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

* Antirobe Antibiotic Capsules 75mg * Antirobe Antibiotic Capsules 150mg

Recommended useVeterinary 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.

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IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical Response

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.

Store away from incompatible materials. Storage

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

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 | 29.4 - 56 |
| | 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

Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen Inhalation

may be necessary.

Remove contaminated clothing immediately and wash skin with soap and water. In case of Skin contact

eczema or other skin disorders: Seek medical attention and take along these instructions.

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.

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

Eye contact

Ingestion

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

General information

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

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

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

Use water spray to cool unopened containers.

equipment/instructions 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

Methods and materials for containment and cleaning up

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.

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.

Environmental precautions

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. 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 | Туре | Value | |
|--|-------------------------------|------------------------------|-------------------------|
| Clindamycin Hydrochloride (CAS 21462-39-5) | TWA | 100 μg/m³ | |
| US. ACGIH Threshold Limit Values | 3 | | |
| Components | Туре | Value | Form |
| Talc (non-asbestiform) (CAS 14807-96-6) | TWA | 2 mg/m3 | Respirable fraction. |
| Canada. Alberta OELs (Occupation | nal Health & Safety Code, Sch | nedule 1, Table 2) | |
| Components | Туре | Value | Form |
| Talc (non-asbestiform) (CAS 14807-96-6) | TWA | 2 mg/m3 | Respirable particles. |
| Canada. British Columbia OELs. (0 Safety Regulation 296/97, as amen | | s for Chemical Substances, 0 | Occupational Health and |
| Components | Туре | 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 | Туре | 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) **Form** Components Value Type

Talc (non-asbestiform) TWA 2 fibers/cc

(CAS 14807-96-6)

2 ma/m3 Respirable fraction.

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

Components Value **Form Type** Talc (non-asbestiform) TWA 2 mg/m3 Respirable dust.

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

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

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

Not available. Control banding approach

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

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

Skin protection

(CAS 14807-96-6)

Hand protection Wear protective gloves.

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable Other

coveralls, etc.) in both production and laboratory areas.

No personal respiratory protective equipment normally required. If engineering controls do not Respiratory protection

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.

Not applicable. Thermal hazards

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

Capsule **Appearance** Solid. **Physical state Form** Solid.

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

Odour Not available. Not available. **Odour threshold** Not available. Ha Melting point/freezing point Not available. Initial boiling point and boiling Not available.

range

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Explosive limit - lower (%) Not available.

Explosive limit - upper Not available.

(%)

Vapour pressureNot available.Vapour densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive. **Oxidising properties** Not oxidising.

10. Stability and reactivity

ReactivityThe 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 | |
| <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 1- | 4807-96-6) | | |

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

Acute Oral

LD50 > 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.

No data available to indicate product or any components present at greater than 0.1% are Germ cell mutagenicity

mutagenic or genotoxic.

Mutagenicity

Clindamycin Hydrochloride **Bacterial Mutagenicity (Ames)**

Result: Negative Species: Salmonella

In Vitro Micronucleus Result: Negative

Based on available data, the classification criteria are not met. Industrial use -Carcinogenicity

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.

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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.

7/9

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

Not applicable.

the IBC Code

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

| Inventory name | On inventory (yes/no)* |
|--|---|
| Australian Inventory of Industrial Chemicals (AICIS) | No |
| Domestic Substances List (DSL) | Yes |
| Non-Domestic Substances List (NDSL) | No |
| Inventory of Existing Chemical Substances in China (IECSC) | No |
| European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes |
| European List of Notified Chemical Substances (ELINCS) | No |
| Inventory of Existing and New Chemical Substances (ENCS) | Yes |
| Existing Chemicals List (ECL) | No |
| New Zealand Inventory | Yes |
| Philippine Inventory of Chemicals and Chemical Substances (PICCS) | Yes |
| Taiwan Chemical Substance Inventory (TCSI) | Yes |
| | Australian Inventory of Industrial Chemicals (AICIS) Domestic Substances List (DSL) Non-Domestic Substances List (NDSL) Inventory of Existing Chemical Substances in China (IECSC) European Inventory of Existing Commercial Chemical Substances (EINECS) European List of Notified Chemical Substances (ELINCS) Inventory of Existing and New Chemical Substances (ENCS) Existing Chemicals List (ECL) New Zealand Inventory Philippine Inventory of Chemicals and Chemical Substances (PICCS) |

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United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

*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 date23-April-2017Revision date20-May-2022

Version No. 02

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 informationThis document has undergone significant changes and should be reviewed in its entirety.

Material name: Antirobe (Clindamycin Hydrochloride) Capsules - 75, 150, and 300 mg