# 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 use** Veterinary product used as antibiotic agent

**Recommended restrictions** Not for human use

**Manufacturer/Importer/Supplier/Distributor information**

**Company Name (US)** 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 (EU)** Zoetis Belgium S.A.
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

**Telephone:** +32 10 808080

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

**Contact E-Mail** VMIPSrecords@zoetis.com

## 2. Hazard(s) identification

| | | |
|---|---|---|
| **Physical hazards** | Not classified. | |
| **Health hazards** | Serious eye damage/eye irritation | Category 2A |
| | Sensitization, skin | Category 1 |
| **Environmental hazards** | Not classified. | |
| **OSHA defined 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/vapors/spray. Wash thoroughly after handling. Contaminated work clothing must 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. 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.

| | |
|---|---|
| **Hazard(s) not otherwise classified (HNOC)** | 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

**Mixtures**

| Chemical name | Common name and synonyms | CAS number | % |
|---|---|---|---|
| Clindamycin Hydrochloride | | # | 29.4 - 56 |
| Talc (non-asbestiform) | | 14807-96-6 | * |

**Composition comments**

#: CAS 21462-39-5 or CAS 58207-19-5
* In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## 4. First-aid measures

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|---|---|
| **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 center 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** | 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. For waste disposal, see section 13 of the SDS. 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.

**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 feedingstuffs. 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**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**Zoetis**

| Components | Type | Value |
|---|---|---|
| Clindamycin Hydrochloride | TWA | 100 µg/m³ |

**US. OSHA Table Z-3 (29 CFR 1910.1000)**

| Components | Type | Value | Form |
|---|---|---|---|
| Talc (non-asbestiform) (CAS 14807-96-6) | TWA | 0.1 mg/m3 | Respirable. |
| | | 20 mppcf | |
| | | 2.4 mppcf | Respirable. |

**US. ACGIH Threshold Limit Values**

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

**US. NIOSH: Pocket Guide to Chemical Hazards**

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

**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. |
| **Color** | 75 mg - Green, 150 mg - Light blue and green (or blue and white), 300 mg - Blue |
| **Odor** | Not available. |
| **Odor 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. |
| **Vapor pressure** | Not available. |
| **Vapor 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. |
| **Oxidizing properties** | Not oxidizing. |

## 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 oxidizing 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 | | |
| **Acute** | | |
| **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 |
| **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<br>Severity: Moderate<br><br>Species: Rat<br>Severity: No effect |

**Respiratory or skin sensitization**

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** 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)<br>Result: Negative<br>Species: Salmonella<br><br>In Vitro Micronucleus<br>Result: Negative |

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

**IARC Monographs. Overall Evaluation of Carcinogenicity**

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

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**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<br>Result: NOAEL<br>Species: Rat<br>Organ: Subcutaneous<br><br>600 mg/kg/day Embryo / Fetal Development, Not Teratogenic<br>Result: NOAEL<br>Species: Mouse<br>Organ: Oral<br><br>600 mg/kg/day Embryo / Fetal Development, Not Teratogenic<br>Result: NOAEL<br>Species: Rat<br>Organ: Oral |

**Reproductivity**

| | |
|---|---|
| Clindamycin Hydrochloride | 300 mg/kg/day Reproductive & Fertility, Fertility<br>Result: NOAEL<br>Species: Rat<br>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

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|---|---|
| **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

**DOT**

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

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)**

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**SARA 302 Extremely hazardous substance**

Not listed.

| | |
|---|---|
| **SARA 311/312 Hazardous chemical** | Yes |

| | |
|---|---|
| **Classified hazard categories** | Serious eye damage or eye irritation<br>Respiratory or skin sensitization |

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

| | |
|---|---|
| **Safe Drinking Water Act (SDWA)** | Not regulated. |
| **US state regulations** | California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. |

**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

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

**California Proposition 65**

**California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Talc (non-asbestiform) (CAS 14807-96-6) Listed: April 1, 1990

**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, including date of preparation or last revision

| | |
|---|---|
| **Issue date** | 10-28-2013 |
| **Revision date** | 04-28-2022 |
| **Version #** | 06 |
| **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. |