

SAFETY DATA SHEET



1. Identification

Product identifier	Antirobe (Clindamycin Hydrochloride) Capsules - 75, 150, and 300 mg	
Other means of identification		
Synonyms	Antirobe® * Antirobe Capsule * Antirobe Antibiotic Capsules * Clindamycin hydrochloride capsules	
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	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
Environmental hazards	Not classified.	

Label elements, including precautionary statements

Hazard symbol(s)



Exclamation mark

Signal word

Warning

Hazard statement(s)

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

Precautionary statement(s)

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. 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.

Storage

Store away from incompatible materials.

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 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 (%)
Clindamycin Hydrochloride	21462-39-5	29.4 - 56
Corn Starch	9005-25-8	*
Magnesium stearate	557-04-0	*
Talc (non-asbestiform)	14807-96-6	*

Composition comments * Non-hazardous Ingredients

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). 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 fire fighters 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.

Hazchem Code None.

General fire hazards During processing, dust may form explosive mixture in air. Fine particles (such as mists) may fuel fires/explosions.

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 Ensure adequate ventilation. Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Keep unnecessary personnel away. Avoid dust formation. Ventilate the contaminated area. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not breathe dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see 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 Ensure adequate ventilation. Avoid dust formation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Prevent product from entering drains. Avoid contact with eyes, skin, and clothing.

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.

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 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	Form
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m ³	Inhalable dust.
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inhalable dust.
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2.5 mg/m ³	

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

Components	Type	Value	Form
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m ³	Inspirable dust.
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	Inspirable dust.
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2.5 mg/m ³	

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m ³	
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m ³	

US. ACGIH Threshold Limit Values

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

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Corn Starch (CAS 9005-25-8)	TWA	4 mg/m ³	Respirable.
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	10 mg/m ³ 1 mg/m ³	Inhalable Respirable dust.

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

Components	Type	Value	Form
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	4 mg/m ³ 0.3 mg/m ³	Inhalable dust. Respirable dust.

Biological limit values

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

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, 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. 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.

Hygiene measures

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

75 mg - Green, 150 mg - Light blue and green (or blue and white), 300 mg - Blue

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

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
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 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 Heat, flames and sparks. Contact with incompatible materials. Avoid dispersion as a dust cloud. Protect from sunlight.

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 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

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)		
<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]
Magnesium stearate (CAS 557-04-0)		
<u>Acute</u>		
Inhalation		
LC50	Rat	> 2000 mg/m ³
Oral		
LD50	Rat	> 2000 mg/kg
Talc (non-asbestiform) (CAS 14807-96-6)		
<u>Acute</u>		
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/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 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

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

ACGIH Carcinogens

Corn Starch (CAS 9005-25-8)

A4 Not classifiable as a human carcinogen.

Magnesium stearate (CAS 557-04-0)

A4 Not classifiable as a human carcinogen.

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

A4 Not classifiable as a human carcinogen.

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.

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.

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 for this product.

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. 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).
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 applicable.

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: 38718 (75 mg) APVMA Registration Number: 38717 (150 mg) APVMA Registration Number: Not registered (300 mg) This SDS replaces version: Issued October 2016
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High Volume Industrial Chemicals (HVIC)

Corn Starch (CAS 9005-25-8)	1000 - 9999 TONNES See the regulation for additional information.
Talc (non-asbestiform) (CAS 14807-96-6)	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

Talc (non-asbestiform) (CAS 14807-96-6)	2000 TONNES/YR Threshold Category: 2B 400 TONNES/YR Threshold Category: 2A
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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

Composition / Information on Ingredients: Ingredients
GHS: Classification