

## Safety Data Sheet

### 1. Identification

<b>Product identifier</b>	<b>Clindamycin Hydrochloride Capsules – 25mg, 75, 150, and 300 mg</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	Clindamycin Hydrochloride Capsules
<b>Recommended use</b>	Veterinary product used as antibiotic agent
<b>Recommended restrictions</b>	Not for human use
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Company Name (US)</b>	Cronus Pharma LLC Two tower centre Boulevard Suite 1101A East Brunswick, New Jersey 08816 (USA)
<b>Emergency telephone number</b>	1-844-227-6687, 1-844-2-CRONUS

Contact Email	<a href="mailto:contact@cronuspharma.com">contact@cronuspharma.com</a>
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### 2. Hazards and Identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Warning
<b>Hazard statement</b>	May cause an allergic skin reaction. Causes serious eye irritation.
<b>Precautionary statement</b>	
<b>Prevention</b>	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.
<b>Response</b>	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. Wash contaminated clothing before reuse.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	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.

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### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
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

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

#### 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 center 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.

#### Most important symptoms/effects, acute and delayed

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.

#### 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.

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### 5. Fire-fighting measures

#### Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>). 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 Special protective equipment and precautions for firefighters

During fire, gases hazardous to health may be formed.

#### Fire fighting equipment/instructions Specific methods

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

#### General fire hazards

Use water spray to cool unopened containers.

Use standard firefighting procedures and consider the hazards of other involved materials.

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. For personal protection, see section 8 of the SDS.

#### 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.

#### 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.

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**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.

#### Cronus

Components	Type	Value
Clindamycin Hydrochloride	TWA	100 µg/m <sup>3</sup>

(CAS 21462-39-5)

U.S. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Corn Starch (CAS 9005-25-8)	PEL	5 mg/m <sup>3</sup>	Respirable fraction.
		15 mg/m <sup>3</sup>	Total dust.

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

Components	Type	Value	Form
Talc (non-asbestiform)	TWA	0.3 mg/m <sup>3</sup>	Total dust.
(CAS 14807-96-6)		0.1 mg/m <sup>3</sup> 20 mppcf 2.4 mppcf	Respirable.

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Corn Starch (CAS 9005-25-8)	TWA	10 mg/m <sup>3</sup>	
Magnesium stearate (CAS 557-04-0)	TWA	10 mg/m <sup>3</sup>	
Talc (non-asbestiform) (CAS 14807-96-6)	TWA	2 mg/m <sup>3</sup>	Respirable fraction.

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

Components	Type	Value	Form
Corn Starch (CAS9005-25-8)	TWA	5 mg/m <sup>3</sup>	Respirable.
Talc (non-asbestiform)	TWA	10 mg/m <sup>3</sup> 2 mg/m <sup>3</sup>	Total 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.

#### Eye/face protection /Skin protection

If contact is likely, safety glasses with side shields are recommended.

#### Hand protection

Wear protective gloves.

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<b>Other</b>	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Not applicable.
<b>General hygiene considerations</b>	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

<b>Appearance</b>	Capsule
<b>Physical state</b>	Solid.
<b>Form</b>	Solid.
<b>Color</b>	25mg – Yellow, 75 mg - Green, 150 mg - blue , 300 mg - Turquoise
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.

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**Viscosity** Not available  
**Other information**  
**Explosive properties** Not explosive.  
**Oxidizing properties** Not oxidizing.

### 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Heat, flames and sparks. Contact with incompatible materials. Protect from sunlight. Avoid dispersion as a dust cloud.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	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** 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 the physical, chemical and toxicological characteristics** 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.

#### Information on toxicological effects

**Acute toxicity** May cause an allergic skin reaction.

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
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Clindamycin Hydrochloride (CAS 21462-39-5)

**Acute**

**Intravenous**

LD50	Mouse	143 mg/kg
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**Oral**

LD50	Mouse	1479 mg/kg
	Rat	2618 mg/kg

**Other**

LD50	Rat	279 mg/kg [Sub-tenon injection (eye)]
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**Subcutaneous**

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<p>LD50</p> <p><b>Chronic Oral</b></p> <p>LOAEL</p> <p>NOAEL</p> <p><b>Subacute Oral</b></p> <p>NOAEL</p> <p>Magnesium stearate (CAS 557-04-0)</p> <p><b>Acute Inhalation</b></p> <p>LC50</p> <p><b>Oral</b></p> <p>LD50</p> <p>Talc (non-asbestiform) (CAS 14807-96-6)</p> <p><b>Acute Oral</b></p> <p>LD50</p> <p><b>Skin corrosion/irritation</b></p> <p><b>Corrosivity</b></p> <p>Clindamycin Hydrochloride</p> <p><b>Serious eye damage/eye irritation</b></p> <p><b>Eye Contact</b></p> <p>Clindamycin Hydrochloride</p> <p><b>Respiratory or skin sensitization</b></p> <p><b>Respiratory sensitization</b></p> <p><b>Skin sensitization</b></p> <p><b>Germ cell mutagenicity</b></p> <p><b>Mutagenicity</b></p> <p>Clindamycin Hydrochloride</p> <p><b>Carcinogenicity</b></p> <p><b>IARC Monographs. Overall Evaluation of Carcinogenicity</b></p> <p>Talc (non-asbestiform)</p>	<p>Rat</p> <p>Dog</p> <p>Rat</p> <p>Dog</p> <p>Rat</p> <p>Rat</p> <p>Rat</p> <p>Rat</p> <p>Prolonged skin contact may cause temporary irritation.</p> <p>Species: Rat Severity: No effect</p> <p>Causes serious eye irritation.</p> <p>Species: Rabbit Severity: Moderate Species: Rat Severity: No effect</p> <p>Not a respiratory sensitizer</p> <p>May cause an allergic skin reaction</p> <p>No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.</p> <p>Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella In Vitro Micronucleus Result: Negative</p> <p>Based on available data, the classification criteria are not met. Industrial use - Inhalation: Not classifiable as to carcinogenicity to humans.</p> <p>2B Possibly carcinogenic to humans. 3 Not classifiable as to carcinogenicity to humans</p>	<p>891 mg/kg</p> <p>600 mg/kg/day, 6 months [Target organ: Gastrointestinal system]</p> <p>600 mg/kg/day, 6 months [No effects at maximum dose] 300 mg/kg/day, 1 years [No effects at maximum dose]</p> <p>300 mg/kg/day, 1 months [No effects at maximum dose]</p> <p>&gt; 2000 mg/m<sup>3</sup></p> <p>&gt; 2000 mg/kg</p> <p>&gt; 1600 mg/kg</p>
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(CAS 14807-96-6)

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

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

Not listed.

**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

**Eco toxicity**

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.

**Bio accumulative 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.



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### 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	None known.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods
<b>IATA</b>	Not regulated as dangerous goods
<b>IMDG</b>	Not regulated as dangerous goods
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

### 15. Regulatory information

<b>US federal regulations</b>	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>SARA 304 Emergency release notification</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not regulated.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard – No
<b>SARA 302 Extremely hazardous substance</b>	Not listed
<b>SARA 311/312 Hazardous</b>	No chemical
<b>SARA 313 (TRI reporting)</b>	Not regulated.
<b>Other federal regulations</b>	

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<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>	Not regulated.
<b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)</b>	Not regulated.
<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
<b>US state regulations</b>	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
<b>US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))</b>	Talc (non-asbestiform) (CAS 14807-96-6)
<b>16. Other information, including date of preparation or last revision</b>	
<b>Issue date</b>	02-07-2019
<b>Revision date</b>	-
<b>Version #</b>	00
<b>Disclaimer</b>	Cronus Pharma LLC 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.
<b>Revision information</b>	This document has undergone significant changes and should be reviewed in its entirety.