

SAFETY DATA SHEET



1. Identification

Product identifier	Antirobe (Clindamycin Hydrochloride) Aquadrops
Other means of identification	
Synonyms	Antirobe® * Antirobe Aquadrops® * Antirobe Aquadrops Liquid * Antirobe drops * Antirobe Aquadrops Antibiotic Liquid * Clindamycin hydrochloride solution
Recommended use of the chemical and restrictions on use	
Recommended use	Veterinary product used as antibiotic agent
Restrictions on use	Not for human use
Details of manufacturer or importer	
Company Name (AU)	Zoetis Australia Pty Ltd ABN 94 156 476 425 Level 6, 5 Rider Boulevard Rhodes NSW 2138 AUSTRALIA
Tel	1800 814 883
Fax	(02) 8876 0444
Email	australia.animalhealth@zoetis.com
Emergency Phone	1800 814 883 (all hours)
Police and Fire Brigade	Dial 000
If ineffective	Dial Poisons Information Centre (13 1126 from anywhere in Australia)

2. Hazard(s) identification

Classification of the hazardous chemical

Physical hazards	Flammable liquids	Category 3
Health hazards	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3

Label elements, including precautionary statements

Hazard symbol(s)



Flame

Exclamation mark

Signal word

Warning

Hazard statement(s)

Flammable liquid and vapour. May cause an allergic skin reaction. Causes serious eye irritation. Harmful to aquatic life.

Precautionary statement(s)

Prevention

Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Avoid breathing mist or vapour. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/eye protection/face protection.

Response

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. IF 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. Wash contaminated clothing before reuse. In case of fire: Use appropriate media for extinction.

Storage

Store in a well-ventilated place. Keep cool.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Other hazards which do not result in classification None known.

Supplemental information Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients (%)
Water	7732-18-5	>50
Ethanol	64-17-5	8.64
Clindamycin Hydrochloride	21462-39-5	2-3

4. First-aid measures

Description of necessary first aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.
Skin contact	Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Personal protection for first-aid responders For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

Symptoms caused by exposure Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause an allergic skin reaction. Dermatitis. Rash. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Medical attention and special treatment Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed. Vapours may form explosive mixtures with air. Vapours may travel considerable distance to a source of ignition and flash back.

Special protective equipment and precautions for fire fighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Hazchem Code None.

General fire hazards Flammable liquid and vapour.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Ensure adequate ventilation. Keep unnecessary personnel away. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Ventilate the contaminated area. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protection recommended in Section 8 of the SDS.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil etc) away from spilled material. Take precautionary measures against static discharge. Use only non-sparking tools. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling Flammable Liquid. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Use this product with adequate ventilation. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store locked up. Store in a well-ventilated place. Store in a cool, dry place out of direct sunlight. Do not handle or store near an open flame, heat or other sources of ignition. Store in original tightly closed container. Keep away from food, drink and animal feeding stuffs. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

Zoetis

Components	Type	Value
Clindamycin Hydrochloride (CAS 21462-39-5)	TWA	100 µg/m ³

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1880 mg/m ³ 1000 ppm

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1880 mg/m ³ 1000 ppm

US. ACGIH Threshold Limit Values

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1920 mg/m ³ 1000 ppm

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	960 mg/m ³ 500 ppm

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Ensure adequate ventilation, especially in confined areas. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate. Provide eyewash station.

Individual protection measures, for example personal protective equipment (PPE)

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Wear protective gloves.

Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Chemical respirator with organic vapour cartridge, full facepiece, dust and mist filter.

Thermal hazards Not applicable.

Hygiene measures When using do not smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point 52.0 °C (125.6 °F)

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Explosive limit - lower (%) 3.3 % v/v (Ethanol)

Explosive limit – upper (%) 19 % v/v (Ethanol)

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.
Decomposition temperature Not available.
Viscosity Not available.

Other physical and chemical parameters

Explosive properties Not explosive.
Oxidising properties Not oxidising.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability Material is stable under normal conditions.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid Contact with incompatible materials. Sunlight. Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point.
Incompatible materials Strong oxidising agents.
Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.

11. Toxicological information

Information on possible routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact May cause an allergic skin reaction.
 Clindamycin Hydrochloride Species: Rat
 Severity: No effect

Eye contact Causes serious eye irritation.
 Clindamycin Hydrochloride Species: Rabbit
 Severity: Moderate

Ethanol Species: Rabbit
 Severity: Severe

Clindamycin Hydrochloride Species: Rat
 Severity: No effect

Ingestion Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to exposure Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause an allergic skin reaction. Dermatitis. Rash. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Acute toxicity May cause an allergic skin reaction.

Components	Species	Test results
Clindamycin Hydrochloride (CAS 21462-39-5)		
Acute		
Intravenous		
LD50	Mouse	143 mg/kg
Oral		
LD50	Mouse	1479 mg/kg
	Rat	2618 mg/kg
Other		
LD50	Rat	279 mg/kg [Sub-tenon injection (eye)]
Subcutaneous		
LD50	Rat	891 mg/kg

Components	Species	Test results
<u>Chronic</u>		
Oral		
LOAEL	Dog	600 mg/kg/day, 6 months [Target organ: Gastrointestinal system]
NOAEL	Rat	600 mg/kg/day, 6 months [No effects at maximum dose] 300 mg/kg/day, 1 years [No effects at maximum dose]
<u>Subacute</u>		
Oral		
NOAEL	Dog	300 mg/kg/day, 1 months [No effects at maximum dose]
Ethanol (CAS 64-17-5)		
<u>Acute</u>		
Inhalation		
LC50	Mouse	39 g/m ³ , 4 hours
	Rat	20000 ppm, 10 hours
Oral		
LD50	Mouse	3450 g/m ³ Intravitreal (eye)
	Rat	7060 mg/kg
Other		
LC50	Rat	20000 mg/l Intravitreal (eye)
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Corrosivity		
Clindamycin Hydrochloride	Species: Rat	Severity: No effect
Serious eye damage/irritation	Causes serious eye irritation.	
Eye contact		
Clindamycin Hydrochloride	Species: Rabbit	Severity: Moderate
Ethanol	Species: Rabbit	Severity: Severe
Clindamycin Hydrochloride	Species: Rat	Severity: No effect
Respiratory or skin sensitisation		
Respiratory sensitisation	Not a respiratory sensitizer.	
Skin sensitisation	May cause an allergic skin reaction.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Mutagenicity		
Clindamycin Hydrochloride	Bacterial Mutagenicity (Ames)	Result: negative Species: Salmonella
	In Vitro Micronucleus	Result: negative
Carcinogenicity	Due to partial or complete lack of data the classification is not possible. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage.	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	

Developmental effects

Clindamycin Hydrochloride

250 mg/kg/day Embryo / Fetal Development, Not Teratogenic
 Result: NOAEL
 Species: Rat
 Organ: Subcutaneous

600 mg/kg/day Embryo / Fetal Development, Not Teratogenic
 Result: NOAEL
 Species: Mouse
 Organ: Oral

600 mg/kg/day Embryo / Fetal Development, Not Teratogenic
 Result: NOAEL
 Species: Rat
 Organ: Oral

Reproductivity

Clindamycin Hydrochloride

300 mg/kg/day Reproductive & Fertility, Fertility
 Result: NOAEL
 Species: Rat
 Organ: Oral

Specific target organ toxicity - single exposure

Not classified.

Specific target organ toxicity - repeated exposure

Due to partial or complete lack of data the classification is not possible. This product may affect Blood. Gastrointestinal tract. Liver. through prolonged or repeated exposure.

Aspiration hazard

Not an aspiration hazard.

Chronic effects

Prolonged inhalation may be harmful.

Other information

Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and congenital malformations. However, occupational handling of this product is not expected to result in relevant exposures.

12. Ecological information**Ecotoxicity**

Harmful to aquatic life. Avoid release to the environment.

Components**Species****Test results**

Ethanol (CAS 64-17-5)

LC50	Fingerling Trout	11200 mg/l, 24 Hours
	Oncorhynchus mykiss (Rainbow Trout)	12900 mg/l, 96 Hours
	Pimephales promelas (Fathead Minnow)	14200 mg/l, 96 Hours

Aquatic

Crustacea	EC50	Water flea (Daphnia magna)	7.7 - 11.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	> 100 mg/l, 96 hours

Persistence and degradability

This material is readily biodegradable.

Bioaccumulative potential

Not expected to bioaccumulate.

Mobility in soil

No data available for this product. The product is soluble in water.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal methods	Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

ADG	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.
General information	Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations. Aqueous products containing alcohol at 24 percent or less are not subject to the requirements of the EU ADR, IATA, or IMDG. They are similarly exempt from US DOT requirements provided that they contain no less than 50 percent water.

15. Regulatory information

Safety, health and environmental regulations	
National regulations	This Safety Data Sheet was prepared in accordance with Australia Model Code of Practice for the preparation of Safety Data Sheets for Hazardous Chemicals (23/12/2011). Poison Schedule (Product) - Schedule 4 APVMA Registration Number: 38720 This SDS replaces version: Issued October 2016
Australia Medicines & Poisons Appendix B	ALCOHOL, DEHYDRATED (CAS 64-17-5)
Australia National Pollutant Inventory (NPI): Threshold quantity	10 TONNES/YR Threshold Category: 1
High Volume Industrial Chemicals (HVIC)	
Ethanol (CAS 64-17-5)	10000 - 99999 TONNES See the regulation for additional information.
Water (CAS 7732-18-5)	1000 - 9999 TONNES See the regulation for additional information.
Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)	Not listed.
National Pollutant Inventory (NPI) substance reporting list	Not listed.
Prohibited Carcinogenic Substances	Not regulated.
Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)	Not listed.

Restricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information**Issue date** 23-April-2017**Disclaimer** Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.**Revision information** Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Material Transportation Information
GHS: Classification