

SAFETY DATA SHEETS

This SDS packet was issued with item:

078927544

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078904887

Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial preparation date: 03.13.2019

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Clindamycin Injection

SECTION 1: Identification

Product identifier

Product name: Clindamycin Injection

Synonyms: Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans -4-propyl-L-2- pyrrolidinecarboxamido)-1-thio-L-threo - α -D-galacto -octopyranoside 2- (dihydrogen phosphate).

Product code: 078904887, 078927544

Recommended use of the product and restriction on use

Relevant identified uses: Pharmaceutical

Uses advised against: Not determined or not applicable.

Reasons why uses advised against: Not determined or not applicable.

Manufacturer or supplier details

Manufacturer:
United States

Alvogen, Inc.
10 Bloomfield Avenue
Bldg B

Pine Brook, NJ 07058
1-844-842-8672
www.alvogen.us.com

Supplier:
Distributor

Patterson Veterinary Supply
822 7th Street
Greeley, Colorado 80631
(800) 225-7911

Emergency telephone number:

United States

CHEMTREC

Within USA and Canada: 1-800-424-9300 (CHEMTREC, 24 hours)

Outside USA and Canada: +1-703-527-3887 (CHEMTREC, 24 hours)

SECTION 2: Hazard(s) identification

GHS classification:

Skin sensitization, category 1

Eye irritation, category 2A

Respiratory sensitization, category 1

Specific target organ toxicity - repeated exposure, category 2

Label elements

Hazard pictograms:



Signal word: Danger

Hazard statements:

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

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Precautionary statements:

- P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P264 Wash hands/eyes/mouth/skin/clothing thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P285 In case of inadequate ventilation wear respiratory protection.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or a rash occurs: Get medical advice/attention
P321 Specific treatment (see supplemental first aid instructions on this label).
P363 Wash contaminated clothing before reuse
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists get medical advice/attention
P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P314 Get medical advice/attention if you feel unwell
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards not otherwise classified: None

SECTION 3: Composition/information on ingredients

Identification	Name	Weight %
CAS number: 24729-96-2	Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo- α -D-galacto-octopyranoside, 2-(dihydrogen phosphate)	15

Additional Information:

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include disodium edetate and benzyl alcohol; sodium hydroxide and/or hydrochloric acid are added to adjust the pH.

SECTION 4: First aid measures

Description of first aid measures

General notes:

Not determined or not applicable.

After inhalation:

- Remove victim to fresh air and place in a position comfortable for breathing
If breathing is difficult, administer oxygen
If experiencing respiratory symptoms or you feel unwell: Seek medical attention

After skin contact:

- Remove contaminated clothing and rinse affected area with plenty of soap and water
If skin irritation or rash persists: seek medical advice/attention
Do not allow contaminated clothing outside of the workplace
Wash contaminated clothing before reuse

After eye contact:

- Rinse eyes cautiously with lukewarm, gently flowing water for several minutes, while holding the eyelids open
Remove contact lenses, if present and easy to do so
Continue rinsing for 15-20 minutes
Get medical advice if eye irritation persists

After swallowing:

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Rinse mouth. Do NOT induce vomiting unless directed to do so by medical personnel
If vomiting spontaneously occurs, place victim on side in the recovery position to prevent aspiration into the lungs
Never give anything by mouth to an unconscious person
If not feeling well or concerned: Call a POISON CENTER or doctor/physician

Most important symptoms and effects, both acute and delayed

Acute symptoms and effects:

This product may cause an allergic skin reaction. Symptoms include: redness, rash, itching, burning sensation and inflammation. Eye contact may cause serious eye irritation. Symptoms include redness, tearing, itching and inflammation. Inhalation may allergy or asthma symptoms such as breathing difficulties, wheezing, shortness of breath and cough

Delayed symptoms and effects:

May cause damage to organs through repeated and/or prolonged exposure

Immediate medical attention and special treatment

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Not determined or not applicable.

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media:

Use appropriate fire suppression agents for adjacent combustible materials or sources of ignition

Unsuitable extinguishing media:

Not determined or not applicable.

Specific hazards during fire-fighting:

Thermal decomposition can lead to release of irritating gases and vapors

Special protective equipment for firefighters:

Use typical firefighting equipment, self-contained breathing apparatus, special tightly sealed suit

Special precautions:

Not determined or not applicable.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Avoid contact with skin and eyes

If skin or eye contact are possible: where protective gloves and eye protection

Wash thoroughly after handling

Environmental precautions:

Should not be released into the environment

Prevent from reaching drains, sewer or waterway

Methods and material for containment and cleaning up:

Absorb with non-combustible liquid-binding material (sand, diatomaceous earth (clay), acid binders, universal binders)

Dispose of contents / container in accordance with local regulations

Reference to other sections:

Not determined or not applicable.

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SECTION 7: Handling and storage

Precautions for safe handling:

- Do not eat, drink, smoke or use personal products when handling chemical substances.
- Avoid contact with skin and eyes.
- Wash thoroughly after handling.
- If skin or eye contact are possible: where protective gloves and eye protection.

Conditions for safe storage, including any incompatibilities:

- Protect containers from physical damage.
- Keep in cool, dry, well-ventilated area in closed containers.

SECTION 8: Exposure controls/personal protection

Only those substances with limit values have been included below.

Occupational Exposure limit values:

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

Biological limit values:

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

Information on monitoring procedures:

Monitoring of the concentration of substances in the breathing zone of workers or in the general workplace may be required to confirm compliance with an OEL and adequacy of exposure controls.
Biological monitoring may also be appropriate for some substances.

Appropriate engineering controls:

Emergency eye wash fountains and safety showers should be available in the immediate vicinity of use or handling.
Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapor and mists below the applicable workplace exposure limits (Occupational Exposure Limits-OELs) indicated above.

Personal protection equipment

Eye and face protection:

Safety glasses or goggles are required where eye contact is possible. If necessary, refer to U.S. OSHA 29 CFR 1910.133.

Skin and body protection:

Avoid skin contact. Select and use gloves and/or protective clothing to prevent skin contact based on results of an exposure assessment. If necessary, refer to U.S. OSHA 29 CFR 1910.138.

Respiratory protection:

Not normally required when using this product. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134) or equivalent.

General hygienic measures:

- Avoid contact with skin, eyes and clothing.
- Wash hands before breaks and at the end of work.
- Wash contaminated clothing before reuse.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance	This product is a clear liquid with no odor.
Odor	Odorless
Odor threshold	Not determined or not available.
pH	6.5

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Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not applicable
Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not applicable
Upper flammability/explosive limit	Not applicable
Lower flammability/explosive limit	Not applicable
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Soluble in water.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Dynamic viscosity	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

Other information

SECTION 10: Stability and reactivity

Reactivity:

This product is not reactive.

Chemical stability:

Stable under conditions of normal storage and use.

Possibility of hazardous reactions:

None known.

Conditions to avoid:

None known.

Incompatible materials:

None known.

Hazardous decomposition products:

Carbon dioxide, carbon monoxide and irritating vapors.

SECTION 11: Toxicological information

Acute toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidiny)carbonyl]amino]-1-thio-L-threo- α -D-galacto-octopyranoside, 2-(dihydrogen phosphate)	oral	LD50 Rat: 1832 mg/kg

Skin corrosion/irritation

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Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Serious eye damage/irritation

Assessment:

Causes serious eye irritation

Product data:

No data available.

Substance data:

Name	Result
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo- α -D-galacto-octopyranoside, 2-(dihydrogen phosphate)	Causes serious eye irritation.

Respiratory or skin sensitization

Assessment:

May cause an allergic skin reaction

May cause allergy or asthma symptoms or breathing difficulties if inhaled

Product data:

This product is considered a possible respiratory system or skin sensitizer.

Substance data:

Name	Result
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo- α -D-galacto-octopyranoside, 2-(dihydrogen phosphate)	May cause an allergic skin reaction.
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo- α -D-galacto-octopyranoside, 2-(dihydrogen phosphate)	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

National Toxicology Program (NTP): None of the ingredients are listed.

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Reproductive toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

None of the ingredients of this product are expected to have adverse effects on the human reproductive system.

Substance data: No data available.

Specific target organ toxicity (single exposure)

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Assessment: Based on available data, the classification criteria are not met.

Product data:

Eyes, skin and respiratory system.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment:

May cause damage to organs through prolonged or repeated exposure

Product data:

Blood, Liver, Kidney and Skin.

Substance data:

Name	Result
Methyl (2S-trans)-7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl)carbonyl]amino]-1-thio-L-threo- α -D-galacto-octopyranoside, 2-(dihydrogen phosphate)	May cause damage to organs through repeated and/or prolonged exposure.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

None.

Substance data: No data available.

Information on likely routes of exposure:

No data available.

Symptoms related to the physical, chemical and toxicological characteristics:

This product may cause an allergic skin reaction. Symptoms include: redness, rash, itching, burning sensation and inflammation. Eye contact may cause serious eye irritation. Symptoms include redness, tearing, itching and inflammation. Inhalation may allergy or asthma symptoms such as breathing difficulties, wheezing, shortness of breath and cough. May cause damage to organs after repeated and/or prolonged exposure.

Other information:

No data available.

SECTION 12: Ecological information

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Persistence and degradability

Product data: No data available.

Substance data: No data available.

Bioaccumulative potential

Product data: No data available.

Substance data: No data available.

Mobility in soil

Product data: No data available.

Substance data: No data available.

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Other adverse effects:

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities

SECTION 14: Transport information

United States Transportation of dangerous goods (49 CFR DOT)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

SECTION 15: Regulatory information

United States regulations

Inventory listing (TSCA): The components of this product are listed on the TSCA Inventory or are exempted from listing. Commercial use of this material is regulated by the FDA.

Significant New Use Rule (TSCA Section 5): None of the ingredients are listed.

Export notification under TSCA Section 12(b): None of the ingredients are listed.

SARA Section 302 extremely hazardous substances: None of the components of this product are subject to the reporting requirements of Sections 302 of Title III of the Superfund Amendments and Reauthorization Act.

SARA Section 313 toxic chemicals: None of the components of this product are subject to the reporting requirements of Sections 313 of Title III of the Superfund Amendments and Reauthorization Act.

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CERCLA: None of the ingredients are listed.

RCRA: There are no specific Threshold Planning Quantities for the components of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.

Section 112(r) of the Clean Air Act (CAA): None of the ingredients are listed.

Massachusetts Right to Know: Not determined.

New Jersey Right to Know: Not determined.

New York Right to Know: Not determined.

Pennsylvania Right to Know: Not determined.

California Proposition 65: None of the ingredients within this product are on the Proposition 65 Lists.

SECTION 16: Other information

Abbreviations and Acronyms: None

Disclaimer:

This product has been classified in accordance with OSHA HCS 2012 guidelines. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

NFPA: 1-0-0

HMIS: 1-0-0

Initial preparation date: 03.13.2019

End of Safety Data Sheet