SAFETY DATA SHEET

1. Identification

Product identifier **Antirobe (Clindamycin Hydrochloride) Capsules - 25 mg**

Other means of identification

Synonyms Antirobe® * Antirobe Capsule * Antirobe Antibiotic Capsules * Clindamycin hydrochloride capsules * Antirobe Antibiotic Capsules 25mg

Recommended use Veterinary product used as antibiotic agent

Recommended restrictions Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (USA) Zoetis Inc.
10 Sylvan Way
Parsippany, New Jersey 07054 (USA)

Rocky Mountain Poison and Drug Center 1-866-531-8896

Product Support/Technical Services 1-888-963-8471

Emergency telephone numbers CHEMTREC (24 hours): 1-800-424-9300

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

Company Name (CA) Zoetis Canada Inc.
16740 Trans-Canada Highway
Kirkland, Quebec, H9H 4M7

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

Contact E-Mail productsupport@zoetis.com

Product Support 1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx

Supplier Not available.

2. Hazard identification

Physical hazards Not classified.

Health hazards

Serious eye damage/eye irritation	Category 2A
Sensitization, skin	Category 1

Environmental hazards Not classified.

Label elements

Signal word Warning

Hazard statement Causes serious eye irritation. May cause an allergic skin reaction.

Precautionary statement

Prevention Avoid breathing dust/fume/gas/mist/vapours/spray. Wash thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wear eye protection/face protection. Wear protective gloves.

Response	IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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.
Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Supplemental information	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.
Other hazards	None known.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Clindamycin Hydrochloride		21462-39-5	< 15
Talc (non-asbestiform)		14807-96-6	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments	*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. 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. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.
Most important symptoms/effects, acute and delayed	Causes serious 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.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	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.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.
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.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	During processing, dust may form explosive mixture in air. Fine particles (such as mists) may fuel fires/explosions.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Avoid dust formation. Ventilate the contaminated area. Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

Avoid contact with eyes, skin, and clothing. Ensure adequate ventilation. Avoid dust formation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Ground/bond container and equipment. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean contaminated surface thoroughly. Prevent release to the environment.

Small Spills: Wipe up with a damp cloth and place in container for disposal. 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.

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.

7. Handling and storage

Precautions for safe handling

Wear personal protective equipment. Avoid contact with skin. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wash contaminated clothing before reuse. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Use care in handling/storage. Store in a well-ventilated place. @ 15-30°C (59-86°F).. Protect from sunlight. Keep away from heat, sparks and open flame. Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components	Type	Value
Clindamycin Hydrochloride (CAS 21462-39-5)	TWA	100 µg/m³

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m3	Respirable particles.

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 fibers/cc	
		2 mg/m3	Respirable fraction.

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m3	Respirable dust.

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	15 minute	6 mg/m3	Respirable fraction.
		20 mg/m3	Inhalable fraction.
	8 hour	2 mg/m3	Respirable fraction.

Biological limit values No biological exposure limits noted for the ingredient(s).

Control banding approach Not available.

Appropriate engineering controls 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.

Individual protection measures, such as personal protective equipment

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. 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. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely.

Thermal hazards Not applicable.

General hygiene considerations 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 Capsule

Physical state Solid.

Form Solid.

Colour White / Yellow

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 Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
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 information	
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	Heat, flames and sparks. Contact with incompatible materials. Protect from sunlight. Avoid dispersion as a dust cloud.
Incompatible materials	Strong oxidising agents.
Hazardous decomposition products	Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. May include hydrogen chloride.

11. Toxicological information

Information on likely 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
		Species: Rat Severity: No effect
Ingestion	May cause discomfort if swallowed.	
Symptoms related to the physical, chemical and toxicological characteristics	Causes serious 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.	

Information on toxicological effects

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

Components	Species	Test Results
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
Chronic		
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]
Subacute		
Oral		
NOAEL	Dog	300 mg/kg/day, 1 months [No effects at maximum dose]
Talc (non-asbestiform) (CAS 14807-96-6)		
Acute		
Oral		
LD50	Rat	> 1600 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Clindamycin Hydrochloride
Species: Rat
Severity: No effect

Serious eye damage/eye irritation Causes serious eye irritation.

Eye contact

Clindamycin Hydrochloride
Species: Rabbit
Severity: Moderate

Species: Rat
Severity: No effect

Respiratory or skin sensitisation

Respiratory sensitisation Not a respiratory sensitiser.

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 Based on available data, the classification criteria are not met. Industrial use - Inhalation: Not classifiable as to carcinogenicity to humans.

ACGIH Carcinogens

Talc (non-asbestiform) (CAS 14807-96-6)
A1 Confirmed human carcinogen.
A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Talc (non-asbestiform) (CAS 14807-96-6)	Confirmed human carcinogen. Not classifiable as a human carcinogen.

Canada - Quebec OELs: Carcinogen category

Talc (non-asbestiform) (CAS 14807-96-6)	Detected carcinogenic effect in humans.

IARC Monographs. Overall Evaluation of Carcinogenicity

Talc (non-asbestiform) (CAS 14807-96-6)	2B Possibly carcinogenic to humans. 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects. Based on available data, the classification criteria are not met.

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. Prolonged exposure may cause chronic effects.

Further 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.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

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 instructions Avoid release to the environment. 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code	None known.
Waste from residues / unused products	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.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

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 applicable.

15. Regulatory information

Canadian regulations

This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

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 Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
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
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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	This document has undergone significant changes and should be reviewed in its entirety.