

SAFETY DATA SHEET



Revision date: 28-Oct-2013

Version: 4.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Antirobe (Clindamycin Hydrochloride) Aquadrops

Trade Name: Antirobe

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as antibiotic agent

Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.

100 Campus Drive, P.O. Box 651

Florham Park, New Jersey 07932 (USA)

Rocky Mountain Poison Control Center Phone: 1-866-531-8896

Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.

Mercuriusstraat 20

1930 Zaventem

Belgium

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Liquid

Classification of the Substance or Mixture

GHS - Classification

Skin Sensitization: Category 1

Flammable liquids- Category 3

EU Classification:

EU Indication of danger: Flammable
Irritant

EU Symbol: Xi

EU Risk Phrases:

R10 - Flammable.

R43 - May cause sensitization by skin contact.

Label Elements

Signal Word: Warning

Hazard Statements: H226 - Flammable liquid and vapor

H317 - May cause an allergic skin reaction

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Precautionary Statements:

- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P233 - Keep container tightly closed
- P240 - Ground/Bond container and receiving equipment
- P241 - Use explosion-proof electrical/ventilating/lighting/equipment
- P242 - Use only non-sparking tools
- P243 - Take precautionary measures against static discharge
- P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P370 + P378 - In case of fire: Use water, dry chemical, foam or CO2 for extinction
- P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
- P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
- P362 - Take off contaminated clothing and wash before reuse
- P403 + P235 - Store in a well-ventilated place. Keep cool
- P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term:

May cause eye and skin irritation. Not acutely toxic. (based on components) Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication. Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Long Term:

Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and congenital malformations.

Known Clinical Effects:

Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may occur. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Clindamycin Hydrochloride	21462-39-5	244-398-6	Xi;R36-43	Acute Tox 5 (H303) Eye Irrit. 2A (H319) Skin Sens.1 (H317)	2 - 3
Ethanol	64-17-5	200-578-6	F; R11	Flam. Liq. 2 (H225)	8.64

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water	7732-18-5	231-791-2	Not Listed	Not Listed	>50

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Flammable liquid and vapor. Vapors will form flammable or explosive mixtures with air at room temperature. Vapors are heavier than air and may travel along surfaces to remote ignition sources and flash back.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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6. ACCIDENTAL RELEASE MEASURES

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Eliminate all sources of ignition and ventilate area using explosion-proof equipment.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Flammable Liquid. Keep away from heat, sparks, flame and all other sources of ignition. Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Keep away from heat, sparks, flame, and other sources of ignition.

Storage Temperature: Store as directed by product packaging.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Clindamycin Hydrochloride

Zoetis OEL TWA 8-hr 100µg/m³

Ethanol

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m ³
Austria OEL - MAKs	1000 ppm
	1900 mg/m ³
Belgium OEL - TWA	1000 ppm
	1907 mg/m ³
Bulgaria OEL - TWA	1000.0 mg/m ³
Czech Republic OEL - TWA	1000 mg/m ³
Denmark OEL - TWA	1000 ppm
	1900 mg/m ³
Estonia OEL - TWA	500 ppm
	1000 mg/m ³
Finland OEL - TWA	1000 ppm
	1900 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

France OEL - TWA	1000 ppm 1900 mg/m ³
Germany - TRGS 900 - TWAs	500 ppm 960 mg/m ³
Germany (DFG) - MAK	500 ppm 960 mg/m ³
Greece OEL - TWA	1000 ppm 1900 mg/m ³
Hungary OEL - TWA	1900 mg/m ³
Latvia OEL - TWA	1000 mg/m ³
Lithuania OEL - TWA	500 ppm 1000 mg/m ³
Netherlands OEL - TWA	260 mg/m ³
Vietnam OEL - TWAs	1000 mg/m ³
OSHA - Final PELs - TWAs:	1000 ppm 1900 mg/m ³
Poland OEL - TWA	1900 mg/m ³
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm 1900 mg/m ³
Slovakia OEL - TWA	500 ppm 960 mg/m ³
Slovenia OEL - TWA	1000 ppm 1900 mg/m ³
Spain OEL - TWA	1000 ppm 1910 mg/m ³
Sweden OEL - TWAs	500 ppm 1000 mg/m ³
Switzerland OEL -TWAs	500 ppm 960 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	No data available.
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)	No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	52
Upper Explosive Limits (Liquid) (% by Vol.):	3.3
Lower Explosive Limits (Liquid) (% by Vol.):	19

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	None
Conditions to Avoid:	Keep away from heat, spark, flames and all other sources of ignition.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Hazardous combustion products may include oxides of carbon and products of chlorine.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Clindamycin Hydrochloride

Rat	Oral	LD 50	2618 mg/kg
Rat	Sub-tenon injection (eye)	LD 50	279mg/kg
Rat	Subcutaneous	LD 50	891mg/kg

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11. TOXICOLOGICAL INFORMATION

Mouse Oral LD 50 1479mg/kg
Mouse Intravenous LD 50 143mg/kg

Ethanol

Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060mg/kg
Mouse Inhalation LC50 4h 39g/m³
Rat Inhalation LC50 10h 20,000ppm

Irritation / Sensitization: (Study Type, Species, Severity)

Clindamycin Hydrochloride

Eye Irritation Rat No effect
Eye Irritation Rabbit Moderate
Skin Irritation Rat No effect

Ethanol

Eye Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Clindamycin Hydrochloride

6 Month(s) Rat Oral 600 mg/kg/day NOEL No effects at maximum dose
6 Month(s) Dog Oral 600 mg/kg/day LOAEL Gastrointestinal system
1 Year(s) Rat Oral 300 mg/kg/day NOEL No effects at maximum dose
1 Month(s) Dog Oral 300 mg/kg/day NOEL No effects at maximum dose

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Clindamycin Hydrochloride

Reproductive & Fertility Rat Oral 300 mg/kg/day NOEL Fertility
Embryo / Fetal Development Mouse Oral 600 mg/kg/day NOEL Not Teratogenic
Embryo / Fetal Development Rat Oral 600 mg/kg/day NOEL Not Teratogenic
Embryo / Fetal Development Rat Subcutaneous 250 mg/kg/day NOEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Clindamycin Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Micronucleus Negative

Carcinogen Status:

Carcinogenicity of the mixture has not been determined. Consumption of alcoholic beverages is considered carcinogenic to humans (Group 1) by IARC, though ethanol itself has not been classified by this agency. No other components are listed as carcinogens by IARC, US OSHA or NTP.

Ethanol

IARC: Group 1 (Carcinogenic to Humans)
OSHA: Listed

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12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ethanol

Fingerling Trout	NPDES	LC50	24 Hours	11,200 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	NPDES	LC50	96 Hours	12,900 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	NPDES	LC50	96 Hours	14,200 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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.

14. TRANSPORT INFORMATION

The following refers to all categories of classifications unless specified below.

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/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

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15. REGULATORY INFORMATION

WHMIS hazard class:

Class B, Division 3

Class D, Division 2, Subdivision B



Clindamycin Hydrochloride

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

EU EINECS/ELINCS List

244-398-6

Ethanol

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

carcinogen initial date 4/29/11 in alcoholic beverages
developmental toxicity initial date 10/1/87 in alcoholic beverages

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

EU EINECS/ELINCS List

200-578-6

Water

CERCLA/SARA 313 Emission reporting

Not Listed

California Proposition 65

Not Listed

Inventory - United States TSCA - Sect. 8(b)

Present

Australia (AICS):

Present

REACH - Annex IV - Exemptions from the obligations of Register:

Present

EU EINECS/ELINCS List

231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor
Acute toxicity, oral-Cat.5; H303 - May be harmful if swallowed
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

F - Highly flammable

Xi - Irritant

R11 - Highly flammable.

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

Data Sources:

The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

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Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical
and Chemical Properties. Updated Section 14 - Transport Information.

Prepared by:

Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material 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.

End of Safety Data Sheet