This SDS packet was issued with item: 078949675

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078949716 078949717



Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS Document: SDS-US008				
			Rev: 1.1	PAGE 1 OF 11
Status: Current	nt Issue Date: 21-Jul-2023 Effective Date: 21-Jul-2023 Review Date: 20-Jul-2028		20-Jul-2028	

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Identifier used on label: Alfaxan Multidose (alfaxalone 10 mg/mL)

Other means of identification:

Product Code:	Jurox Product codes – 520795 (10 mL); 520800 (20 mL) Zoetis SAP codes – 10026696 (10 mL); 10026697 (20 mL)		
Common name / synonyms:	10 mg/mL Alfaxalone so	olution for injection; Alfaxan; Alfaxan Multidose.	
Recommended Use of the	Chemical and Restric	tions on Use:	
Recommended Use:	Intravenous injectable a	nesthetic for use in dogs and cats.	
Restrictions on Use:	For veterinary use only order of a licensed vete	. Federal law restricts this drug to use by or on the rinarian.	
Name, address, and telep responsible party:	hone number of the	chemical manufacturer, importer, or other	
Importer:	Zoetis Inc.		
Address:	10 Sylvan Way Parsippany, New Jersey	/ 07054, USA	
Telephone number:	1-800-366-5288		
Emergency telephone num	iber:		
Rocky Mountain Poison and	Drug Center:	1-866-531-8896	

CHEMTREC (24 hours):

International CHEMTREC (24 hours):

+1-703-527-3887

1-800-424-9300

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications:

This product has been assessed according to GHS (Rev 3) in accordance with OSHA Standard §1910.1200 paragraph (d).

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

Signal Word:

WARNING

GHS Symbols:







Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS Document: SDS-US008				
			Rev: 1.1	PAGE 2 OF 11
Status: Current	Issue Date: 21-Jul-2023	Effective Date: 21-Jul-2023	Review Date: 20-Jul-2028	

GHS Precautionary Statements:

P210Keep away from heat / sparks / open flames / hot surfaces – No smoking.P233Keep container tightly closed.P240Ground and bond container and receiving equipment.P241Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.P242Use only non-sparking tools.P243Take precautionary measures against static discharge.P264Wash hands thoroughly after handling.P280Wear protective gloves / eye protection / face protection.ResponseIn case of fire: Use water spray / fog for extinction.P303 + P361 + P353IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P337 + P313If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	Prevention	
P240Ground and bond container and receiving equipment.P241Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.P242Use only non-sparking tools.P243Take precautionary measures against static discharge.P264Wash hands thoroughly after handling.P280Wear protective gloves / eye protection / face protection. Response In case of fire: Use water spray / fog for extinction.P370 + P378In case of fire: Use water spray / fog for extinction.P303 + P361 + P353IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313P307 + P235Store in a well-ventilated place. Keep cool. Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	P210	Keep away from heat / sparks / open flames / hot surfaces – No smoking.
P241Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.P242Use only non-sparking tools.P243Take precautionary measures against static discharge.P264Wash hands thoroughly after handling.P280Wear protective gloves / eye protection / face protection.ResponseP370 + P378In case of fire: Use water spray / fog for extinction.P303 + P361 + P353IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Dispose of unused product in accordance with local regulations. Dispose of empty	P233	Keep container tightly closed.
P242Use only non-sparking tools.P243Take precautionary measures against static discharge.P264Wash hands thoroughly after handling.P280Wear protective gloves / eye protection / face protection.ResponseIn case of fire: Use water spray / fog for extinction.P303 + P361 + P353In case of fire: Use water spray / fog for extinction.P305 + P351 + P338IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P337 + P313If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Dispose of unused product in accordance with local regulations. Dispose of empty	P240	Ground and bond container and receiving equipment.
P243Take precautionary measures against static discharge.P264Wash hands thoroughly after handling.P280Wear protective gloves / eye protection / face protection. Response P370 + P378P303 + P361 + P353In case of fire: Use water spray / fog for extinction.P305 + P351 + P338IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P337 + P313If eye irritation persists: Get medical advice/attention. Storage P403 + P235Store in a well-ventilated place. Keep cool. Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	P241	Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.
P264Wash hands thoroughly after handling.P280Wear protective gloves / eye protection / face protection.ResponseIn case of fire: Use water spray / fog for extinction.P370 + P378In case of fire: Use water spray / fog for extinction.P303 + P361 + P353IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Dispose of unused product in accordance with local regulations. Dispose of empty	P242	Use only non-sparking tools.
P280Wear protective gloves / eye protection / face protection.Response P370 + P378In case of fire: Use water spray / fog for extinction.P303 + P361 + P353In case of fire: Use water spray / fog for extinction.P305 + P351 + P338IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Dispose of unused product in accordance with local regulations. Dispose of empty	P243	Take precautionary measures against static discharge.
ResponseP370 + P378P303 + P361 + P353P305 + P351 + P338IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338P307 + P313IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.Storage P403 + P235P307Dispose of unused product in accordance with local regulations. Dispose of empty	P264	Wash hands thoroughly after handling.
P370 + P378In case of fire: Use water spray / fog for extinction.P303 + P361 + P353IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.P307 + P313If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	P280	Wear protective gloves / eye protection / face protection.
P370 + P378In case of fire: Use water spray / fog for extinction.P303 + P361 + P353IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.P307 + P313If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty		
P303 + P361 + P353IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.P337 + P313If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	<u>Response</u>	
Rinse skin with water / shower.P305 + P351 + P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P337 + P313If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	P370 + P378	In case of fire: Use water spray / fog for extinction.
P337 + P313lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	P303 + P361 + P353	
P337 + P313If eye irritation persists: Get medical advice/attention.Storage P403 + P235Store in a well-ventilated place. Keep cool.Disposal P501Dispose of unused product in accordance with local regulations. Dispose of empty	P305 + P351 + P338	
P403 + P235Store in a well-ventilated place. Keep cool.DisposalDispose of unused product in accordance with local regulations. Dispose of empty	P337 + P313	
P403 + P235Store in a well-ventilated place. Keep cool.DisposalDispose of unused product in accordance with local regulations. Dispose of empty	Storage	
Disposal P501 Dispose of unused product in accordance with local regulations. Dispose of empty		Store in a well-ventilated place. Keep cool.
P501 Dispose of unused product in accordance with local regulations. Dispose of empty		
	<u>Disposal</u>	
container by wrapping with paper and placing in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.	P501	container by wrapping with paper and placing in garbage. Discarded needles should

Hazards not otherwise classified that have been identified during the classification process:

None.

Ingredient(s) with unknown acute Toxicity:

None.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

CHEMICAL NAME	CAS No.	GHS Classification	CONTENT
Alfaxalone	23930-19-0	Not listed	1 %
Ethanol	64-17-5	Eye Irritant Category 2A Flammable Liquid Category 3	< 24%
Chlorocresol	59-50-7	Skin Sensitizer Category 1	< 1 %
Ingredients not contributing to hazards	-	Not listed	> 60 %

• 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.

SAFETY DATA SHEET				
Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS Document: SDS-US008				S-US008
			Rev: 1.1	PAGE 3 OF 11
Status: Current Issue Date: 21-Jul-2023 Effective Date: 21-Jul-2023		Review Date:	20-Jul-2028	

Section 4: FIRST AID MEASURES

Description of First aid measures:

General:	Consult the CHEMTREC on 1-800-424-9300 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:	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:	DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. Seek medical advice immediately.
Skin:	Wash affected area thoroughly with plenty of soap and water for at least 15 minutes. If skin irritation or rash occurs, get medical advice / attention.
Eye:	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. If overdose has occurred, remove the individual from the source of exposure and seek medical attention. Respiratory depression should be treated by artificial ventilation and oxygen.
Facilities:	Ready access to running water and soap. Accessible eyewash.
Most important sym	ptoms/effects, acute and delayed:
Symptoms:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Indication of the Imr	nediate Medical Attention and Special Treatment Needed:

Note to Physician: This product contains an injectable neurosteroid anesthetic. Treat symptomatically with attention to the maintenance of cardiovascular and respiratory functions.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media:

Suitable media: Foam, dry chemical powder, BCF (where regulations permit), carbon dioxide, water spray or fog (large fires only).

Special Hazards Arising from the Chemical:

Fire Incompatibility: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.



Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS Document: SDS-US008			S-US008	
			Rev: 1.1	PAGE 4 OF 11
Status: Current Issue Date: 21-Jul-2023 Effective Date: 21-Jul-2023 Review Date: 20-Jul-20		20-Jul-2028		

Hazardous Combustion Products:

Combustion products include carbon monoxide, carbon dioxide and other pyrolysis products typical of burning organic material.

Special protective equipment and precautions for fire-fighters:

Fire Fighting:	 Alert Fire Brigade and tell them location and nature of hazard. May be violently or explosively reactive. Wear breathing apparatus plus protective gloves. Prevent by any means available, spillage from entering drains or water course. If safe, switch off electrical equipment until vapour fire hazard removed. Use water delivered as a fine spray to control fire and cool adjacent area.
Fire Explosion Hazard:	Liquid and vapour are flammable. Moderate fire hazard when exposed to heat or flame. 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.

Section 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures:

Ensure adequate ventilation. Use appropriate personal protective equipment to avoid breathing vapours and contact with skin and eyes (see section 8).

Methods and materials for containment and cleaning up:

Minor Spills:	Clean up all spills immediately. Contain and absorb small quantities with paper towel or other suitable absorbent material. Wipe up and rinse area with water.
Major Spills:	Exclude non-essential people from the area. Alert Fire Brigade and tell them location and nature of hazard. May be violently or explosively reactive. 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. Prevent, by any means available, spillage from entering drains or water course.
Protective Clothing:	For appropriate personal protective equipment see section 8.
Environmental Precautions:	Place waste in an appropriately labelled, sealed container for disposal. Prevent waste from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Precautions for safe handling:

This is a Controlled Drug (Class 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



Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS Document: SDS-US008				S-US008
			Rev: 1.1	PAGE 5 OF 11
Status: Current	Current Issue Date: 21-Jul-2023 Effective Date: 21-Jul-2023 Review Date: 20-Jul-20		20-Jul-2028	

States in which they are practising and their licencing boards. If discrepancies between Federal and State laws exist, the more stringent of the two must be followed.

Use in a well-ventilated area. Avoid naked lights or ignition sources. 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 (see section 8).

Conditions for safe storage, including any incompatibilities:

Storage:	Store in original container at controlled room temperature 20°C - 25°C (68° to 77°F) with excursions between 15° and 30°C (59° and 86°F). No smoking, naked lights, heat or ignition sources. ALFAXAN MULTIDOSE contains preservatives. The product can be used for 56 days after broaching the vial. Any unused ALFAXAN MULTIDOSE remaining after 56 days should be discarded.
Incompatibilities:	Avoid oxidising agents, acids, acid chlorides, acid anhydrides, chloroformates.
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 into eyes, or accidental self-injection.

Exposure limits for the major components are as follows:

Occupational Exposure Limits (OEL):

Component	Exposure				
Component	Туре	TWA mg/m ³	STEL ppm		
Alfaxalone	US NIOSH Recommended Exposure Limits (RELs)	NE	NE		
Alfaxalone	US ACGIH Threshold Limit Values (TLV) NE		NE		
Alfaxalone	US OSHA Permissible Exposure Levels (PELs) NE		NE		
Ethanol	US NIOSH Recommended Exposure Limits (RELs)	1000 ppm / 1900 mg/m ³	NE		
Ethanol	US ACGIH Threshold Limit Values (TLV)	NE	1000 ppm		
Ethanol	US OSHA Permissible Exposure Levels (PELs)	1000 ppm / 1900 mg/m ³	NE		
Chlorocresol	US NIOSH Recommended Exposure Limits (RELs)	0.5 mg/m ³	NE		
Chlorocresol	US ACGIH Threshold Limit Values (TLV)	0.5 mg/m ³	NE		
Chlorocresol	US OSHA Permissible Exposure Levels (PELs)	0.5 mg/m ³	NE		

NE – Not established.



Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS				Document: SDS-US008	
			Rev: 1.1	PAGE 6 OF 11	
Status: Current	Issue Date: 21-Jul-2023	Effective Date: 21-Jul-2023	Review Date: 20-Jul-2028		

Emergency Limits:

Component	TEEL-1	TEEL-2	TEEL-3
Alfaxalone	N/A	N/A	N/A
Ethanol	N/A	N/A	15000 ppm
Chlorocresol	5.5 mg/m ³	60 mg/m ³	360 mg/m ³

N/A – not available

Appropriate Engineering Controls:

Use only in a well-ventilated area. Ensure that the work environment remains clean.

Individual protection measures, such as personal protective equipment:

Protective Equipment (PPE):

Eye protection: Hand protection: Feet protection:	Safety glasses / chemical goggles. Chemical protective gloves e.g. PVC. Safety footwear. Safety gumboots e.g. rubber if working with large quantities.
Body protection:	Protective clothing / Overalls / PVC apron. PVC protective suit may be required if exposure severe.
Respiratory Protection:	Not required for the normal use of this product. If required – Type AB-P filter of sufficient capacity is recommended.
Other protection:	Eyewash unit and ready access to a safety shower.
Hygiene precautions:	Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

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.
рН	Approx. 7	Relative Density / Specific Gravity	1.01
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:

Stable under normal conditions of storage and handling. When stored appropriately this product should show no significant degradation before the



Rev: 1.		
	.1 PAGE 7 OF 11	
Status: Current Issue Date: 21-Jul-2023 Effective Date: 21-Jul-2023 Review	Review Date: 20-Jul-2028	

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:

Heating may cause expansion or decomposition leading to violent rupture of containers. Avoid contamination with oxidising agents as ignition may result.

- **Conditions to Avoid:** Avoid smoking, naked lights, heat, spark, flames and all other sources of ignition. Avoid prolonged exposure to higher temperatures and/or direct sunlight.
- Incompatible Materials: Avoid oxidising agents, acids, acid chlorides, acid anhydrides, chloroformates.

Hazardous Decomposition Products:

Combustion products include carbon monoxide, carbon dioxide, other pyrolysis products typical of burning organic material.

Section 11: TOXICOLOGICAL INFORMATION

Routes of Exposure and symptoms related to the physical, chemical and toxicological characteristics:

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:	The product is not thought to produce adverse health effects or irritation of the respiratory tract. 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 : 124.7 mg/L/4h
Ingestion:	Ingestion of ethanol (ethyl alcohol, "alcohol") may produce nausea, vomiting, bleeding from the digestive tract, abdominal pain, and diarrhoea. Effects may also include impaired vision, reduces co-ordination and reaction time, emotional instability, flushing, sweating, changes in heart rate, and central nervous system depression. Ingestion of alfaxalone may produce drowsiness or sedation and central nervous system depression.
	Ethanol: Oral (rat) LD ₅₀ : 1501 mg/kg Alfaxalone: Oral (rat) LD ₅₀ : 297 mg/kg Chlorocresol: Oral (mouse) LD ₅₀ : 600 mg/kg
Skin:	The product is not thought to produce adverse health effects or skin irritation following contact. However, open cuts, abraded or irritated skin should not be exposed to this material. Entry into the bloodstream through for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
	Alfaxalone:Dermal (rat) LD50: > 2,200 mg/kgChlorocresol:Dermal (rat) LD50: > 500 mg/kg
Eye:	The product is considered to be an Eye Irritant Category 2A and may cause eye irritation is some persons.

Jurox	SAFETY	DATA SHEET		
Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS Document: SDS-US008				
			Rev: 1.1	PAGE 8 OF 11
Status: Current	Issue Date: 21-Jul-2023	Effective Date: 21-Jul-2023	Review Date:	20-Jul-2028
Injection:	Alfaxalone is an or anaesthesia.	Eye (rabbit): 500 mg - Severe irritat Eye (rabbit) 100 mg / 24 hr - Moder a anaesthetic. The product will o Overdose is likely to cause o nsion, bradycardia and/or apnea	ate irritation. cause drowsir cardiorespirate	
		Intravenous LD ₅₀ (rat): 19.4 mg/kg Intraperitoneal LD ₅₀ (rat): 116 mg/kg Subcutaneous LD ₅₀ (rat): 2200 mg/		
	Chlorocresol:	Intravenous LD ₅₀ (mouse): 70 mg/k Subcutaneous LD ₅₀ (mouse): 360 n	g	
	Ethanol:	Intravenous LD50 (rat): 1440 mg/kg Intraperitoneal LD $_{50}$ (rat): 3.6 mg/kg Subcutaneous LD $_{50}$ (mouse): 8285		
Chronic Effects	5			

- **Short term:** 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.
- **Long term:** Prolonged exposure to ethanol may cause damage to the liver and cause scarring. It may also worsen damage caused by other agents.

Reproductive Toxicity:

Neither the product nor its ingredients are considered 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.

Carcinogenicity:

There are no reports of the carcinogenicity of the product in animals or humans in the published literature or pharmacovigilance data, and no pre-neoplastic lesions were observed in repeat dose toxicity or target species safety studies.

Ingredient	National Toxicology Program (NTP) 14 th Report on Carcinogens (2016)	International Agency for Research on Cancer (IARC) Monographs	29 CFR 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA)
Alfaxalone	Not listed	Not listed	Not listed
Ethanol	Not listed	Not listed	Not listed
Chlorocresol	Not listed	Not listed	Not listed

Section 12: ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined for product.

Alfaxalone:	No data available.
Ethanol:	LC₅₀ (96 hr) (fish): 11 mg/L
	EC ₅₀ (48 hr) (crustacea): 2 mg/L
	EC ₅₀ (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



Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS Document: SDS-US008				
Rev: 1.1 PAGE 9 OF				PAGE 9 OF 11
Status: Current	Issue Date: 21-Jul-2023	Effective Date: 21-Jul-2023	Review Date: 20-Jul-2028	

 EC_{50} (48 hr) (crustacea): 1.5 mg/L EC_{50} (72 hr) (algae / aquatic plants): 4.2 mg/L NOEC (672 hr) (fish): 0.15 mg/L

Persistence and degradability: 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. Place waste in an appropriately labelled, sealed container for disposal. Further, disposal should be performed in accordance with federal, state and local regulatory requirements. Prevent waste from entering drains, waterways or sewers.

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.
- US DOT: Not Regulated. 49CFR173.150(e)(2): An aqueous solution containing 24 % 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
NDC Number:	54771-6696
FDA Information:	NADA 141-342
Harmonised Tariff Code:	3004.90.9203



Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS			Document: SDS-US008	
			Rev: 1.1	PAGE 10 OF 11
Status: Current	Issue Date: 21-Jul-2023	Effective Date: 21-Jul-2023	Review Date: 20-Jul-2028	

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

Section 16: OTHER INFORMATION

Legend:	
AAPCC	American Association of Poison Control Centres
ACGIH	American Conference of Governmental Industrial Hygienists
BCF	Bromochlorodifluoromethane (fire extinguishing media)
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
EC ₅₀	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
EPA	US Environmental Protection Agency
FDA	Food and Drug Administration, US Dept. of Health and Human Services
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
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
LC ₅₀	The median lethal concentration, being a statistically derived concentration of a substance that can be
L O 50	expected to cause death in 50% of animals
LD ₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to
2230	cause death in 50% of animals
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
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



Title: ALFAXAN MULTIDOSE (ALFAXALONE 10 MG/ML) ZOETIS			Document: SDS-US008		
				Rev: 1.1	PAGE 11 OF 11
Status: Co	Current Issue Date: 21-Jul-2023 Effective Date: 21-Jul-2023 Review Date: 20-Jul-202		20-Jul-2028		
			-		
TEEL-1 TEEL-2	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			c, nonsensory ion of exposure tion, including ealth effects or	
TEEL-3	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			tion, including	
TSCA	Toxic Substance Control Act				
TLV	Threshol	d Limit Value			
TWA	Time-Weighted Average. The average exposure over a specified period, usually a nominal eight hours			ght hours	

References:

VSD

National Toxicology Program (NTP) 14th Report on Carcinogens (online). Available at: <u>https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf</u>, accessed 20 Jan 2020.

International Agency for Research on Cancer (IARC) Monographs (online) Available at: <u>https://monographs.iarc.fr/list-of-classifications</u>, last updated 12th Dec 2019.

29 CFR 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA), (online) Available at: <u>https://www.ecfr.gov/cgi-bin/text-</u>

 $\underline{idx?SID=3820a5c408e622a700e481f46eb4a153\&mc=true\&node=pt29.6.1910\&rgn=div5}$ current as of 16th Jan 2020.

Veterinary Substances Data Base (VSDB) Alphaxalone (online) Available at: <u>http://sitem.herts.ac.uk/aeru/vsdb/Reports/1759.htm</u> last updated 3rd June 2019.

ChemIDplus https://chem.nlm.nih.gov/chemidplus/

Veterinary Substances Database

The format follows that prescribed in the Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)) revised in 2012.

Revision History:

Date of Revision	Reason
19 June 2023	New SDS for Zoetis distributed products
21 July 2023	Addition of Zoetis SAP codes to Section1

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 whosoever 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