

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 & Drug Safety	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	CHEMTREC (24 hours): 1-800-424-9300
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	May cause an allergic skin reaction. Causes serious eye irritation.
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 water. 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. Take off contaminated clothing and wash it before reuse.
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. Get medical attention if irritation develops and persists. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse.
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 unconscious person.
Most important symptoms/effects, acute and delayed	Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Causes serious eye irritation. 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. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. For personal protection, see section 8 of the SDS. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	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	No unusual fire or explosion hazards noted. 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. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not breathe dust. Avoid dust formation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

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

Large Spills: Stop the flow of material, if this is without risk. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean contaminated surface thoroughly.

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. Prevent release to the environment.

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

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

Conditions for safe storage, including any incompatibilities

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

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components

Clindamycin Hydrochloride
(CAS 21462-39-5)

Type

TWA

Value

100 µg/m³

US. ACGIH Threshold Limit Values (TLV)

Components

Talc (non-asbestiform)
(CAS 14807-96-6)

Type

TWA

Value

2 mg/m³

Form

Respirable fraction.

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

Components

Talc (non-asbestiform)
(CAS 14807-96-6)

Type

TWA

Value

2 mg/m³

Form

Respirable particles.

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

Components

Talc (non-asbestiform)
(CAS 14807-96-6)

Type

TWA

Value

2 mg/m³

Form

Respirable.

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

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m ³	Respirable fraction.

Canada. New Brunswick OELs: Threshold Limit Values (TLVs) Based on the 1991 and 1997 ACGIH TLVs and BEIs Publication (New Brunswick Regulation 91-191)

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m ³	Respirable fibers.

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

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 fibers/cc	
		2 mg/m ³	Respirable fraction.

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

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m ³	Respirable dust.

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

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	15 minute	6 mg/m ³	Respirable fraction.
		20 mg/m ³	Inhalable fraction.
	8 hour	2 mg/m ³	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. Provide eyewash station.

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

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

Respiratory protection

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

Physical state Solid.

Form Solid.

Colour White / Yellow

Odour Not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Causes serious eye irritation. 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)		
<u>Acute</u>		
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
<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]

Talc (non-asbestiform) (CAS 14807-96-6)

Acute**Oral**

LD50	Rat	> 1600 mg/kg
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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**Canada - Alberta OELs: Irritant**

Talc (non-asbestiform) (CAS 14807-96-6)	Irritant
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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	Industrial use - Inhalation: Not classifiable as to carcinogenicity to humans.
ACGIH Carcinogens Talc (non-asbestiform) (CAS 14807-96-6)	A4 Not classifiable as a human carcinogen.
Canada - Manitoba OELs: carcinogenicity Talc (non-asbestiform) (CAS 14807-96-6)	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.
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	Avoid release to the environment. 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.
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. Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company. 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
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
Revision date	27-January-2025
Version No.	03
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.