

**1. UNDERTAKING IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY /****1.1 Product identifier:**

**ALFAXAN MULTIDOSE  
10 MG / ML SOLUTION FOR INJECTION  
FOR DOGS, CATS AND PET RABBITS**

**1.2 Relevant identified uses of the substance or mixture and uses advised against:****Relevant identified uses:**

- i. As an induction agent prior to inhalation anaesthesia in dogs, cats and pet rabbits.
- ii. As a sole anaesthetic agent for the induction and maintenance of anaesthesia for the performance of examination or surgical procedures in dogs and cats.

**Uses advised against:**

- i. Do not use in combination with other anaesthetic agents.
- ii. Do not use in animals with known hypersensitivity to the active substance or any other excipients.
- iii. Do not use in rabbits intended for human consumption.

**Reason why uses advised against:**

- i. Animal studies have not been carried out on the use of the product in combination with other anaesthetic agents.
- ii. Another anaesthetic agent could be used in animals with known hypersensitivity reactions.
- iii. Not using in rabbits for human consumption is a legal requirement.

**1.3 Details of the Supplier of the Safety Data Sheet**

**Supplier:** JUROX (UK) Private Limited Company  
**Street:/P.O. Box:** Second Floor, Richmond House, 105 High Street,  
**Postcode / City:** Crawley, West Sussex RH10, 1DD,  
**Country:** UK  
**Telephone:** +44 1293 510 681  
**E-mail (competent person):** info@jurox.co.uk  
**National contact:** richard.beckwith@jurox.co.uk

**1.4 Emergency telephone number**

**Please contact:** 01293510681  
**Opening hours:** 24 hours a day, 365 days a year  
**Other comments:** *Language(s) of the phone service: English*

**2. HAZARDS IDENTIFICATION**

**2.1 Classification according to regulation (EC) No 1272/2008:**

H226 Flammable Liquid Category 3;  
 H336\* Specific target organ toxicity – single exposure Category 3 (narcotic effects). \**Limited evidence*

**Hazard pictograms:**



GHS02: Flame



GHS07: Exclamation Mark

**Signal word:** WARNING

**Hazard statements:**

H226	Flammable liquid and vapour
H319	Causes serious eye irritation

**Supplementary statements:**

	<i>Not applicable</i>
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**Precautionary statements – Prevention:**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P240	Ground / 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.

**Precautionary statements – Response:**

P370+P378	In case of fire: Use alcohol resistant foam or normal protein foam to extinguish.
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.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water / shower.

**Precautionary statements – Storage:**

P403+P235	Store in a well-ventilated place. Keep cool.
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**Precautionary statements – Disposal:**

P501	Dispose of contents / container in accordance with local regulations.
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**Other hazards:**

Cumulative effects may result following exposure.  
 Vapours potentially cause drowsiness and dizziness.  
 REACH – Art.57-59 The mixture does not contain Substances of Very High Concern (SVHC) at the SDS issue date.

**3. COMPOSITION / INFORMATION ON ACTIVE INGREDIENTS**

1.CAS No. 2.EC No. 3.Index No. 4.REACH No.	% w/w	NAME	HAZARD (according to regulation (EC) No 1272/2008 [CLP])
1.64-17-5 2.200-578-6 3.603-002-00-5 4.01-2119457610-43-XXXX 01-2120063206-63-XXXX	10 - 15%	Ethanol	Flammable Liquid Category 2 [H225]
1.23930-19-0 2.Not available 3.Not available 4.Not available	1%	Alfaxalone	Acute Toxicity (Oral) Category 4 [H302]
1.Not available 2.Not available 3.Not available 4.Not available	0 - 1%	Other non-hazardous ingredients	Not applicable
1.7732-18-5 2.231-791-2 3.Not available 4.Not available	>60%	Water	Not applicable

**4. FIRST AID MEASURES**

<b>Most important symptoms and effects, both acute and delayed:</b>	May cause central nervous system and cardiovascular system effects. May cause drowsiness, dizziness, respiratory depression and unconsciousness
<b>Following eye contact:</b>	If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.
<b>Following skin contact:</b>	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.
<b>Following ingestion:</b>	If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. Seek medical assistance immediately.
<b>Following injection:</b>	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 show the product literature to the doctor.
<b>Following inhalation:</b>	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.
<b>Recommended First Aid Facilities:</b>	Ready access to running water and soap is required. Accessible eyewash is required.
<b>Advice to Doctor:</b>	Treat symptomatically. Following recent ingestion or overdose of anxiolytic sedatives, hypnotics and neuroleptics, the stomach may be emptied by gastric lavage and aspiration. Patients should be managed with intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of oxygenation, respiratory, cardiovascular and renal functions. Electrolyte balance should also be maintained.

**5. FIRE-FIGHTING MEASURES (BULK PRODUCT)**

<b>Flammability:</b>	Flammable liquid and vapour. Moderate fire hazard when exposed to heat or flame.
<b>Extinguishing media:</b>	Foam, dry chemical powder, BCF (where regulations permit), carbon dioxide, water spray or fog (Large fires only).
<b>Protective equipment:</b>	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.
<b>Explosive hazards:</b>	Vapour forms an explosive mixture with air. Moderate explosion hazard when exposed to heat or flame. Vapour may travel a considerable distance to source of ignition. Heating may cause expansion or decomposition leading to violent rupture of containers.
<b>Hazardous combustion products:</b>	Combustion products include carbon monoxide, carbon dioxide and other pyrolysis products typical of burning organic material.

**6. ACCIDENTAL RELEASE MEASURES (Large spills)**

<b>Spillage:</b>	Wear appropriate protective clothing (See Section 8). 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.
<b>Environmental precautions:</b>	Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.
<b>Decontamination procedure:</b>	Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this substance.

**7. HANDLING AND STORAGE**

<b>Handling:</b>	The product should be handled with care to avoid exposure. 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.
<b>Storage:</b>	Store below 25°C. Keep the vial in the outer carton in order to protect from light.
<b>Other Information:</b>	Always read the label before use. See label for further information on handling and storage.

**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.**

<b>Exposure limits:</b>	No exposure limits have been assigned for this product. Known UK Workplace Exposure Limits (WELs) for ingredients are as follows: Ethanol: TWA: 1920 mg/m <sup>3</sup> / 1000 ppm Known Emergency Limits for ingredients are as follows: Ethanol: TEEL-3: 15000 ppm 4-chloro-m-cresol: TEEL-1: 5.5 mg/m <sup>3</sup> , TEEL-2: 60 mg/m <sup>3</sup> , TEEL-3: 360 mg/m <sup>3</sup>
<b>Protective Equipment:</b>	<u>Eye Protection:</u> Protective glasses or goggles are recommended when handling bulk quantities of this product. <u>Skin Protection:</u> When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC. <u>Respiratory Protection:</u> Type A Filter of sufficient capacity. <u>Other:</u> For the bulk product, overalls, PVC apron or protective suit. Have eyewash unit at hand. Ensure there is ready access to a safety shower.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

APPEARANCE: Clear colourless liquid	SPECIFIC GRAVITY: Not available	pH: Approx. 7
SOLUBILITY IN WATER: Miscible in water	FLASH POINT: 43.5°C (110.3 °F)	ODOUR: Not available

**10. STABILITY AND REACTIVITY**

<b>Stability:</b>	When stored appropriately this product should show no significant degradation within the expiry period shown on the label. Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
<b>Reactivity:</b>	May react with oxidizing agents.

**11. TOXICOLOGICAL INFORMATION**

<b>Inhalation:</b>	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. <u>Ethanol</u> : Inhalation (rat) LC <sub>50</sub> : 63926.976 mg/l/4h
<b>Ingestion:</b>	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. <u>Ethanol</u> : Oral (rat) LD <sub>50</sub> : 7060 mg/kg <u>Alfaxalone</u> : Oral (rat) LD <sub>50</sub> : 297 mg/kg
<b>Injection:</b>	Significant CNS effects are expected only from the intravenous route, and this is unlikely from accidental self-injection. <u>Alfaxalone</u> : Intravenous LD <sub>50</sub> ; 19 mg/kg (rat)
<b>Skin contact:</b>	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.
<b>Eye contact:</b>	No data for the mixture is available. Ethanol may cause eye irritation. <u>Ethanol</u> : Eye (rabbit): 500 mg - Severe irritation, 100 mg / 24 hr - Moderate irritation
<b>Chronic effects:</b>	Prolonged exposure to ethanol may cause damage to the liver and cause scarring. It may also worsen damage caused by other agents.

**12. ECOLOGICAL INFORMATION**

No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as ecotoxic by GHS criteria.

Ethanol: LC<sub>50</sub> (96 hr) (fish): 42 mg/L  
 EC<sub>50</sub> (48 hr) (crustacea): 2 mg/L  
 EC<sub>50</sub> (96 hr) (algae / aquatic plants): 17.921 mg/L  
 NOEC (2016 hr) (fish): 0.000375 mg/L

Alfaxalone: No data available.

<b>Ingredient</b>	<b>Persistence: Water/Soil</b>	<b>Persistence: Air</b>	<b>Bioaccumulation</b>	<b>Mobility</b>
Ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)	LOW (LogKOW = -0.31)	HIGH (KOC = 1)

**13. DISPOSAL CONSIDERATIONS**

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with the label instructions and local regulations and procedures.

**14. TRANSPORT INFORMATION**

<b>DG label:</b>	
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<b>Marine Pollutant:</b>	NO	
<b>HAZCHEM:</b>	•2Y	
<b>Land transport (DOT)</b>		
▪ UN number	1170	
▪ UN proper shipping name	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	
▪ Transport hazard classes	▪ Class	3
	▪ Sub-risk	Not applicable
▪ Packing group	III	
▪ Environmental hazard	Not applicable	
▪ Special precautions for user	▪ Hazard identification (Kemler)	30
	▪ Classification code	F1
	▪ Hazard Label	3
	▪ Special provisions	144 601
	▪ Limited quantity	5 L
<b>Air transport (ICAO-IATA / DGR)</b>		
▪ UN number	1170	
▪ UN proper shipping name	Ethanol or ethanol solution	
▪ Transport hazard classes	▪ ICAO/IATA Class	3
	▪ ICAO/IATA Sub-risk	Not applicable
	▪ ERG Code	3L
▪ Packing group	III	
▪ Environmental hazard	Not applicable	
▪ Special precautions for user	▪ Special provisions	A3 A58 A180
	▪ Cargo Only Packing Instructions	366
	▪ Cargo Only Maximum Qty / Pack	220 L
	▪ Passenger and Cargo Packing Instructions	355
	▪ Passenger and Cargo Maximum Qty / Pack	60 L
	▪ Passenger and Cargo Limited Quantity Packing Instructions	Y344
	▪ Passenger and Cargo Limited Maximum Qty / Pack	10 L
<b>Sea transport (IMDG-Code / GGVSee)</b>		
▪ UN number	1170	
▪ UN proper shipping name	ETHANOL (ETHYL ALCOHOL) or ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	
▪ Transport hazard classes	▪ IMDG Class	3
	▪ IMDG Sub-risk	Not applicable
▪ Packing group	III	
▪ Environmental hazard	Not applicable	

<ul style="list-style-type: none"> <li>▪ Special precautions for user</li> </ul>	<ul style="list-style-type: none"> <li>▪ EMS Number</li> </ul>	F-E, S-D
	<ul style="list-style-type: none"> <li>▪ Special provisions</li> </ul>	144 223
	<ul style="list-style-type: none"> <li>▪ Limited Quantities</li> </ul>	5 L
<b>Inland waterways transport (ADN)</b>		
<ul style="list-style-type: none"> <li>▪ UN number</li> </ul>	1170	
<ul style="list-style-type: none"> <li>▪ UN proper shipping name</li> </ul>	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	
<ul style="list-style-type: none"> <li>▪ Transport hazard classes</li> </ul>	3	Not applicable
<ul style="list-style-type: none"> <li>▪ Packing group</li> </ul>	III	
<ul style="list-style-type: none"> <li>▪ Environmental hazard</li> </ul>	Not applicable	
<ul style="list-style-type: none"> <li>▪ Special precautions for user</li> </ul>	<ul style="list-style-type: none"> <li>▪ Classification code</li> </ul>	F1
	<ul style="list-style-type: none"> <li>▪ Special provisions</li> </ul>	144, 601
	<ul style="list-style-type: none"> <li>▪ Limited quantity</li> </ul>	5 L
	<ul style="list-style-type: none"> <li>▪ Equipment required</li> </ul>	PP, EX, A
	<ul style="list-style-type: none"> <li>▪ Fire cones number</li> </ul>	0
<b>Transport in bulk according to Annex II of MARPOL and the IBC code:</b> Not applicable		

## 15. REGULATORY INFORMATION

### European Union classification and labelling:

POM-V Prescription Only Medicine – Veterinarian (UK).

VPO (Ireland)

For this substance, a chemical safety assessment (CSA) is not required, since it is neither manufactured or imported in quantities of 10 tonnes or more per year.

## 16. OTHER INFORMATION

<b>Revision date</b>	Not applicable
<b>Initial date</b>	12 June 2018

<b>Abbreviations and acronyms</b>	
BCF	Bromochlorodifluoromethane
CNS	Central Nervous System
DG	Dangerous Good
EC	European Commission
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.
ERG Code	ERG = Emergency Response Guidebook: A Guidebook for First Responders During the Initial Phase of a Dangerous Goods / Hazardous Materials Transportation Incident. This contains hazard identification codes.
GGV/See	Transport of Dangerous Goods by Sea Ordinance
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.
IATA	International Air Transport Association
IBC	Intermediate Bulk Container
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods (Code)
KOC	Soil/water partition coefficient



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.
Log-KOW	The logarithm of the KOW (Octanol Water Partition Coefficient). The KOW is 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.
MARPOL	The International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 thereto (Federal Law Gazette 1982 II p. 2, 1996 II p. 399) as amended by Resolution MEPC.193(61) (Federal Law Gazette 2013 II p. 1098, 1099) adopted in London by the Marine Environment Protection Committee of the International Maritime Organization (IMO).
NOEC	No Observed Effect Concentration
POM-V	Prescription Only Medicine – Veterinarian (UK).
pH	Partial pressure of Hydrogen
PVC	Polyvinyl chloride
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals. This is the key chemical control regulation in the European Union.
SDS	Safety Data Sheet
SVHC	Substances of Very High Concern
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, non-sensory 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. The average exposure over a specified period, usually a nominal eight hours.
TWA	Time Weighted Average
UN	United Nations
UN Number	Number identifying a hazardous substance, assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods.
VPO	Veterinary Practitioner Only
UK	United Kingdom
WEL	Workplace Exposure Limit

*This information is based on data believed by Jurox (UK) 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 (UK) 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.*