



SAFETY DATA SHEET

Quality Affordable Healthcare Products™

1. IDENTIFICATION

Product identifier: Clindamycin Palmitate Hydrochloride for Oral Solution, USP 75 mg
Synonym: 3G2

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug – Antibacterial Agent

Restrictions on use: Use only as directed.

Date of Preparation: February 15, 2015

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Combustible Dust	Not Hazardous

Label Elements:

WARNING: May form combustible dust concentrations in air.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Clindamycin Palmitate HCl	25507-04-4	5-10%
Sucrose	57-50-1	Proprietary
Poloxamer 188	9003-11-6	Proprietary
Dextrin	9004-53-9	Proprietary
Ethylparaben	120-47-8	Proprietary
Simethicone	8050-81-5	Proprietary
Flavor, wild cherry	Mixture	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: Wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if large amount is ingested or if symptoms develop.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Inhalation of dust may cause upper respiratory irritation. Ingestion may cause gastrointestinal effects And typical antibiotic effects (see Section 11).

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is generally not required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Airborne dust may present a potential fire and explosion hazard if suspended in air at high concentrations. Settled dust presents a fire hazard. Resuspension of the dust into the air by vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source could result in a dust explosion. Minimize the generation and accumulation of dust.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. Eliminate all ignition sources.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Wet down powder and collect in a manner to minimize the generation of airborne dusts or vacuum with a high efficiency vacuum cleaner. If a vacuum is used, explosion proof equipment is required. Nonsparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air.)

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid breathing powder. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Dry powders can build static electricity charges when subjected to friction of transfer and in mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Clindamycin Palmitate HCl	100 ug/m3 TWA Perrigo OEL
Sucrose	10 mg/m3 TWA ACGIH TLV 15 mg/m3 (total dust) TWA OSHA PEL 5 mg/m3 (respirable dust) TWA OSHA PEL
Poloxamer 188	None Established
Dextrin	None Established
Ethylparaben	None Established
Simethicone	None Established
Flavor, wild cherry	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment). Use only appropriately classified electrical equipment and powered industrial trucks.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES
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Appearance (physical state, color, etc.): Granules.

Odor: Cherry odor

Odor threshold: Not determined	pH: Not applicable
Melting point/freezing point: Not determined	Boiling Point: Not applicable
Flash point: None	Evaporation rate: Not applicable
Flammability (solid, gas): Dust is combustible and may be a fire of dust explosion hazard	VOC: Not applicable
Flammable limits: LEL: Not determined	UEL: Not determined
Vapor pressure: Not applicable	Vapor density: Not applicable
Relative density: Not available	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: Avoid heat, sparks and flames in the presence of dust.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dust may cause irritation of the mucous membranes and upper respiratory tract and effects similar to ingestion.

Ingestion: Swallowing may cause gastrointestinal effects. Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in patient death. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of systemic clindamycin.

Skin contact: No adverse effects are expected. Minor irritation is possible.

Eye contact: Contact may cause slight irritation.

Chronic Effects: None known. One year oral toxicity studies in rats and beagle dogs at dose levels up to 300 mg/kg/day have shown clindamycin to be well tolerated. No appreciable difference in pathological findings has been observed between groups of animals treated with clindamycin and comparable control groups. Rats receiving clindamycin hydrochloride at 600 mg/kg/day for 6 months tolerated the drug well; however, dogs dosed at this level vomited, would not eat, and lost weight.

Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

Germ Cell Mutagenicity: No adverse effects are expected. Genotoxicity tests performed with clindamycin palmitate hydrochloride included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative.

Reproductive Toxicity: Reproduction studies in rats using oral doses of clindamycin hydrochloride and clindamycin palmitate hydrochloride have revealed no evidence of impaired fertility. Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of clindamycin phosphate, clindamycin hydrochloride and clindamycin palmitate hydrochloride. These studies revealed no evidence of fetal harm.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA Long term studies in animals have not been performed with clindamycin to evaluate carcinogenic potential.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 416,666 mg/kg
Clindamycin: LD50 oral rat 2619 mg/kg.

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 2 Instability = 0
HMIS Rating: Health = 1 Flammability = 2 Physical Hazard = 0

SDS Revision History: New SDS format with GHS classification.

Date of preparation: February 15, 2015

Date of last revision: June 20, 2010

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).