

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Clindamycin Palmitate Hydrochloride for Oral Solution, USP

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Amneal Pharmaceuticals
85 Adams Ave
Hauppauge, NY 11788

1.4. Emergency telephone number

T 631-952-0214 - F 631-656-1009

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Comb. Dust H232

2.2. Label elements

GHS-US labelling

Signal word (GHS-US) : Warning
Hazard statements (GHS-US) : H232 - May form combustible dust concentrations in air

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable
Full text of H-phrases: see section 16

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Sucrose	(CAS No) 57-50-1	Trade Secret	Not classified
L-threo-.alpha.-D-galacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[[[(2S,4R)-1-methyl-4-propyl-2-pyrrolidinyl]carbonyl]amino]-1-thio-, 2-hexadecanoate, monohydrochloride	(CAS No) 25507-04-4	Trade Secret	Not classified
Oxirane, methyl-, polymer with oxirane	(CAS No) 9003-11-6	Trade Secret	Not classified
Artificial Cherry Flavor	None	Trade Secret	Not classified
Ethyl 4-hydroxybenzoate	(CAS No) 120-47-8	Trade Secret	Not classified
Dextrin	(CAS No) 9004-53-9	Trade Secret	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

First-aid measures after skin contact : Flush with water for at least 15 minutes. Seek medical attention if irritation develops or persists.

First-aid measures after eye contact : Flush with plenty of water for at least 15 minutes. Seek medical advice if irritation develops or persists.

First-aid measures after ingestion : Do NOT induce vomiting. Seek medical attention.

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4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: None under normal use.
Symptoms/injuries after skin contact	: May cause moderate irritation.
Symptoms/injuries after eye contact	: May cause slight irritation.
Symptoms/injuries after ingestion	: None under normal use.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry chemical, foam, carbon dioxide.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: High dust concentrations have a potential for combustion or explosion.
Explosion hazard	: High concentrations of finely divided dusts can explode when exposed to heat or by chemical reaction.

5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Minimize generation of dust. Shovel or sweep up and put in a closed container for disposal. Dispose of waste in accordance with local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Avoid generating dust. Take precautionary measures against static discharge.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container tightly closed. Store in dry, cool, well-ventilated area.
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7.3. Specific end use(s)

Pharmaceutical

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sucrose (57-50-1)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	5 mg/m ³

8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: Use impervious gloves such as neoprene, nitrile, or rubber for hand protection.
Eye protection	: Safety glasses.

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Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder
Color	: White to off-white
Odor	: Odorless.
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Dusts or fumes may form explosive mixtures in air.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under fire conditions, toxic fumes may be evolved.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
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Oxirane, methyl-, polymer with oxirane (9003-11-6)

LC50 inhalation rat (mg/l)	320 mg/m ³ (Exposure time: 4 h)
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Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT

Not a dangerous good as defined in transport regulations

SECTION 15: Regulatory information

15.1. US Federal regulations

Ethyl 4-hydroxybenzoate (120-47-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sucrose (57-50-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Oxirane, methyl-, polymer with oxirane (9003-11-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Dextrin (9004-53-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Sucrose (57-50-1)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

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SECTION 16: Other information

Full text of H-phrases:

Comb. Dust	Combustible Dust
H232	May form combustible dust concentrations in air

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product