

# MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, and Canadian WHMIS

## PART I What is the material and what do I need to know in an emergency?

### 1. PRODUCT IDENTIFICATION

**TRADE NAME/MATERIAL NAME: Clindamycin Phosphate Lotion**

<b>DESCRIPTION:</b>	Clindamycin Phosphate Topical Suspension
<b>NDC #:</b>	0168-0203-60
<b>CHEMICAL NAME (for active ingredient):</b>	Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl- <i>trans</i> -4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L- <i>threo</i> - $\alpha$ -D-galactooctopyranoside 2-(Dihydrogen Phosphate)
<b>CHEMICAL FAMILY (for active ingredient):</b>	Lincosamide
<b>HOW SUPPLIED:</b>	1% Topical Suspension
<b>FORMULA (for active ingredient):</b>	C <sub>18</sub> H <sub>34</sub> ClN <sub>2</sub> O <sub>8</sub> PS
<b>PRODUCT USE:</b>	Pharmaceutical for Human Use
<b>SUPPLIER/MANUFACTURER'S NAME:</b>	<b>NYCOMED US INC.</b>
<b>ADDRESS:</b>	60 Baylis Road Melville, NY 11747
<b>BUSINESS PHONE/GENERAL MSDS INFORMATION:</b>	1-631-454-7677
<b>EMERGENCY PHONE (U.S./Canada/Puerto Rico):</b>	<b>1-800-424-9300 (24-hrs)</b>
<b>EMERGENCY PHONE (OUTSIDE U.S.):</b>	<b>+1-631-454-7677</b>

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, and Canadian WHMIS [Controlled Products Regulations] required information is included in appropriate sections based on the U.S. ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

### 2. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW: Product Description:** This product is a white to off-white liquid with a slight odor. **Health Hazards:** Employees administering the product should not experience adverse effects if handled properly. The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing the active ingredient, Clindamycin Phosphate (or any other components of this product) may experience allergic reactions to this product. **Flammability Hazards:** If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, phosphorus oxides, sulfur oxides, and hydrogen chloride). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** This product has not been tested for environmental effects. **Emergency Considerations:** Emergency responders should wear appropriate protection for situations to which they respond.

### 3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% w/w
Clindamycin Phosphate	24729-96-2	1%
Methylparaben	99-76-3	Proprietary
Glyceryl Stearate	123-94-4	Proprietary
Stearic Acid	57-11-4	Proprietary
Cetostearyl Alcohol	67762-27-0	Proprietary
Isostearyl Alcohol	59231-38-8	Proprietary
Glycerin	56-81-5	Proprietary
Water	7732-18-5	Balance

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## PART II What should I do if a hazardous situation occurs?

### 4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

**SKIN EXPOSURE:** If adverse skin effects occur, discontinue use. Seek medical attention.

**EXPOSURE:** If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

**INHALATION:** If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

**INGESTION:** If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

**RECOMMENDATIONS TO PHYSICIANS:** This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure. Vancomycin has been found to be effective in the treatment of antibiotic-associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dosage is 500 mg to 2 grams of vancomycin orally per day in three to four divided doses administered for 7 to 10 days. Cholestyramine or colestipol resins bind vancomycin *in vitro*. If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug.

### 5. FIRE-FIGHTING MEASURES

**FLASH POINT:** Not established.

**AUTOIGNITION TEMPERATURE:** Not established.

**FLAMMABLE LIMITS (in air by volume, %):**

Lower (LEL): Not applicable. Upper (UEL): Not applicable.

**FIRE EXTINGUISHING MATERIALS:** Use extinguishing media appropriate for surrounding fire.

Water Spray: OK

Carbon Dioxide: OK

Foam: OK

Dry Chemical: OK

Halon: OK

Other: Any "ABC" Class

**FIRE EXTINGUISHING MATERIALS NOT TO BE USED:** None known.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, phosphorus oxides, sulfur oxides, and hydrogen chloride).

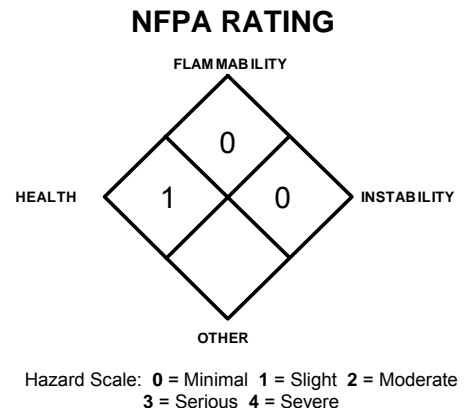
Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

**SPECIAL FIRE-FIGHTING PROCEDURES:** Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

### 6. ACCIDENTAL RELEASE MEASURES

**SPILL AND LEAK RESPONSE:** Proper protective equipment should be used. In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA).



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## 6. ACCIDENTAL RELEASE MEASURES (Continued)

### SPILL AND LEAK RESPONSE (continued):

**Small Spills:** Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

**Large Spills:** Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.** Absorb spilled liquid using polypads or other suitable absorbent material. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Monitor area and confirm levels are below exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

### PART III How can I prevent hazardous situations from occurring?

## 7. HANDLING and USE

**WORK PRACTICES AND HYGIENE PRACTICES:** As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration.

**STORAGE AND HANDLING PRACTICES:** Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container.

**PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL:** Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

**SPECIFIC USE(S):** This product is a human pharmaceutical. Follow all industry standards for use of this product.

**PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT:** When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and dispose of according to applicable U.S. Federal, State, and local hazardous waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

**VENTILATION AND ENGINEERING CONTROLS:** Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

### EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							OTHER mg/m <sup>3</sup>
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELS		NIOSH	
		TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	IDLH mg/m <sup>3</sup>	
Clindamycin Phosphate	24729-96-2	NE	NE	NE	NE	NE	NE	NE	NE
Methylparaben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
Glyceryl Stearate (Exposure limits are for Stearates)	123-94-4	10	NE	NE	NE	NE	NE	NE	NE
Stearic Acid	57-11-4	NE	NE	NE	NE	NE	NE	NE	NE
Cetostearyl Alcohol	67762-27-0	NE	NE	NE	NE	NE	NE	NE	NE
Isostearyl Alcohol	59231-38-8	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established.

See Section 16 for Definitions of Terms Used.

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## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

### EXPOSURE LIMITS/GUIDELINES (continued):

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	TWA mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	IDLH mg/m <sup>3</sup>	
Glycerin	56-81-5	10 (mist)	NE	15 (Total dust) 5 (Resp. fraction) 10 (Total) 5 (Resp. fraction) [vacated 1989 PEL]	NE	NE	NE	NE	DFG MAKs: TWA = 50 (Inhalable fraction) PEAK = 2•MAK 15 min, average value, 1-hr interval DFG MAK Pregnancy Risk Classification: C

NE = Not Established.

See Section 16 for Definitions of Terms Used.

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-07). Please reference applicable regulations and standards for relevant details.

**RESPIRATORY PROTECTION:** A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

**EYE PROTECTION:** Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or Canadian CSA Standard Z94.3-07.

**HAND PROTECTION:** For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate standards of Canada.

**BODY PROTECTION:** During patient administration, use of lightweight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136 and the Canadian CSA Standard Z195-02, *Protective Footwear*.

## 9. PHYSICAL and CHEMICAL PROPERTIES

**BOILING POINT:** Not established.

**EVAPORATION RATE (nBuAc = 1):** Not established.

**VAPOR PRESSURE (air = 1):** Not established.

**ODOR THRESHOLD:** Not established.

**COEFFICIENT WATER/OIL DISTRIBUTION:** Not established.

**APPEARANCE AND COLOR:** This product is a white to off-white liquid with a slight odor.

**HOW TO DETECT THIS SUBSTANCE (warning properties):** The appearance of this product can be a distinguishing characteristic to identify it in event of accidental release.

**FREEZING/MELTING POINT:** Not established.

**SOLUBILITY IN WATER:** Partially Soluble.

**SPECIFIC GRAVITY @ 50°C (water = 1):** 0.90-1.05

**pH:** 3-6

## 10. STABILITY and REACTIVITY

**STABILITY:** This product is stable.

**DECOMPOSITION PRODUCTS:** If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, phosphorus oxides, sulfur oxides, and hydrogen chloride).

**MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:** This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

**HAZARDOUS POLYMERIZATION:** Will not occur.

**CONDITIONS TO AVOID:** Avoid heat, light, and contact with incompatible chemicals.

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## PART IV *Is there any other useful information about this material?*

### 11. TOXICOLOGICAL INFORMATION

**SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE:** The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.

**INHALATION:** Inhalation of vapors of this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air. Due to the presence of Methylparaben, this product may cause respiratory sensitization in susceptible individuals; subsequent exposure to very small amounts may cause an asthma-like reaction in persons who have been sensitized.

**CONTACT WITH SKIN or EYES:** Skin contact may cause burning sensation, itching, dryness, redness, oily skin, and peeling. Due to the presence of Methylparaben, skin contact may cause an allergic reaction in sensitive individuals; subsequent exposure to very small amounts may cause an allergic reaction once sensitized, with symptoms of redness, itching, welts and irritation. Eye contact can cause irritation, stinging, redness, and tearing.

**SKIN ABSORPTION:** The Clindamycin Phosphate component of this product can be absorbed through intact skin. Symptoms of chronic and acute overexposure by this route may include diarrhea, bloody diarrhea, colitis, pseudomembranous colitis, and abdominal cramps. Severe colitis may be fatal.

**INGESTION:** Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause diarrhea, bloody diarrhea, colitis, pseudomembranous colitis, and abdominal cramps. Severe colitis may be fatal.

**INJECTION:** Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for "Ingestion".

**GENERAL TOXICITY INFORMATION:** Individuals who have had allergic reactions to products containing the Clindamycin Phosphate component of this product or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following:

For Males and Females: Persons using the product in therapeutic doses may experience burning, itching, skin dryness, redness, oily skin, and peeling skin.

**IRRITANCY OF PRODUCT:** This product may mildly to moderately irritate contaminated tissue.

**SENSITIZATION OF PRODUCT:** Due to the presence of Methylparaben, susceptible persons may experience allergic skin and/or respiratory reaction. Rarely, the Cetostearyl Alcohol component of this product can cause allergic skin reaction with hives.

**HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms.** Overexposure to this product may cause the following health effects:

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Skin absorption, ingestion, and injection of large quantities of this product may cause diarrhea, bloody diarrhea, colitis, and abdominal cramps. Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of oral and parenteral therapy with Clindamycin. Severe colitis may be fatal. Eye contact will cause irritation.

Chronic: Prolonged or repeated skin contact may cause dermatitis.

#### **TARGET ORGANS:**

Acute: Occupational Exposure: Skin, eyes. Therapeutic Doses: Skin, gastrointestinal system.

Chronic: Occupational Exposure: Skin. Therapeutic Doses: Skin, gastrointestinal system.



#### HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	1
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FLAMMABILITY HAZARD	(RED)	0
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PHYSICAL HAZARD	(YELLOW)	0
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#### PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate  
3 = Serious 4 = Severe \* = Chronic hazard

## 11. TOXICOLOGICAL INFORMATION (Continued)

**TOXICITY DATA:** The toxicity data available for the active component of this product, Clindamycin Phosphate, are presented in this MSDS. Additional data are available for the excipient components of this product, but are not presented in this MSDS; Contact Nycomed US Inc. for more information.

**CLINDAMYCIN PHOSPHATE:**

TDLo (Intravenous-Woman) 12 mg/kg: Cardiac: pulse rate increase, without fall in BP; Cardiac: other changes; Vascular: BP lowering not characterized in autonomic section  
 LD<sub>50</sub> (Oral-Rat) 1832 mg/kg: Behavioral: somnolence (general depressed activity)  
 LD<sub>50</sub> (Oral-Mouse) 2539 mg/kg  
 LD<sub>50</sub> (Intraperitoneal-Rat) 745 mg/kg  
 LD<sub>50</sub> (Intraperitoneal-Mouse) 784 mg/kg  
 LD<sub>50</sub> (Subcutaneous-Rat) 3861 mg/kg  
 LD<sub>50</sub> (Subcutaneous-Mouse) 1036 mg/kg  
 LD<sub>50</sub> (Intravenous-Rat) 321 mg/kg  
 LD<sub>50</sub> (Intravenous-Mouse) 820 mg/kg

**CLINDAMYCIN PHOSPHATE (continued):**

LD<sub>50</sub> (Intramuscular-Rat) > 3500 mg/kg  
 LD<sub>50</sub> (Intramuscular-Mouse) 1100 mg/kg  
 TDLo (Intraperitoneal-Rat) 700 mg/kg: female 9-15 days after conception: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death  
 TDLo (Intraperitoneal-Rat) 1400 mg/kg: female 9-15 days after conception: Effects on Newborn: growth statistics (e.g.%, reduced weight gain)  
 TDLo (Intraperitoneal-Mouse) 700 mg/kg: female 7-13 days after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system

**CLINDAMYCIN PHOSPHATE (continued):**

TDLo (Intraperitoneal-Mouse) 2800 mg/kg: female 7-13 days after conception: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)  
 TDLo (Subcutaneous-Rat) 700 mg/kg: female 9-15 days after conception: Reproductive: Effects on Fetus: fetal death; Specific Developmental Abnormalities: musculoskeletal system  
 TDLo (Subcutaneous-Mouse) 700 mg/kg: female 7-13 days after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system  
 TDLo (Subcutaneous-Mouse) 1400 mg/kg: female 7-13 days after conception: Effects on Newborn: growth statistics (e.g.%, reduced weight gain)

**CARCINOGENIC INFORMATION:** Long-term animal studies have not been performed to evaluate the carcinogenic potential of Clindamycin Phosphate. The incipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

**GLYCERYL STEARATE (as a stearate compound):** ACGIH TLV-A4 (Not Classifiable as Human Carcinogen)

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

**REPRODUCTIVE TOXICITY INFORMATION:** The active component of this product, Clindamycin Phosphate, is rated as Pregnancy Category B (NO EVIDENCE OF RISK, Human evidence is negative, but animal evidence is positive. Alternately, there is no human evidence and animal evidence is negative). Listed below is information concerning the effects of this product and its components on animal or human reproductive systems.

**Mutagenicity:** Genotoxicity tests performed included a rat micronucleus test and an Ames test. Both tests were negative. No human data are available.

**Embryotoxicity:** Animal studies have not been performed to evaluate the embryotoxicity of Clindamycin Phosphate. No human data are available.

**Teratogenicity:** Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of Clindamycin ranging from 100 to 600 mg/kg/day and have revealed no evidence of harm to the fetus due to Clindamycin. In one mouse strain, cleft palates were observed in treated fetuses; this outcome was not produced in other mouse strains or in other species and is, therefore, considered to be a strain specific effect. No human data are available.

**Reproductive Toxicity:** Clindamycin Phosphate vaginal cream 2% has been studied in pregnant women during the second trimester. In women treated for seven days, abnormal labor was reported in 1.1% of patients who received Clindamycin Phosphate vaginal cream 2% compared with 0.1% of patients who received placebo. Reproduction studies have been performed in rats and mice using subcutaneous and oral doses of Clindamycin ranging from 100 to 600 mg/kg/day and have revealed no evidence of impaired fertility due to Clindamycin.

*A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryo toxin is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.*

**ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs):** Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for components of this product.

## 12. ECOLOGICAL INFORMATION

**ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.**

**ENVIRONMENTAL STABILITY:** This product has not been tested for persistence, biodegradability, bioconcentration, soil adsorption or mobility. The following environmental data are available for the components of this product:

**GLYCERIN:**

**Persistence and Biodegradability:** If released to soil, glycerin is expected to undergo rapid biodegradation under aerobic conditions. It is expected to display very high mobility in soil and it is not expected to significantly volatilize to the atmosphere. If released to water, glycerin is expected to rapidly degrade under aerobic conditions. Biodegradation in seawater and under anaerobic conditions is also expected. Glycerin is not expected to bioconcentrate in fish and aquatic organisms nor is it expected to adsorb to sediment and suspended organic matter. Volatilization to the atmosphere is expected to be slower than for water itself. If released to the atmosphere, Glycerin may undergo a gas-phase oxidation with photochemically produced hydroxyl radicals with a half-life of 33 hrs. It may also undergo atmospheric removal by wet deposition processes.

**Bioconcentration:** Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1,220,000 mg/L at 5°C, bioconcentration factors for Glycerin can be estimated at 3 and 0.2, respectively, using regression-derived equations. The magnitude of these values indicate that bioconcentration of Glycerin in fish and aquatic organisms will not be significant. Log K<sub>ow</sub> = -1.76.

**Soil Adsorption/Mobility:** Based on an experimental log octanol/water partition coefficient of -1.76 and its water solubility, 1,220,000 mg/L at 5°C, soil adsorption coefficients for Glycerin can be estimated at 3 and 2, respectively, using regression-derived equations. The magnitude of these values indicate that glycerin will display very high mobility in soil.

## 12. ECOLOGICAL INFORMATION (Continued)

### ENVIRONMENTAL STABILITY (continued):

#### STEARIC ACID:

Persistence and Biodegradability: If released into the atmosphere, Stearic Acid will exist in both the vapor and particulate phases in the ambient atmosphere, based on an extrapolated vapor pressure of  $7.2 \times 10^{-7}$  mm Hg at 25°C. Vapor phase Stearic Acid is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals with a half-life of about 17 hours. An estimated Koc value of  $7.2 \times 10^5$  suggests that Stearic Acid will be immobile in soil. Volatilization from moist soil is not expected based upon an estimated Henry's Law constant of  $4.8 \times 10^{-7}$  atm-cu m/mole. Volatilization from dry soil surfaces should not be important given the vapor pressure of this compound. The half-lives of Stearic Acid in Williamsburg surface sandy loam, Williamsburg subsurface silt loam, and Sault Ste Marie subsurface sand were determined to be 1.9, 13, and 3.4 days, respectively. Aerobic screening studies reveal that biodegradation of Stearic Acid is a relatively quick process; using a marine water inoculum, 5 ppm Stearic Acid was determined to be 43.9% of theoretical BOD after 5 days. In water, Stearic Acid is expected to adsorb to sediment or particulate matter based on its Koc value. This compound is not expected to volatilize from water surfaces given its estimated Henry's Law constant. Bioconcentration in aquatic organisms should be very high based upon an estimated BCF value of  $1.1 \times 10^6$ .

Bioconcentration: An estimated BCF value of  $1.1 \times 10^6$  was calculated for Stearic Acid, using an experimental log Kow of 8.23 and a recommended regression-derived equation. According to a classification scheme, this BCF value suggests that bioconcentration in aquatic organisms is very high.

Soil Adsorption/Mobility: The Koc of Stearic Acid is estimated as approximately  $7.2 \times 10^5$ , using a measured log Kow of 8.23 and a regression-derived equation. According to a recommended classification scheme, this estimated Koc value suggests that Stearic Acid is expected to be immobile in soil. The adsorption of stearate, the anion of Stearic Acid, was determined to be 99 percent adsorption onto the sediment solid phase of anoxic clastic mud, fine carbonate beach sand, and stream sediment.

**EFFECT OF MATERIAL ON PLANTS or ANIMALS:** No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities.

**EFFECT OF CHEMICAL ON AQUATIC LIFE:** Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

#### GLYCERIN:

EC<sub>0</sub> (*Pseudomonas putida* bacteria) 16 hours = >10,000 mg/L

EC<sub>0</sub> (*Microcystis aeruginosa* algae) 8 days = 2,900 mg/L

EC<sub>0</sub> (*Scenedesmus quadricauda* green algae) 7 days = > 10,000 mg/L

EC<sub>0</sub> (*Entosiphon sulcatum* protozoa) 72 hours = 3,200 mg/L

#### GLYCERIN (continued):

EC<sub>0</sub> (*Uronema parduczi* Chatton-Lwoff protozoa) = > 10,000 mg/L

LC<sub>50</sub> (goldfish) 24 hours = > 5,000 mg/l

#### STEARIC ACID:

Lethal Dose (goldfish) 14 mg/L (sodium salt)

LC<sub>50</sub> (*Oryzias latipes* Red killifish) 96 hours = 125 mg/L (sodium salt)

**ENVIRONMENTAL EXPOSURE CONTROLS:** Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

**OTHER ADVERSE EFFECTS:** No component of this product is known to have ozone depletion potential.

## 13. DISPOSAL CONSIDERATIONS

**DISPOSAL METHODS:** It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.

**DISPOSAL CONTAINERS:** Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

**PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING:** Wear proper protective equipment when handling waste materials.

**PREPARING WASTES FOR DISPOSAL:** Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

**U.S. EPA WASTE NUMBER:** Not applicable to wastes consisting only of this product.

## 14. TRANSPORTATION INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:** This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

**TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS:** This product is not classified as Dangerous Goods, per regulations of Transport Canada.

## 15. REGULATORY INFORMATION

### UNITED STATES REGULATIONS:

**U.S. SARA REPORTING REQUIREMENTS:** The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

# Nycomed US Inc.

## 15. REGULATORY INFORMATION (Continued)

### UNITED STATES REGULATIONS (continued):

**U.S. SARA THRESHOLD PLANNING QUANTITY:** There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

**U.S. CERCLA REPORTABLE QUANTITIES (RQ):** Not applicable.

**U.S. TSCA INVENTORY STATUS:** This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.

**CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):** The components of this product are not on the California Proposition 65 lists.

**OTHER U.S. FEDERAL REGULATIONS:** Not applicable.

**ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):** **CAUTION! MAY CAUSE ALLERGIC SKIN AND RESPIRATORY REACTION. MAY CAUSE SKIN AND EYE IRRITATION.** Avoid prolonged or repeated contact with skin and clothing. Avoid contact with eyes. Wash thoroughly after handling. Wear gloves, safety glasses, and appropriate body protection during handling or administration. **FIRST-AID:** In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting, seek immediate medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO<sub>2</sub>, or "alcohol" foam. **IN CASE OF SPILL:** Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

### CANADIAN REGULATIONS:

**CANADIAN DSL/NDSL INVENTORY STATUS:** This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempt from requirements of the DSL/NDSL Inventory.

**CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:** The components of this product are not on the CEPA Priorities Substances Lists.

**OTHER CANADIAN REGULATIONS:** Not applicable.

**CANADIAN WHMIS CLASSIFICATION AND SYMBOLS:** Not applicable.

## 16. OTHER INFORMATION

This Material Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Nycomed US Inc.'s knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

**PREPARED BY:** CHEMICAL SAFETY ASSOCIATES, Inc.  
PO Box 3519, La Mesa, CA 91944-3519  
800/441-3365 • 619/670-0609

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### **DEFINITION OF TERMS**

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

**CAS #:** This is the Chemical Abstract Service Number that uniquely identifies each constituent.

#### **EXPOSURE LIMITS IN AIR:**

**CEILING LEVEL:** The concentration that shall not be exceeded during any part of the working exposure.

**DFG MAK Germ Cell Mutagen Categories:** **1:** Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed humans. **2:** Germ cell mutagens that have been shown to increase the mutant frequency in the progeny of exposed mammals. **3A:** Substances that have been shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form. **3B:** Substances that are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but that are clearly mutagenic *in vitro* and structurally related to known *in vivo* mutagens. **4:** Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.) **5:** Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

#### **EXPOSURE LIMITS IN AIR (continued):**

**DFG MAK Pregnancy Risk Group Classification:** **Group A:** A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can lead to damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A-C is not yet possible because, although the data available may indicate a trend, they are not sufficient for final evaluation.

**IDLH:** Immediately Dangerous to Life and Health. This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

**LOQ:** Limit of Quantitation.

**MAK:** Federal Republic of Germany Maximum Concentration Values in the workplace.

**NE:** Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

**NIC:** Notice of Intended Change.

**NIOSH CEILING:** The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

## DEFINITION OF TERMS (Continued)

### EXPOSURE LIMITS IN AIR (continued):

**NIOSH RELs:** NIOSH's Recommended Exposure Limits.

**PEL:** OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL" is placed next to the PEL that was vacated by Court Order.

**SKIN:** Used when there is a danger of cutaneous absorption.

**STEL:** Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

**TLV:** Threshold Limit Value. An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

**TWA:** Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

**WEEL:** Workplace Environmental Exposure Limits from the AIHA.

### HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS:

This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

**HEALTH HAZARD: 0 Minimal Hazard:** No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation:* Essentially non-irritating. Mechanical irritation may occur. PII or Draize = 0. *Eye Irritation:* Essentially non-irritating, minimal effects clearing in < 24 hours. Mechanical irritation may occur. Draize = 0. *Oral Toxicity LD<sub>50</sub> Rat:* > 5000 mg/kg. *Dermal Toxicity LD<sub>50</sub> Rat or Rabbit:* > 2000 mg/kg. *Inhalation Toxicity 4-hrs LC<sub>50</sub> Rat:* > 20 mg/L. **1 Slight Hazard:** Minor reversible injury may occur; may irritate the stomach if swallowed; may defat the skin and exacerbate existing dermatitis. *Skin Irritation:* Slightly or mildly irritating. PII or Draize > 0 < 5. *Eye Irritation:* Slightly to mildly irritating, but reversible within 7 days. Draize > 0 ≤ 25. *Oral Toxicity LD<sub>50</sub> Rat:* > 500–5000 mg/kg. *Dermal Toxicity LD<sub>50</sub> Rat or Rabbit:* > 1000–2000 mg/kg. *Inhalation Toxicity LC<sub>50</sub> 4-hrs Rat:* > 2–20 mg/L. **2 Moderate Hazard:** Temporary or transitory injury may occur; prolonged exposure may affect the CNS. *Skin Irritation:* Moderately irritating; primary irritant; sensitizer. PII or Draize ≥ 5, with no destruction of dermal tissue. *Eye Irritation:* Moderately to severely irritating; reversible corneal opacity; corneal involvement or irritation clearing in 8–21 days. Draize = 26–100, with reversible effects. *Oral Toxicity LD<sub>50</sub> Rat:* > 50–500 mg/kg. *Dermal Toxicity LD<sub>50</sub> Rat or Rabbit:* > 200–1000 mg/kg. *Inhalation Toxicity LC<sub>50</sub> 4-hrs Rat:* > 0.5–2 mg/L. **3 Serious Hazard:** Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation:* Severely irritating and/or corrosive; may cause destruction of dermal tissue, skin burns, and dermal necrosis. PII or Draize > 5–8, with destruction of tissue. *Eye Irritation:* Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD<sub>50</sub> Rat:* > 1–50 mg/kg. *Dermal Toxicity LD<sub>50</sub> Rat or Rabbit:* > 20–200 mg/kg. *Inhalation Toxicity LC<sub>50</sub> 4-hrs Rat:* > 0.05–0.5 mg/L. **4 Severe Hazard:** Life-threatening; major or permanent damage may result from single or repeated exposures; extremely toxic; irreversible injury may result from brief contact. *Skin Irritation:* Not appropriate. Do not rate as a 4, based on skin irritation alone. *Eye Irritation:* Not appropriate. Do not rate as a 4, based on eye irritation alone. *Oral Toxicity LD<sub>50</sub> Rat:* ≤ 1 mg/kg. *Dermal Toxicity LD<sub>50</sub> Rat or Rabbit:* ≤ 20 mg/kg. *Inhalation Toxicity LC<sub>50</sub> 4-hrs Rat:* ≤ 0.05 mg/L.

**FLAMMABILITY HAZARD: 0 Minimal Hazard:** Materials that will not burn in air when exposure to a temperature of 815.5°C (1500°F) for a period of 5 minutes. **1 Slight Hazard:** Materials that must be pre-heated before ignition can occur. Material requires considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. This usually includes the following: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C (200°F) (i.e. OSHA Class IIIB); and Most ordinary combustible materials (e.g. wood, paper, etc.). **2 Moderate Hazard:** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres with air. This usually includes the following: Liquids having a flash-point at or above 37.8°C (100°F); Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp); and Solids and semisolids (e.g. viscous and slow flowing as asphalt) that readily give off flammable vapors. **3 Serious Hazard:** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions. This usually includes the following: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 38°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. OSHA Class IB and IC);

### HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

**FLAMMABILITY HAZARD: 3 (continued)** Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air (e.g., dusts of combustible solids, mists or droplets of flammable liquids); and Materials that burn extremely rapidly, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). **4 Severe Hazard:** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and that will burn readily. This usually includes the following: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. OSHA Class IA); and Materials that ignite spontaneously when exposed to air at a temperature of 54.4°C (130°F) or below (pyrophoric).

**PHYSICAL HAZARD: 0 Water Reactivity:** Materials that do not react with water. *Organic Peroxides:* Materials that are normally stable, even under fire conditions and will not react with water. *Explosives:* Substances that are Non-Explosive. *Compressed Gases:* No Rating. *Pyrophorics:* No Rating. *Oxidizers:* No 0 rating. *Unstable Reactives:* Substances that will not polymerize, decompose, condense, or self-react. **1 Water Reactivity:** Materials that change or decompose upon exposure to moisture. *Organic Peroxides:* Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy violently. *Explosives:* Division 1.5 & 1.6 explosives. Substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases:* Pressure below OSHA definition. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group III oxidizers; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives:* Substances that may decompose, condense, or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosion hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors. Substances that readily undergo hazardous polymerization in the absence of inhibitors. **2 Water Reactivity:** Materials that may react violently with water. *Organic Peroxides:* Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives:* Division 1.4 explosives. Explosive substances where the explosive effects are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases:* Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group II oxidizers. Solids: any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. Liquids: any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives:* Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential (or low risk) for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature. **3 Water Reactivity:** Materials that may form explosive reactions with water. *Organic Peroxides:* Materials that are capable of detonation or explosive reaction, but require a strong initiating source or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives:* Division 1.3 explosives. Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases:* Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group I oxidizers. Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. Liquids: any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives:* Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a moderate potential (or moderate risk) to cause significant heat generation or explosion. **4 Water Reactivity:** Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides:* Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives:* Division 1.1 & 1.2 explosives. Explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases:* No Rating. *Pyrophorics:* Add to the definition of Flammability 4. *Oxidizers:* No 4 rating. *Unstable Reactives:* Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure and have a high potential (or high risk) to cause significant heat generation or explosion.

## DEFINITION OF TERMS (Continued)

### NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

**HEALTH HAZARD: 0** Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials. Gases and vapors with an LC<sub>50</sub> for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC<sub>50</sub> for acute inhalation toxicity greater than 200 mg/L. Materials with an LD<sub>50</sub> for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD<sub>50</sub> for acute oral toxicity greater than 2000 mg/kg. Materials essentially non-irritating to the respiratory tract, eyes, and skin. **1** Materials that, under emergency conditions, can cause significant irritation. Gases and vapors with an LC<sub>50</sub> for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC<sub>50</sub> for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD<sub>50</sub> for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD<sub>50</sub> for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **2** Materials that, under emergency conditions, can cause temporary incapacitation or residual injury. Gases with an LC<sub>50</sub> for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC<sub>50</sub> for acute inhalation toxicity, if its LC<sub>50</sub> is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC<sub>50</sub> for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD<sub>50</sub> for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. Materials whose LD<sub>50</sub> for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. **3** Materials that, under emergency conditions, can cause serious or permanent injury. Gases with an LC<sub>50</sub> for acute inhalation toxicity greater than 1,000 ppm but less than or equal to 3,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than its LC<sub>50</sub> for acute inhalation toxicity, if its LC<sub>50</sub> is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Dusts and mists with an LC<sub>50</sub> for acute inhalation toxicity greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials with an LD<sub>50</sub> for acute dermal toxicity greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials corrosive to the skin. Cryogenic gases that cause frostbite and irreversible tissue damage. Compressed liquefied gases with boiling points below -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials with an LD<sub>50</sub> for acute oral toxicity greater than 5 mg/kg but less than or equal to 50 mg/kg. **4** Materials that, under emergency conditions, can be lethal. Gases with an LC<sub>50</sub> for acute inhalation toxicity less than or equal to 1,000 ppm. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than ten times its LC<sub>50</sub> for acute inhalation toxicity, if its LC<sub>50</sub> is less than or equal to 1000 ppm. Dusts and mists whose LC<sub>50</sub> for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD<sub>50</sub> for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD<sub>50</sub> for acute oral toxicity is less than or equal to 5 mg/kg.

**FLAMMABILITY HAZARD: 0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur. Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D of NFPA 704. Liquids, solids, and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendations on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85% by weight. Liquids that have no fire point when tested by ASTM D 92, *Standard Test Method for Flash and Fire Points by Cleveland Open Cup*, up to the boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Most ordinary combustible materials. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air. Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures with air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal, and hemp.

### NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

**FLAMMABILITY HAZARD (continued): 2 (continued):** Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions. Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily. Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air. Solids containing greater than 0.5% by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

**INSTABILITY HAZARD: 0** Materials that in themselves are normally stable, even under fire conditions. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures. Materials that have an instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures. Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater.

### FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). **Flash Point:** Minimum temperature at which a liquid gives off sufficient vapor to form an ignitable mixture with air near the surface of the liquid or within the test vessel used. **Autoignition Temperature:** Minimum temperature of a solid, liquid, or gas required to initiate or cause self-sustained combustion in air with no other source of ignition. **LEL:** Lowest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame. **UEL:** Highest concentration of a flammable vapor or gas/air mixture that will ignite and burn with a flame.

### TOXICOLOGICAL INFORMATION:

**Human and Animal Toxicology:** Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. **LD<sub>50</sub>:** Lethal Dose (solids & liquids) that kills 50% of the exposed animals. **LC<sub>50</sub>:** Lethal Concentration (gases) that kills 50% of the exposed animals. **ppm:** Concentration expressed in parts of material per million parts of air or water. **mg/m<sup>3</sup>:** Concentration expressed in weight of substance per volume of air. **mg/kg:** Quantity of material, by weight, administered to a test subject, based on their body weight in kg. **TDLo:** Lowest dose to cause a symptom. **ICLo:** Lowest concentration to cause a symptom. **TDo, LDLo, and LDo, or TC, TCo, LCoLo, and LCo:** Lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** **IARC:** International Agency for Research on Cancer. **NTP:** National Toxicology Program. **RTECS:** Registry of Toxic Effects of Chemical Substances. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI:** ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

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## DEFINITION OF TERMS (Continued)

### ECOLOGICAL INFORMATION:

EC: Effect concentration in water. BCE: Bioconcentration Factor, which is used to determine if a substance will concentrate in life forms that consume contaminated plant or animal matter. TLM: Median threshold limit. log K<sub>ow</sub> or log K<sub>oc</sub>: Coefficient of Oil/Water Distribution is used to assess a substance's behavior in the environment.

### REGULATORY INFORMATION:

#### U.S.:

EPA: U.S. Environmental Protection Agency. ACGIH: American Conference of Governmental Industrial Hygienists, a professional association that establishes exposure limits. OSHA: U.S. Occupational Safety and Health Administration. NIOSH: National Institute of Occupational Safety and Health, which is the research arm of OSHA. DOT: U.S. Department of Transportation. TC: Transport Canada. SARA: Superfund Amendments and Reauthorization Act. TSCA: U.S. Toxic Substance Control Act. CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act. Marine Pollutant status according to the DOT; CERCLA or Superfund; and various state regulations. This section also includes information on the precautionary warnings that appear on the material's package label.

#### CANADA:

WHMIS: Canadian Workplace Hazardous Materials Information System. TC: Transport Canada. DSL/NDL: Canadian Domestic/Non-Domestic Substances List.