



MATERIAL SAFETY DATA SHEET

Revision date: 22-Oct-2012

Version: 1.3

Page 1 of 7

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Clindamycin Phosphate Sterile Solution

Trade Name:	DALACIN C; DALACIN; CLEOCIN
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless solution
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:

Short Term: Active ingredient may be harmful if swallowed. May cause eye irritation; May cause skin irritation. (based on components) .

Known Clinical Effects: Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused sore throat, fever, gastrointestinal disturbances, abnormal liver function tests, kidney dysfunction. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur.

EU Indication of danger: Irritant

EU Hazard Symbols:

Xi



EU Risk Phrases:

R43 - May cause sensitization by skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Sterile Solution
Revision date: 22-Oct-2012

Page 2 of 7
Version: 1.3

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Clindamycin Phosphate	24729-96-2	246-433-0	Xi;R36-43 Xn;R22	15
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	<1.0
Edetate disodium	139-33-3	205-358-3	Not Listed	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Sterile Solution
Revision date: 22-Oct-2012

Page 3 of 7
Version: 1.3

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	Minimize generating airborne mists and vapors. Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Clindamycin Phosphate	
Pfizer OEL TWA-8 Hr:	100µg/m ³
Benzyl Alcohol	
Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	40 mg/m ³
Finland OEL - TWA	10 ppm
	45 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Poland OEL - TWA	240 mg/m ³

Analytical Method:	Analytical method available for clindamycin. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Sterile Solution
Revision date: 22-Oct-2012

Page 4 of 7
Version: 1.3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution	Color:	Clear, colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Clindamycin Phosphate

Rat	Oral	LD 50	1832 mg/kg
Rat	Para-periosteal	LD 50	321 mg/kg
Rat	Intraperitoneal	LD 50	745 mg/kg
Mouse	Oral	LD 50	2359 mg/kg
Mouse	Intravenous	LD 50	820 mg/kg

Benzyl Alcohol

Rat	Oral	LD50	1230 mg/kg
Rat	Para-periosteal	LD50	53 mg/kg
Rat	Inhalation	LC50	46 mg/m ³

Edetate disodium

Rat	Oral	LD50	2000-2200 mg/kg
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Irritation / Sensitization: (Study Type, Species, Severity)

Clindamycin Phosphate

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Benzyl Alcohol

Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Moderate
Skin Irritation	Guinea Pig	Moderate

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Sterile Solution
Revision date: 22-Oct-2012

Page 5 of 7
Version: 1.3

11. TOXICOLOGICAL INFORMATION

Clindamycin Phosphate

6 Month(s)	Rat	Oral	600 mg/kg/day	NOAEL	No effects at maximum dose
6 Month(s)	Dog	Oral	600 mg/kg/day	NOAEL	Gastrointestinal system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Clindamycin Phosphate

Prenatal & Postnatal Development	Rat	Subcutaneous	250 mg/kg	NOAEL	Not teratogenic
Prenatal & Postnatal Development	Rat	Oral	300 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Mouse	Oral	600 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Rabbit	Subcutaneous	5 mg/kg/day	NOAEL	Not Teratogenic, Maternal Toxicity
Reproductive & Fertility	Rat	Oral	300 mg/kg/day	NOAEL	No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Clindamycin Phosphate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Micronucleus	Rat	Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol:	Xi
EU Indication of danger:	Irritant

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Sterile Solution
Revision date: 22-Oct-2012

Page 6 of 7
Version: 1.3

15. REGULATORY INFORMATION

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

EU Safety Phrases:

S24 - Avoid contact with skin.

S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

WARNING

May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Clindamycin Phosphate

EU EINECS/ELINCS List	246-433-0
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Benzyl Alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-859-9

Edetate disodium

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-358-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

R20/22 - Harmful by inhalation and if swallowed.

MATERIAL SAFETY DATA SHEET

Material Name: Clindamycin Phosphate Sterile Solution
Revision date: 22-Oct-2012

Page 7 of 7
Version: 1.3

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 7 - Handling and Storage. Updated Section 5 - Fire Fighting Measures.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet