

**Product Name:** Clindamycin Phosphate  
**Issued:** Dec-21-2012

## **SAFETY DATA SHEET**

### **Section 1. Identification of the substance/mixture and of the company/undertaking**

#### **1.1 Product Identifier**

**Product Name:** Clindamycin Phosphate  
**Chemical Name:** 7(s)-Chloro-7-deoxylincomycin Phosphate  
**Synonyms:** Clindamycin Phosphate, USP: Clindamycin Phosphate, EP: Clindamycin Phosphate, Crude:  
**List Number:** 5127  
**Drug Code Number:** 20797: 20798: 37159: 60732: 64741: 49648: 44420: 22427: 32404: 24931

#### **1.2 Relevant identified uses of the substance or mixture and uses advised against**

**Recommended use:** Pharmaceuticals

#### **1.3 Details of the supplier of the safety data sheet**

**Supplier:** AbbVie Inc.  
North Chicago, IL 60064  
U.S.A.  
1-800-255-5162  
+1-847-937-7433  
**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)  
+1-847-937-7433  
**E-mail Address:** AbbVie.SDS@abbvie.com

#### **1.4 Emergency telephone number**

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)  
or +1-703-527-3887 (international)

### **Section 2. Hazards identification**

#### **2.1 Classification of the substance or mixture**

**Regulation (EC) No 1272/2008**

**Acute oral toxicity** Category 4  
**None**

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

**Indication of danger:** Xn - Harmful  
**Risk Phrases:** R22 - Harmful if swallowed

#### **2.2 Label elements**

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## Section 2. Hazards identification



**Signal Word:** Warning

**Hazard Statements:** H302 - Harmful if swallowed

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents/container to an approved waste disposal plant

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Clindamycin Phosphate 24729-96-2	100	246-433-0	Xn, R22	Acute Tox. 4 (H302)	No data available

**For the full text of the R-phrases mentioned in this Section, see Section 16**

**For the full text of the H-Statements mentioned in this Section, see Section 16**

## Section 4. First aid measures

### 4.1 Description of first aid measures

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

#### **4.2 Most important symptoms and effects, both acute and delayed**

**Signs and Symptoms:** Clinical data suggests the following: rash, diarrhea, abdominal pain,

**Medical Conditions**  
**Aggravated by Exposure:** Clinical data suggests any pre-existing ailments of the following organs: gastrointestinal system, skin. Hypersensitivity to the material and/or similar materials.

#### **4.3 Indication of any immediate medical attention and special treatment needed**

**Notes To Physician:** Treat symptomatically

### **Section 5. Firefighting measures**

#### **5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

#### **5.2 Special hazards arising from the substance or mixture**

**Special Exposure Hazards:** Not determined

#### **5.3 Advice for firefighters**

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

### **Section 6. Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

**Personal Precautions:** For personal protection see section 8

#### **6.2. Environmental precautions**

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

#### **6.3. Methods and material for containment and cleaning up**

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

#### **6.4. Reference to other sections**

Refer to Sections 8, 12, and 13 for further information.

### **Section 7. Handling and storage**

#### **7.1. Precautions for safe handling**

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Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice.

## **7.2. Conditions for safe storage, including any incompatibilities**

Store according to label instructions.

## **7.3. Specific end use(s)**

**Recommended use:** Pharmaceuticals

# **Section 8. Exposure controls/personal protection**

## **8.1. Control parameters**

### **Exposure limits:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Clindamycin Phosphate 24729-96-2	2 mg/m <sup>3</sup> TWA	None

## **8.2. Exposure controls**

**Engineering Controls:** Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to handling activities.

**Gloves:** Impervious gloves.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls:** Not determined

# **Section 9. Physical and chemical properties**

## **9.1. Information on basic physical and chemical properties**

**Appearance:** White to off-white Crystalline Powder

**Odor:** Odorless.

**Odor Threshold:** Not determined

**pH:** 3.5-4.5 as a 1% solution.

**Boiling Pt. @ 760 mm Hg (°C):** Not determined.

**Melting/Freezing Point (°C):** Not determined

**Flash Point (°C):** Not determined.

**Evaporation Rate at 20°C:** Not determined.

**Flammability (Solid):** Not determined.

**Lower Explosive Limit:** Not determined.

**Upper Explosive Limit:** Not determined.

**Vapor Pressure (mm Hg):** Not determined.

**Vapor Density (Air = 1):** Not determined.

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<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Soluble in: water (11.2 grams/l)
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

## **9.2. Other information**

Not determined

**Max. rate of pressure rise (bar/sec):** 76.8

**Min. Ignition Energy-Cloud (mJ):** 800

**Min. Ignit. Temp. Dust Cloud (°C):** 455

**Min. Explosive Conc. (g/m<sup>3</sup>):** 270

## **Section 10. Stability and reactivity**

### **10.1. Reactivity**

Not determined

### **10.2. Chemical stability**

Stable under normal conditions

### **10.3. Possibility of hazardous reactions**

**Hazardous reactions:** Not determined.

### **10.4. Conditions to avoid**

Not determined.

### **10.5 Incompatible materials**

Not determined

### **10.6 Hazardous decomposition products**

Not determined.

## **Section 11. Toxicological information**

### **11.1. Information on toxicological effects**

**Routes of Exposure:**

<b>Oral:</b>	Clinical Route
<b>Dermal:</b>	Yes
<b>Inhalation:</b>	Yes

**Product Name:** Clindamycin Phosphate  
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**Acute Toxicity - Oral:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Clindamycin Phosphate	LD50 =	1832	mg/kg	Rats
24729-96-2		2539	mg/kg	Mice

**Acute Toxicity - Dermal:** Not determined.

**Acute Toxicity - Inhalation:** Not determined.

**Other Toxicology Data:** Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Clindamycin Phosphate	LD50 (sc) =	356 - 3861	mg/kg	Mice	None.
24729-96-2				Rats	

**Corrosivity:** Not Corrosive.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** In clinical use target organ effects include: gastrointestinal tract.

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Not determined.

**Aspiration hazard:** Not determined

**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

## Section 12. Ecological information

### 12.1. Toxicity

Not determined.

### 12.2. Persistence and degradability

Not determined.

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

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### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

#### **Notes:**

- 1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
- 2. LC50: Concentration in water that produces 50% mortality in fish.**
- 3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

## **Section 13. Disposal considerations**

### 13.1 Waste treatment methods

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

## **Section 14. Transport information**

### ADR, DOT, ICAO/IATA, IMDG/IMO

**Status:** Not regulated

- 14.1. UN Number:** Not applicable  
**14.2. Proper shipping name:** Not applicable  
**14.3. Hazard class:** Not applicable  
**14.4. Packing group:** Not applicable  
**14.5. Environmental hazard:** Not applicable  
**14.6. Special Provisions:** Not applicable  
**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable

## **Section 15. Regulatory Information**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Clindamycin Phosphate 24729-96-2	246-433-0	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Clindamycin Phosphate 24729-96-2	-	-	X	-	KE-23682	HSR007013

#### **Legend**

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

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DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

### Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Clindamycin Phosphate	100	Not Listed	Not Listed	Not Listed

### SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Clindamycin Phosphate	100	No	Not Applicable	Not applicable

**Immediate Health:** Yes

**Delayed Health:** No

**Fire:** No

**Sudden Pressure:** No

**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

**WHMIS Hazard Class:** NON-CONTROLLED.

### NFPA Rating:

Health: 1

Fire: 1

Reactivity: 0

### Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

### 15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

## Section 16. Other information

**Risk Phrases:** R22 - Harmful if swallowed

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