 1)
- Chlorocresol: LOW (KOC = 717.6)

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

IMDG Code: Not Regulated.
SP No. 144: An aqueous solution containing not more than 24% alcohol by volume is not subject to the provisions of the IMDG Code.

ICAO/IATA: Not Regulated.
SP No. A58 (144): An aqueous solution containing not more than 24% alcohol by volume is not subject to the IATA Dangerous Goods Regulations.

49CFR173.150(e)(2): An aqueous solution containing 24 percent or less alcohol by volume and no other hazardous material is not subject to the requirements of Subchapter C. HAZARDOUS MATERIALS REGULATIONS if it contains no less than 50 percent water.

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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>SARA 302 Status</th>
<th>SARA 304 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfaxalone</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

Canadian Regulations:

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

Section 16: OTHER INFORMATION

Legend:

AAPCC American Association of Poison Control Centres
ACGIH American Conference of Governmental Industrial Hygienists
ADG Australian Dangerous Goods Code
ADR European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF Bromochlorodifluoromethane
BCF Bio Concentration Factor
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation and Liability Act
DOT US Department of Transport regulations
EC50 The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms or a 50% reduction in growth or in the growth rate of organisms
EMS Number EMS = Emergency Response Procedures for Ships Carrying Dangerous Goods. EMS codes are assigned to each UN Number in column 15 of the Dangerous Goods List in IMDG Code Chapter 3.2.
EPA US Environmental Protection Agency
FDA Food and Drug Administration, US Dept. of Health and Human Services
GGV/See Transport of Dangerous Goods by Sea Ordinance
GHS Globally Harmonized System of Classification and Labelling of Chemicals
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
KOC Soil-Water Partition Coefficient. The ratio of a chemical’s concentration that is adsorbed in the soil to the concentration of chemical in solution
KOW Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium
LC50 The median lethal concentration, being a statistically derived concentration 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
NADA New Animal Drug Application
NDSL Non-Domestic Substances List
NOEC No Observed Effect Concentration
NTP National Toxicology Program
OSHA Occupational Safety & Health Administration (United States Department of Labor)
OEL Occupational Exposure Limits
PEL Permissible Exposure Limit
PPE Personal Protective Equipment
Prop 65 California Proposition 65
PVC Polyvinyl chloride
RCRA US EPA, Resource Conservation and Recovery Act
SARA | Superfund Amendments and Reauthorization Act  
SDS | Safety Data Sheet  
SP | Special Provision  
STEL | Short term exposure limit  
TEELs | Temporary Emergency Exposure Limits. Guidelines designed to predict the response of members of the general public to different concentrations of a chemical during an emergency response incident  
TEEL-1 | The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure  
TEEL-2 | The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting, adverse health effects or an impaired ability to escape  
TEEL-3 | The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening adverse health effects or death  
TSCA | Toxic Substance Control Act  
TLV | Threshold Limit Value  
TWA | Time-Weighted Average. The average exposure over a specified period, usually a nominal eight hours  
UN | United Nations  
VMD | United Kingdom Veterinary Medicines Directorate  
VSD | Veterinary Substances Database  
WHMIS | Canadian Workplace Hazardous Materials Information System

References:

Summary of Product Characteristics (SPC) of Alfaxan Multidose 10 mg/mL solution for injection for dogs, cats and pet rabbits. [www.vmd.defra.gov.uk/productinformationdatabase/SPC.../SPC_1365063.DOC](http://www.vmd.defra.gov.uk/productinformationdatabase/SPC.../SPC_1365063.DOC)

Veterinary Substances Data Base (VSDB) entry on Alphaxalone ([http://sitem.herts.ac.uk/aeru/vsdb/Reports/1759.htm](http://sitem.herts.ac.uk/aeru/vsdb/Reports/1759.htm))


Supersedes: Version issued 17 August 2018.

Revision History:

<table>
<thead>
<tr>
<th>Date of Revision</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 August 2018</td>
<td>Change of address of importer.</td>
</tr>
<tr>
<td>22 May 2019</td>
<td>Update to Section 14: Transport Information, to reflect that this product is not regulated under IMDG Code, IATA Dangerous Goods Regulations and US DOT Regulations.</td>
</tr>
</tbody>
</table>

This information is based on data believed by the manufacturer 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 whatsoever 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