

SAFETY DATA SHEET

Title: ALFAXAN MULTIDOSE ANAESTHETIC INJECTION		Document: SDS-AU002	
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Status: Current	Issue Date: 26-Jun-2024	Effective Date: 26-Jun-2024	Review Date: 26-Jun-2029

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	ALFAXAN Multidose Anaesthetic Injection
Product Identifier:	10 mg/mL Alfaxalone solution for injection.
Recommended Use:	An injectable steroid anaesthetic for use in dogs and cats. It can be used as an induction agent prior to gaseous anaesthesia or as a sole anaesthetic agent for the induction and maintenance of anaesthesia for the performance of examination or surgical procedures.
Restrictions on Use:	For animal treatment only.
Company Identification:	Zoetis Australia Pty Ltd ABN: 94 156 476 425
Address:	Level 6, 5 Rider Boulevard Rhodes NSW 2138 Australia
Telephone:	1800 814 883
Fax:	(02) 8876 0444
Email:	productsupport.au@zoetis.com
National Poisons Information Centre:	13 11 26 (24 hours)
Police, Fire Brigade, Ambulance:	Dial 000
Emergency Telephone Number:	1800 814 883 (all hours)

Section 2: HAZARDS IDENTIFICATION

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

GHS Category	Hazard code	Hazard Statement
Flammable Liquid Category 3	H226	Flammable liquid and vapour
Eye Irritant Category 2A	H319	Causes serious eye irritation

Signal Word: **WARNING**

Pictograms:



Flame



Exclamation Mark

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Precautionary Statements:

Prevention

- P210 Keep away from heat / sparks / open flames / hot surfaces – No smoking.
- P233 Keep container tightly closed.
- 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

- 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
- P370 + P378 In case of fire: Use water spray / fog for extinction.

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.

N.B.: The above statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Other hazards: None known.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Ethanol	64-17-5	10 – 30%
Alfaxalone	23930-19-0	1%
Ingredients not contributing to the hazards	-	> 60%

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

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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. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. First aid is not generally required. For advice, contact a doctor or the National Poisons Centre on 13 1126.

Skin: If skin or hair contact occurs, flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Eye: If eye contact occurs, wash out immediately with running water. Continue rinsing. 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. 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. 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.

Section 5: FIRE FIGHTING MEASURES

Flash Point: 43.5 °C.

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.

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

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.

Hazchem Code: •3Y.

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

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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: 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.

Storage: Store below 25°C (air conditioning). Protect from light. Do not freeze.

Other Information: 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. Known exposure limits for ingredients are as follows:

Occupational Exposure Limits (OEL)

Australian Exposure Standards

INGREDIENT	TWA	STEL
Ethanol	1880 mg/m ³ / 1000 ppm	Not available

Emergency Limits

INGREDIENT	TEEL-1	TEEL-2	TEEL-3
Ethanol	Not available	Not available	15000 ppm

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

Personal Protective Equipment (PPE):

Eye Protection: Protective glasses or goggles are recommended when handling bulk quantities of this product.

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.

Other: For the bulk product, overalls, PVC apron or protective suit. Have eyewash unit at hand. Ensure there is ready access to a safety shower.

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Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colourless liquid	Upper / Lower Flammability Limits:	Not available.
Odour:	Not available.	Vapour Pressure:	Not available.
Odour Threshold:	Not available.	Vapour Density:	Not available.
pH:	Approx. 7	Relative Density / Specific Gravity:	Not available.
Melting Point / Freezing Point:	Not available.	Solubility:	Miscible in water.
Boiling Point and Boiling Range:	Not available.	Partition Coefficient (n-octanol/water):	Not available.
Flash Point:	43.5°C	Auto-Ignition Temperature:	Not available.
Evaporation Rate:	Not available.	Decomposition Temperature:	Not available.
Flammability:	Flammable	Viscosity:	Not available.

Section 10: STABILITY AND REACTIVITY

Reactivity: May react with oxidizing agents.

Chemical Stability: 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.

Conditions to Avoid: Extreme temperatures.

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

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.

Ethanol: Oral (rat) LD₅₀: 7060 mg/kg

Alfaxalone: Oral (rat) LD₅₀: 297 mg/kg

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.

Ethanol: Inhalation (rat) LC₅₀: 6400 ppm/4h

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.

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

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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: 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

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. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant.

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

Narcotic Effects: Anesthetic 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 classified as ecotoxic by GHS criteria.

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

Alfaxalone: No data available.

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Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)	LOW (LogKOW = -0.31)	HIGH (KOC = 1)
Alfaxalone	Not Available	Not Available	Not Available	Not Available

Section 13: DISPOSAL INFORMATION

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

Container Disposal: Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Under special provisions 144 of the Australian Dangerous Goods Code, an aqueous solution containing not more than 24% alcohol by volume is not subject to this Code. Therefore not considered a Dangerous Good for land, sea and air transport.

Hazchem Code: •3Y

Section 15: REGULATORY INFORMATION

Poisons Schedule (Product): Schedule 4

APVMA No.: 83248

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 Zoetis Australia Pty Ltd 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 Zoetis Australia Pty Ltd 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.

Legend:

AICS	Australian Inventory of Chemical Substances.
BCF	Bromochlorodifluoromethane.
CAS No.	Chemical Abstracts Service Registry Number.
CNS	Central Nervous System.
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.
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.
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.

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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.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
OEL	Occupational Exposure Limits.
PPE	Personal Protective Equipment.
PVC	Polyvinyl chloride.
STEL	Short term exposure limit.
STOT	Specific Target Organ Toxicity.
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.
TWA	Time-Weighted Average. The average exposure over a specified period, usually a nominal eight hours.

References:

ChemID Plus
EPA New Zealand Chemical Classification and Information Database (CCID)
HSDB (Hazardous Substances Data Bank)

Revision History:

Date of Revision	Reason
29 March 2018	Name change from Alfaxan multi to Alfaxan multidose
01 March 2023	Updates of Customer Service and emergency contact telephone numbers to Zoetis numbers.
26 June 2024	5 year review. Minor revision to update the company details to Zoetis Australia. Minor formatting changes.

END OF SDS