
	Sagent Pharmaceuticals, Inc.				
	Clindamycin Injection, USP			Safety Data Sheet (SDS)	
	SDS Issue Date: Sep 25, 2014	SDS No.: SDS 014	SDS Version No.: 3.0	Form No.: R-SOP-009-F001	Page: 1 of 9


Section 1 - Identification

- (a) **Product Identifier:** Clindamycin Injection, USP
- (b) **Product Code:** 25021-115 (150 mg/mL)
- Common/Trade Name:** Cleocin, Clindamycin phosphate
- Chemical Name:** L-threo- α -Dgalacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[[[(1-methyl-4-propyl-2-pyrrolidinyl) carbonyl] amino]-1-thio-, 2-(dihydrogen phosphate), (2S-trans)-.
- Chemical Family:** Antibiotic
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** Acute toxicity, Oral (Category 4)
- HMIS Rating**
- | | |
|-----------------|---|
| Health Hazard | 1 |
| Flammability | 0 |
| Physical Hazard | 0 |
- NFPA Rating**
- | | |
|-------------------|---|
| Health Hazard | 1 |
| Fire Hazard | 0 |
| Reactivity Hazard | 0 |

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
	- <u>Signal Word:</u> Warning


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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Hazard Statements:</u> H302	- Harmful if swallowed
<u>Precautionary Statements:</u> P264 P270 P301 + P312 P330 P501	- Wash skin thoroughly after handling - Do not eat, drink, or smoke when using this product - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell - Rinse mouth - Dispose of contents/container to an approved waste disposal plant

(d) Unknown Acute Toxicity: N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
<i>L-threo-α-Dgalactooctopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[[1-methyl-4-propyl-2-pyrrolidinyl] carbonyl] amino]-1-thio-, 2-(dihydrogen phosphate), (2S-trans)-</i>	Clindamycin Phosphate	150 mg/vial	24729-96-2	N/A
Disodium Edetate	Disodium Edetate	0.5 mg/vial	139-33-3	N/A
Benzyl Alcohol	Benzyl Alcohol	10.395 mg/vial	100-51-6	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s.	1310-73-2	N/A
Hydrochloric Acid	Hydrochloric Acid	q.s.	7674-01-0	N/A
Nitrogen	Nitrogen	q.s.	7727-37-9	N/A
Water for Injection	Water for Injection	q.s. to 1 mL	7732-18-5	N/A

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Section 4 - First Aid Measures


- Eye Exposure:** Flush eyes continuously with large volumes of water for at least 15 minutes.
- Skin Exposure:** Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention.
- Ingestion:** Flush mouth out with water immediately. Seek medical attention. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.
- Injection:** Not available.
- Inhalation:** No information.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use dry chemical powder for small fires. Use water spray, fog or foam for large fires.
- (b) **Hazardous Combustion Products:** Not Established
- (c) **Special Protective Equipment / Precautions:** Wear self-contained breathing apparatus and protective clothing.

Section 6 - Accidental Release Measures

- Spill:** Wear recommended personal protective equipment (See Section 8 – Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.
- Release to Air:** If aerosolized, reduce exposures by ventilating area. Clean up immediately.
- Release to Water:** Refer to local and regional water authority requirements.

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Section 7 - Handling and Storage

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Storage Conditions: Store at Controlled room temperature 20° to 25°C (68° to 77°F) [see USP]. Do not refrigerate.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
Clindamycin phosphate	OSHA	TLV	NE
	ACGIH	PEL	NE
	----	STEL	NE
Edetate Disodium	OSHA	TLV	NE
	ACGIH	PEL	NE
	----	STEL	NE
Benzyl Alcohol	OSHA	TLV	NE
	ACGIH	PEL	NE
	----	STEL	NE

(b) Engineering Controls

Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures


Respiratory Protection:	With satisfactory ventilation, respiratory protection is usually not required.
Eye Protection:	Safety glasses or goggles recommended.
Skin Protection:	Disposable garments if direct skin contact is anticipated.
Other Protective Equipment:	No information.

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Additional Exposure Precautions:	This product is contained in closed or sealed vials. Under normal conditions in a clinical setting, personnel would not be exposed to liquid. In a clinical setting, the solution is intended for either intramuscular or intravenous injection, under the care of a physician.
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Section 9 - Physical and Chemical Properties

(a)	Appearance	Colorless to pale yellow liquid
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	5.5 – 7.0
(e)	Melting Point:	Not applicable
(f)	Initial Boiling Point:	Not Established
(g)	Flash Point	Not Established
(h)	Evaporation Rate:	Not Established
(i)	Flammability	Not Established
(j)	Upper Lower Flammability or Explosion Limits	Not Established
(k)	Vapor Pressure:	Not Established
(l)	Vapor Density:	Not Established
(m)	Relative Density	Not Established
(n)	Solubility(ies)	Clindamycin phosphate is very soluble in water; slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically insoluble in chloroform, ether, or benzene.
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not Established
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

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Section 10 - Stability and Reactivity


(a)	Reactivity	Not Reactive
(b)	Chemical Stability	Stable under normal conditions
(c)	Possibility of Hazardous Reactions	Hazardous polymerization not anticipated to occur with this material
(d)	Conditions to Avoid	Keep away from strong oxidizers
(e)	Incompatible Materials	Strong Oxidizers
(f)	Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), oxides of phosphate and sulfur, and hydrogen chloride.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact, or ingestion.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Hypersensitivity reactions may include rash, fever, urticaria, pruritus, hypotension and, rarely, polyarthritis.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Anaphylaxis, which may involve difficulty in breathing, respiratory distress, and may be fatal, has been reported in a few patients receiving therapeutic doses of clindamycin phosphate. If an allergic reaction should occur, get medical attention immediately.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Clindamycin	LD ₅₀	Oral	Rat	2190 mg/kg
Clindamycin	LD ₅₀	Intramuscular	Rat	3500 mg/kg
Clindamycin	LD ₁₀	Oral	Rabbit	1 mg/kg
Clindamycin	LD ₁₀	Oral	Hamster	1 gm/kg
Clindamycin	TD ₁₀	Oral	Man	89.6 mg/kg
Clindamycin	TD ₁₀	IV	Rabbit	5 mg/kg
Clindamycin	TD ₁₀	IP	Rat	100 mg/kg

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(e) Hazardous Chemical Listings

NTP: No IARC: No OSHA: No

Section 12 - Ecological Information

(a)	Ecotoxicity	No data available
(b)	Persistence and degradability	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
(c)	Bioaccumulative potential	Long term degradation products may arise
(d)	Mobility in soil	No data available
(e)	Other Adverse Effects	No data available


Section 13 - Disposal Considerations

Dispose of waste in accordance with all applicable Federal, State and local laws.

Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not Regulated
ICAO/IATA: Not Regulated
IMO: Not Regulated

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA - Not on this list

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List

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ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System