SAFETY DATA SHEETS

This SDS packet was issued with item:

078914524

N/A

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

Product information

Product Name:	Clindamycin Hydrochloride oral liquid 25 mg/ml
MSDS Number:	122000009871

Use : unfinished drug mixture

Company
BAYER HEALTHCARE LLC
Animal Health Division
12707 Shawnee Mission Parkway
(West 63rd)
Shawnee, KS 66216-1846
USA
(800) 633-3796

In case of emergency: (800) 422-9874
Chemtrec: (800) 424-9300
BAYER INFORMATION PHONE:(800) 633-3796
INTERNATIONAL:(703) 527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

Form: liquid

GHS Classification:

Not a dangerous substance / mixture according to GHS.

GHS Label element:

Not a dangerous substance / mixture according to GHS.

Other hazards which do not result in classification:

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Other Ingredients

Weight percent	Components	CAS-No.
2.2%	Clindamycin HCL (anhydrous)	21462-39-5

4. FIRST AID MEASURES

General advice: Take off all contaminated clothing immediately. Consult a physician if necessary.

If inhaled: Remove to fresh air.

Oxygen or artificial respiration if needed.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water.

After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: Immediately flush eye(s) with plenty of water. If eye irritation persists, consult a specialist.

If swallowed: If the patient is conscious, rinse out mouth with water and have the patient drink a glass of water or milk to dilute the material.

Contact Number: Use the Bayer Emergency Number in Section 1

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO2)

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment.

Methods for cleaning up: Cover spilt product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labelled, closable containers.

Additional advice: No special precautions required.

Further Accidental Release Notes No special precautions required.

7. HANDLING AND STORAGE

Handling:
Avoid contact with skin, eyes and clothing.

No special protective measures against fire required.

Storage:
Store at temperatures and conditions as indicated on the product label.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Trade secret
US. AIHA Workplace Environmental Exposure Level (WEEL) Guides
Time Weighted Average (TWA): 10 mg/m3 (Aerosol.)

US. ACGIH Threshold Limit Values
Short Term Exposure Limit (STEL): 1,000 ppm
US. NIOSH: Pocket Guide to Chemical Hazards
Recommended exposure limit (REL): 1,000 ppm, 1,900 mg/m3
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
PEL: 1,000 ppm, 1,900 mg/m3

US. ACGIH Threshold Limit Values
Time Weighted Average (TWA): 10 mg/m3
US. NIOSH: Pocket Guide to Chemical Hazards
Recommended exposure limit (REL): 10 mg/m3 (Total)
US. NIOSH: Pocket Guide to Chemical Hazards
Recommended exposure limit (REL): 5 mg/m3 (Respirable.)
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
PEL: 5 mg/m3 (Respirable fraction.)
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
PEL: 15 mg/m3 (Total dust.)

Tradesecret
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

PEL: 5 mg/m3 (Respirable fraction.)
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)
PEL: 15 mg/m3 (Total dust.)

Respiratory protection:
not required

Hand protection:
Chemically resistant gloves.

Eye protection:
Safety glasses

Safety glasses with side-shields

Other protective measures:
Use general room ventilation.

Please consult label for end-user requirements.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form:	liquid
Colour:	No applicable information is available
Odour:	No applicable information is available
Odour Threshold:	No applicable information is available
Melting point:	No applicable information is available
Boiling point/boiling range:	No applicable information is available
Density:	1 g/cm³
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available
Miscibility with water:	No applicable information is available
Water solubility:	No applicable information is available
pH:	No applicable information is available
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	No applicable information is available
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	No applicable information is available
Explosion limits:	No applicable information is available

10. STABILITY AND REACTIVITY

Conditions to avoid: no data available

Materials to avoid: Oxidizing agents

Hazardous reactions: no data available

Thermal decomposition:

no data available

Hazardous decomposition products:
Carbon monoxide (CO), Carbon dioxide (CO2)

Oxidizing properties:

No statements available.

11. TOXICOLOGICAL INFORMATION

Other information on toxicity:
Tradesecret
Inhalation of vapors causes irritation of the respiratory tract.

Ingestion of large quantities: Vomiting, Abdominal pain, headaches, Dizziness, Diarrhoea, Cyanosis

Other information on toxicity:
Trade secret
Breathing of the fumes may lead to narcotic symptoms.

If inhaled: headaches, Vomiting, Nausea

After absorption of large quantities hypotension, coma, Unconsciousness, respiratory paralysis

Acute oral toxicity:
Tradesecret
LD50 rat: > 2,000 mg/kg
The substance or mixture has no acute oral toxicity

Trade secret
LD50 rat: 22,000 mg/kg
The substance or mixture has no acute oral toxicity

Trade secret
LD50 rat: 10,470 mg/kg
The substance or mixture has no acute oral toxicity
Method: OECD Test Guideline 401

Acute inhalation toxicity:
Tradesecret
LC50 rat, male: > 2.75 mg/l, 4 h
The substance or mixture has no acute inhalation toxicity
Method: Calculation method

Trade secret
LC50 rabbit: > 317 mg/l, 2 h
The substance or mixture has no acute inhalation toxicity

Trade secret
LC50 rat: 124.7 mg/l, 4 h
ca. 65360 ppm, 4 h
The substance or mixture has no acute inhalation toxicity
Method: OECD Test Guideline 403

Acute dermal toxicity:
Tradesecret
LD50 rabbit: > 18,700 mg/kg
The substance or mixture has no acute dermal toxicity

Trade secret
LD50 rabbit: > 5,000 mg/kg
The substance or mixture has no acute dermal toxicity

Trade secret
LD50 rabbit: 15,800 mg/kg
The substance or mixture has no acute dermal toxicity

Skin irritation:
Tradesecret
rabbit
Result: No skin irritation

Trade secret
rabbit
Result: No skin irritation

Trade secret
rabbit
Result: No skin irritation
Method: OECD Test Guideline 404

Eye irritation:
Tradesecret
rabbit
Result: No eye irritation

Trade secret
rabbit
Result: No eye irritation
slight irritation

Trade secret
rabbit
Result: Causes eye irritation.
Method: OECD Test Guideline 405

Sensitisation:
Tradesecret

Patch test on human volunteers did not demonstrate sensitization properties.

Trade secret
Human experience
Result: Does not cause skin sensitization.

guinea pig
Result: Does not cause skin sensitization.

Method: OECD Test Guideline 406

Trade secret
Skin sensitization guinea pig
Result: Does not cause skin sensitization.
Method: Local lymph node test (LLNA)

Subacute, subchronic and prolonged toxicity:
Trade secret
NOEL 50,000 mg/kg, rat Oral, Exposure time 24 month

NOEL 1 mg/l, rat Inhalation, Exposure time 3 month
Number of exposures: once daily

Genotoxicity in vitro:
Tradesecret
Ames test
Result: negative

Trade secret
Ames test Bacteria
Dose: yes
Result: negative
Method: OECD TG 471

Mammalian cells
Result: negative
Method: OECD TG 476

Trade secret
Ames test Salmonella typhimurium
Result: negative
Method: OECD TG 471

Mouse lymphoma assay
Result: negative
Method: OECD TG 476

Genotoxicity in vivo:
Trade secret

Result: negative
Method: OECD TG 478

Trade secret
Chromosome aberration test in vivo, mouse
Result: ambiguous
Method: OECD TG 478

Micronucleus test, mouse
Result: negative
Method: OECD TG 474

Carcinogenicity:
Trade secret
rat:
Exposure time: 2 a
Number of exposures: once daily
Result: negative

Trade secret
Result: Animal testing did not show any carcinogenic effects.

Reproductive toxicity:
Trade secret
Application Route: Oral
rat, female: Test period: 18 d
NOAEL: 1600 mg/kg
Result: Animal testing did not show any effects on fertility.

Trade secret
Application Route: Oral
mouse: NOAEL: 15%
Result: Animal testing did not show any effects on fertility.
Method: OECD Test Guideline 416

Teratogenicity:
Trade secret
rat, male: Number of exposures: once daily
Test period: 15 d
NOAEL: 1600 mg/l
Result: No indication of teratogenic effects.

Trade secret
Application Route: inhalation
rat: NOAEL: 38 mg/l
Result: Animal studies have produced no evidence of harmful effects on development.
Method: OECD TG 414

Carcinogenicity:
No Carcinogenic substances as defined by IARC, NTP and/or OSHA

STOT - single exposure:
no data available

STOT - repeated exposure:
no data available

12. ECOLOGICAL INFORMATION

General advice:
Do not allow to enter surface waters or groundwater.

Toxicity to fish:
Tradesecret
Acute Fish toxicity: LC50 > 5,000 mg/l
Test species: Carassius auratus (goldfish) Duration of test: 24 h

Acute Fish toxicity: LC100 51,000 - 57,000 mg/l
Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Acute Fish toxicity: LC50 > 250 mg/l
Test species: Leuciscus idus (Golden orfe) Duration of test: 48 h

Trade secret
Acute Fish toxicity: LC50 40,613 mg/l
Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

Trade secret
LC50 8,140 mg/l
Test species: Leuciscus idus (Golden orfe) Duration of test: 48 h

Toxicity to daphnia and other aquatic invertebrates:
Tradesecret
EC50 > 10,000 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 24 h

EC0 > 500 mg/l
Test species: Daphnia magna (Water flea) Duration of test: 24 h

Trade secret
LC50 18,340 mg/l
Test species: Ceriodaphnia dubia Duration of test: 48 h

Trade secret
EC50 9,268 - 14,221 mg/l
Test species: Daphnia magna (Water flea)

Toxicity to algae:
Tradesecret
IC5 > 10,000 mg/l
tested on: Scenedesmus quadricauda (Green algae) Duration of test: 7 d

Trade secret
IC50 19,100 mg/l
tested on: Pseudokirchneriella subcapitata (green algae)

Trade secret
Toxic limit concentration 5,000 mg/l
tested on: Scenedesmus quadricauda (Green algae)

Toxicity to bacteria:
Tradesecret
EC5 > 10,000 mg/l
tested on: Pseudomonas putida
Duration of test: 16 h

EC5 3,200 mg/l
tested on: Protozoa
Duration of test: 72 h

Trade secret
NOEC 20,000 mg/l
tested on: Pseudomonas putida
Duration of test: 18 h

Trade secret
Toxic limit concentration 6,500 mg/l
tested on: Pseudomonas putida

Biodegradability:
Tradesecret
63 %, 14 d rapidly biodegradable
Method: OECD Test Guideline 301C

Trade secret
87 - 92 %, 28 d rapidly biodegradable
Method: OECD Test Guideline 301C

Trade secret
rapidly biodegradable

Bioaccumulation:
Tradesecret

Bioaccumulation is unlikely.

Trade secret

Bioconcentration factor (BCF)
0.09

Trade secret

Bioaccumulation is unlikely.

13. DISPOSAL CONSIDERATIONS

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

14. TRANSPORT INFORMATION

Land transport (CFR)
non-regulated

US Sea transport (IMDG)
non-regulated

US Air transport (ICAO / IATA cargo aircraft only)
non-regulated

US Air transport (ICAO / IATA passenger and cargo aircraft)
non-regulated

International IATA	**non-regulated**
IMDG	non-regulated

15. REGULATORY INFORMATION

Other regulations: No statements available.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)
Components
None

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required
Components
None

US. EPA CERCLA Hazardous Substances (40 CFR 302) Components
None

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight percent	Components	CAS-No.
3 - 7%	Tradesecret	
7 - 13%	Trade secret	
5 - 10%	Trade secret	

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Non-Hazardous

16. OTHER INFORMATION

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards and the Global Harmonization Standard

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

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME (AS LABELED): **CLINDAMYCIN HYDROCHLORIDE ORAL LIQUID**

CHEMICAL NAME: Active Ingredient: 7-chloro-6,7,8-trideoxy-6-(1methyl- *trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-α-D-*galacto*-octopyranosidemonohydrochloride

CHEMICAL CLASS: Active Ingredient: Pyran

PRODUCT USE: Animal Antibiotic

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME: Bayer Animal Health

ADDRESS: 12707 Shawnee Mission Parkway
Shawnee Mission, KS 66216

BUSINESS PHONE: 913-268-2000 [08:00 AM - 05:00 PM]

WEB ADDRESS: www.bayeranimalhealth.com

EMERGENCY PHONE: United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
International: 01-703-527-3887 (Chemtrec) [24-hours]

EMAIL: john.sheehan@bayer.com

DATE OF PREPARATION: September 4, 2012

DATE OF REVISION: February 14, 2013/Bayer

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The product is also classified per all applicable requirements of the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION: This product has been classified under current GHS standards.

Classification: Acute Oral Toxicity Cat. 5, Eye Irritation Cat. 2A, STOT (Ingestion) RE Cat. 2

Signal Word: Warning

Hazard Statement Codes: H303, H319, H373

Precautionary Statement Codes: P260, P264, P280, P305 + P351 + P338, P337 + P313, P312, P501

Hazard Symbol/Pictogram: GHS07, GHS08

EMERGENCY OVERVIEW: Product Description: This product is a clear, colorless liquid with a mild alcohol odor. **Health Hazards:** Ingestion may be harmful. Chronic ingestion exposure can result in *Clostridium difficile*-associated diarrhea (CDAD), which may range in severity from mild diarrhea to fatal colitis. Ingestion exposure may result in serious hypersensitivity reactions. May be irritating by skin contact or inhalation. Eye contact may cause burning and more intense irritation. This product may be absorbed via intact skin. Topical preparations of Clindamycin Hydrochloride have resulted in serious hypersensitivity reactions and other systemic effects. **Flammability Hazards:** This product is not normally combustible. Involvement in a fire can cause evaporation of the water, causing it to become combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides and hydrogen chloride). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** This product is not expected to cause significant harm if accidentally released to the terrestrial or aquatic environment; however, all release should be avoided. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/v	LABEL ELEMENTS EU Classification (67/548/EEC) GHS and EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Clindamycin Hydrochloride 7-chloro-6,7,8-trideoxy-6-(1methyl- *trans*-4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-*threo*-α-D-*galacto*-octopyranosidemonohydrochloride	21462-39-5	244-398-6	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Harmful, Irritant Risk Phrase Codes: R36, R48/20 Hazard Symbols: Xn/Xi GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Eye Irritation Cat. 2A, 1, STOT (Ingestion) RE Cat. 2 Hazard Codes: H303, H319, H373 Hazard Symbol/Pictogram: GHS07, GHS08

See Section 16 for full classification information of product and components.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/v	LABEL ELEMENTS EU Classification (67/548/EEC) GHS and EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
EXCIPIENTS				
Ethyl Alcohol	64-17-5	200-578-6	Proprietary	EU (67/548/EEC): Classification: Highly Flammable Risk Phrases: R11 Symbol: F EU/GHS 1272/2008: Classification: Flammable Liquid Cat. 2 Hazard Statement Codes: H225 Hazard Symbols/Pictograms: GHS02
Purified Water, USP	7732-18-5	231-791-2	Proprietary	EU 67/548 Classification Not Applicable EU/GHS 1272/2008 Classification Not Applicable

See Section 16 for full classification information of product and components.

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

4. FIRST-AID MEASURES

IMPORTANT SYMPTOMS AND EFFECTS: Refer to Sections 2 (Hazard Identification) and 11 (Toxicological Information) for acute, chronic or delayed health effects.

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

SKIN EXPOSURE: If contact with this product results in adverse effect, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

EYE EXPOSURE: If this product enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

INHALATION: If aerosols of this product are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, give victim up to three glasses of water. 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 emergency medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Skin disorders may be aggravated by exposure to this product.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

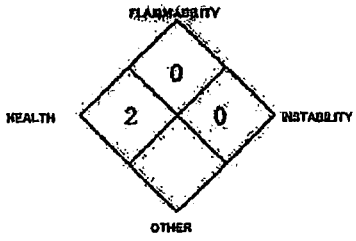
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE PRODUCT: This product is not normally combustible. Involvement in a fire can cause evaporation of the water, causing it to become combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides and hydrogen chloride).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

ADVICE TO FIRE-FIGHTERS: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows and a small scoop to collect glass fragments (if applicable). Absorbents should be incinerable. Finally, the kit should contain two large waste-disposal bags. Avoid generating aerosols from this product.

6. ACCIDENTAL RELEASE MEASURES (Continued)

PROTECTIVE EQUIPMENT:

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection should immediately clean spills of less than 5 mL outside a hood.

Large Spills: Use proper protective equipment, including double nitrile or appropriate gloves, protective clothing (i.e. Tyvek coveralls), and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Spills: The spilled product should be gently covered with absorbent pads. Clean spill with pad and dispose of properly. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Spills in Hoods: Decontamination of all interior hood surfaces may be required after the above procedures have been followed. If the HEPA filter of a hood is contaminated, label the unit "Do not use-contaminated" and have trained personnel wearing appropriate protective equipment change and dispose of the filter properly as soon as possible.

Large Spills: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. Restrict access to the spill areas. For spills of amounts larger than 5 mL limit spread by gently covering with absorbent sheets, or spill-control pads or pillows. Be sure not to generate aerosols. The dispersion of aerosols into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

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

7. HANDLING and STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this material should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this material. Appropriate personal protective equipment must be worn (see Section 8, Engineering Controls and Personal Protection). Avoid generation of aerosols.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F) [USP Controlled Room Temperature]. Protect from freezing. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual product; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is an animal pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat or other protective clothing. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water. Dispose of all contaminated disposable items properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Decontaminate work areas routinely to prevent accumulation of product as appropriate.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	TWA mg/m³	STEL mg/m³	IDLH mg/m³	ppm
Clindamycin HCl	21462-39-5	NE	NE	NE	NE	NE	NE	NE	NE
Ethyl Alcohol	64-17-5	NE	1000	1000	NE	1000	NE	1000 (based on 10% of LEL)	DFG MAK: TWA = 500 PEAK = 2•MAK 15 min. average value, 1-hr interval 4 per shift DFG MAK Pregnancy Risk Classification: C DFG MAK Germ Cell Mutagen Category: 5 Carcinogen: MAK-5, TLV-A3
Water	7732-18-5	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

PROTECTIVE EQUIPMENT: *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, including* U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR1910.132), *equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02,* Z94.3-M1982, *Industrial Eye and Face Protectors and* CSA Standard Z195-02, *Protective Footwear). Please reference applicable regulations and standards for relevant details.*

RESPIRATORY PROTECTION: Maintain airborne contaminant concentrations below exposure limits listed above. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. 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 U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

EYE PROTECTION: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

HAND PROTECTION: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

SKIN PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Liquid.
COLOR: Clear, colorless.
ODOR: Mild.
ODOR THRESHOLD: Not available.
MOLECULAR FORMULA: Mixture.
MOLECULAR WEIGHT: Mixture
FREEZING POINT: Not available.
BOILING POINT: Not available.
RELATIVE VAPOR DENSITY (air = 1): Not available.
EVAPORATION RATE (n-BuAc = 1): Not available.
SPECIFIC GRAVITY (water = 1): Not available.
FLAMMABILITY: Not normally flammable or combustible.
VAPOR PRESSURE, mm Hg @ 20°C: Not available.
pH: Not available.
OXIDIZING PROPERTIES: Not an oxidizer.
EXPLOSIVE PROPERTIES: Not applicable.
SOLUBILITY IN WATER: Soluble
OTHER SOLUBILITY: Not available.
COEFFICIENT OF OIL/WATER DISTRIBUTION (PARTITION COEFFICIENT): Not available.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product may be an identification or warning property to identify it in event of an accidental release.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Not reactive. Stable under normal conditions.
DECOMPOSITION PRODUCTS: *Combustion:* Carbon and nitrogen oxides and hydrogen chloride. *Hydrolysis:* None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong acids and other material incompatible with typical medical preparations and materials incompatible with water.
POSSIBILITY OF HAZARDOUS REACTIONS OR POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, incompatible chemicals.

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

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The main routes of occupational exposure to this product are via inhalation and contact with skin or eyes.
INHALATION: If mists or sprays of this compound are inhaled, irritation of the nose and upper respiratory system may occur. Symptoms of such exposure may include sneezing, coughing, and nasal congestion.
CONTACT WITH SKIN or EYES: It is anticipated that this product may irritate contaminated skin. Symptoms of eye contact can include redness, pain, and watering and burning. Prolonged skin contact may cause dermatitis.
SKIN ABSORPTION: Use of the topical formulation of Clindamycin results in absorption of the antibiotic from the skin surface. This product can be absorbed via intact skin and may cause adverse systemic effects by this route of exposure.
INGESTION: Ingestion of this product is not anticipated to be a significant route of occupational exposure. Ingestion of this material (i.e., through poor hygiene practices) may irritate the mouth, throat, and other tissues of the gastrointestinal system. Chronic ingestion can cause serious allergic reaction in susceptible individuals and systemic effects as described under 'Other Potential Health Effects'.
INJECTION: No information available.
OTHER POTENTIAL HEALTH EFFECTS: Therapeutic human use of Clindamycin Hydrochloride products have caused adverse effects including nausea (may be dose-limiting), diarrhea, pseudomembranous colitis, allergic reactions, hepatoxicity, transient neutropenia and eosinophilia and agranulocytosis.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS (continued): Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic Clindamycin.

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Ingestion of large quantities of this product can cause gastrointestinal upset and may cause adverse systemic effects described under 'Other Potential Health Effects'.

Chronic: Effects from chronic exposure may include those described under "Other Potential Health Effects".

TARGET ORGANS: Acute: Occupational Exposure: Skin, eyes, repiratory system. Chronic: Occupational Exposure: Skin, eyes, repiratory system..

TOXICITY DATA: The following data are available for the ingredient of this products. For the Ethyl Alcohol component, only human data and available LD50 Oral Rat and Mouse and LC50 Inhalation Rat and Rabbit data are presented in this SDS. Contact Bayer for information on additional data available.

CLINDAMYCIN HYDROCHLORIDE:

LD_{50} (Oral-Rat) 2193 mg/kg: Behavioral: somnolence (general depressed activity)

LD_{50} (Oral-Mouse) 2539 mg/kg: Behavioral: somnolence (general depressed activity)

LD_{50} (Intraperitoneal-Rat) 745 mg/kg: Behavioral: somnolence (general depressed activity)

LD_{50} (Intraperitoneal-Mouse) 361 mg/kg

LD_{50} (Subcutaneous-Rat) 2618 mg/kg: Behavioral: somnolence (general depressed activity), convulsions or effect on seizure threshold

LD_{50} (Subcutaneous-Mouse) 1038 mg/kg: Behavioral: somnolence (general depressed activity), convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: dyspnea

LD_{50} (Intramuscular-Rat) 273 mg/kg

LD_{50} (Intramuscular-Mouse) 1100 mg/kg: Behavioral: altered sleep time (including change in righting reflex), somnolence (general depressed activity), ataxia

LD_{50} (Intravenous-Mouse) 245 mg/kg: Behavioral: somnolence (general depressed activity), convulsions or effect on seizure threshold

ETHANOL:

Open Irritation Test (Skin-Rabbit) 400 mg: Mild

Standard Draize Test (Skin-Rabbit) 20 mg/24 hours: Moderate

Standard Draize Test (Eye-Rabbit) 500 mg: Severe

Standard Draize Test (Eye-Rabbit) 500 mg/24 hours: Mild

Rinsed with Water (Eye-Rabbit) 100 mg/ seconds: Moderate

TDLo (Oral-Human) 22,500 mg/kg/4 weeks-intermittent: Endocrine: other changes; Blood: other changes

TDLo (Oral-Human) 0.5 mg/kg: Behavioral: changes in psychophysiological tests

TDLo (Oral-Human) 400 mg/kg: Behavioral: alteration of operant conditioning

TDLo (Oral-Human) 0.7 gm/kg/10 minutes: Behavioral: changes in psychophysiological tests

TDLo (Oral-Human) 0.5 gm/kg: Behavioral: somnolence (general depressed activity), changes in psychophysiological tests

TDLo (Oral-Human) 1.4 gm/kg: Behavioral: euphoria, changes in psychophysiological tests; Gastrointestinal: nausea or vomiting

ETHANOL (continued):

TDLo (Oral-Infant) 11,712 µL/kg: Behavioral: general anesthetic; Cardiac: arrhythmias (including changes in conduction); Lungs, Thorax, or Respiration: dyspnea

TDLo (Oral-Child) 14400 mg/kg/30 minutes (intermittent): Behavioral: coma; Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting

TDLo (Oral-Woman) 1200 mg/kg/3 hours: Endocrine: changes in gonadotropins; Endocrine: other changes; Blood: other changes

TDLo (Oral-Woman) 256 gm/kg/12 weeks: Behavioral: hallucinations, distorted perceptions; Endocrine: effect on menstrual cycle

TDLo (Oral-Woman) 0.7 gm/kg: Behavioral: changes in psychophysiological tests

TDLo (Oral-Woman) 41 gm/kg: female 41 week(s) after conception: Reproductive: Effects on Newborn: Apgar score (human only), other neonatal measures or effects, drug dependence

TDLo (Oral-Woman) 250 mg/kg: female 37 week(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo

TDLo (Oral-Woman) 5860 mL/kg: female 3 year(s) pre-mating: 100 day(s) post-birth: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue); Effects on Newborn: behavioral, delayed effects

TDLo (Oral-Man) 3371 µL/kg: Behavioral: altered sleep time (including change in righting reflex), excitement, coma

TDLo (Oral-Man) 700 mg/kg: Behavioral: changes in psychophysiological tests

TDLo (Oral-Man) 50 mg/kg: Gastrointestinal: alteration in gastric secretion, other changes

TDLo (Oral-Man) 1430 µg/kg: Behavioral: changes in motor activity (specific assay), ataxia, antipsychotic

TDLo (Intravenous-Human) 1.6 gm/kg/6 hours: Biochemical: Metabolism (Intermediary): other

TDLo (Intravenous-Human) 0.89 mL/kg: Vascular: regional or general arteriolar constriction, measurement of regional blood flow

TDLo (Intravenous-Man) 0.57 gm/kg: Behavioral: changes in psychophysiological tests

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2
FLAMMABILITY HAZARD	(RED)	0
PHYSICAL HAZARD	(YELLOW)	0

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

ETHANOL (continued):

TDLo (Intravenous-Woman) 8 gm/kg: female 32 week(s) after conception: Reproductive: Effects on Newborn: Apgar score (human only), other neonatal measures or effects

TDLo (Intraarterial-Man) 0.071 mL/kg: Vascular: acute arterial occlusion

TDLo (Intrauterine-Woman) 200 mg/kg: female 6 day(s) pre-mating: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)

TDLo (Multiple Routes-Man) 3660 mg/kg: Endocrine: evidence of thyroid hypofunction

TCLo (Inhalation-Human) 2500 mg/m³/20 minutes: Peripheral Nerve and Sensation: recording from afferent nerve

LDLo (Oral-Child) 2 gm/kg: Lungs, Thorax, or Respiration: other changes; Liver: fatty liver degeneration; Blood: other changes

LDLo (Oral-Human) 1400 mg/kg: Behavioral: sleep, headache; Gastrointestinal: nausea or vomiting

LDLo (Subcutaneous-Infant) 19,440 mg/kg: Behavioral: convulsions or effect on seizure threshold, coma; Nutritional and Gross Metabolic: body temperature decrease

LC_{50} (Inhalation-Rat) 20,000 ppm/10 hours

LC_{50} (Inhalation-Mouse) 39 gm/m³/4 hours

LD_{50} (Oral-Rat) 7060 mg/kg: Lungs, Thorax, or Respiration: other changes

LD_{50} (Oral-Rat) 7 gm/kg

LD_{50} (Oral-Mouse) 3450 mg/kg

CARCINOGENIC POTENTIAL OF COMPONENTS: Long term studies in animals have not been performed with Clindamycin to evaluate carcinogenic potential.

The excipient components of the product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

Ethyl Alcohol: ACGIH TLV-A3 (Confirmed Animal Carcinogen); MAK-5 (substances with Carcinogenic and Genotoxic Effects, the potency of which is considered to be so low that, provided the MAK and BAT values are observed, no significant contribution to cancer risk is to be expected.)

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.

IRRITANCY OF PRODUCT: Skin contact and inhalation may cause irritation. Can cause significant eye irritation.

11. TOXICOLOGICAL INFORMATION (Continued)

SENSITIZATION TO THE PRODUCT: Generalized mild to moderate bumpy skin rashes are the most frequently reported adverse reactions from human therapeutic use. Rashes with blisters, as well as hives, have been observed during drug therapy. Rare instances of erythema multiforme (a reaction that can cause fever, itching, lesions and other symptoms), some resembling Stevens-Johnson syndrome, and a few cases of anaphylactoid reactions have also been reported.

REPRODUCTIVE TOXICITY INFORMATION: This material is rated Pregnancy Risk Category B (Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester).

Mutagenicity: Genotoxicity tests performed included a rat micronucleus test and an Ames Salmonella reversion test. Both tests were negative.

Embryotoxicity/Teratogenicity: Reproduction studies performed in rats and mice using oral doses of Clindamycin up to 600 mg/kg/day (3.2 and 1.6 times the highest recommended adult human dose based on mg/m^2, respectively) or subcutaneous doses of Clindamycin up to 250 mg/kg/day (1.3 and 0.7 times the highest recommended adult human dose based on mg/m^2, respectively) revealed no evidence of teratogenicity.

Reproductive Toxicity: Fertility studies in rats treated orally with up to 300 mg/kg/day (approximately 1.6 times the highest recommended adult human dose based on mg/m^2) revealed no effects on fertility or mating ability.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY IN SOIL: This product has not been tested for mobility in soil. Due to liquid form, it is expected to be mobile.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that some biodegradation will occur to this product; however, no specific information is known.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: This product is not excepted to cause harm to terrestrial or aquatic organisms. This product has not been tested for aquatic toxicity. The following data are available for the Ethyl Alcohol component (only select data are presented-contact Teva for information on additional data).

ETHYL ALCOHOL:

EC_{50} (*Chlorella pyrenoidosa* Green algae; growth inhibition) 48 hours = 9310 mg/L; static

EC_{50} (*Pimephales promelas* fathead minnows) 96 hours = 12.9 g/L; age 30 days old, water hardness 47.3 mg/L ($CaCO_3$), temp 24.3°C, pH 7.60, dissolved oxygen 8.8 mg/L, alkalinity 43.7 mg/L ($CaCO_3$); tank vol: 6.3 L; additions: 3.81 vol/day /Flow-through bioassay

LC_{50} (*Salmo gairdneri* Rainbow trout) 96 hours = 13,000 mg/L at 12°C (95% Confidence limit 12000-16000 mg/L), wt 0.8 g /Static bioassay

OTHER ADVERSE EFFECTS: The components of this product are not known to have ozone depletion potential.

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

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: 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. All protective clothing, 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. 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. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

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.

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

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

15. REGULATORY INFORMATION

ADDITIONAL U.S. 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.

15. REGULATORY INFORMATION (Continued)

ADDITIONAL U.S. REGULATIONS (continued):

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA HAZARD CATEGORIES (SECTION 311/312, 40 CFR 370-21): ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

U.S. CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: Animal medicinal products are regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA.

OTHER U.S. FEDERAL REGULATIONS: Animal medical preparation are regulated under USDA and FDA regulations. Other requirements from the Center for Veterinary Medicine (CVM), and the Food Safety and Inspection Service (FSIS) may be applicable. In addition, this product may meet the definition of an animal feed additive, which then has requirements under U.S. Animal Food Additive Petitions and Generally Recognized as Safe determinations.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The Ethyl Alcohol component is listed on the Proposition 65 Lists, but only when consumed as an alcoholic beverage and not when it is a component in a product used in the workplace. No other component of this product is on the California Proposition 65 lists.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDSL STATUS: This product is regulated under the Veterinary Drug Directorate of Health Canada; it is exempt from the requirements of CEPA.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITY SUBSTANCES LISTS: Components are not on the CEPA substances lists.

OTHER CANADIAN REGULATIONS: This product, when used for treatment of food-product animals, may have requirements under Canadian Single Ingredient Feed Registration regulations. Food residue MRLs may be applicable.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act, including animal medicines.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **WARNING!** MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. MAY BE HARMFUL IF SWALLOWED. INGESTION MAY CAUSE SEVERE ALLERGIC REACTION IN SUSCEPTIBLE PERSONS. CHRONIC INGESTION MAY CAUSE ADVERSE SYSTEMIC EFFECTS. Do not take taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Wear gloves, goggles, and suitable body protection. FIRST-AID: If exposed, seek immediate medical attention. If swallowed, do not induce vomiting. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If ingested, do not induce vomiting. . IN CASE OF FIRE: Use water fog, dry chemical or CO_2, or alcohol foam. IN CASE OF SPILL:
Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION LABELING AND CLASSIFICATION:

- Classification: Acute Oral Toxicity Category 5, Eye Irritation Category 2A, Specific Target Organ Toxicity (Ingestion) Repeated Exposure Category 2
- Signal Word: Warning
- Hazard Statement Codes: H303: May be harmful if swallowed. H319: Causes serious eye irritation. H373: May cause damage to organs (gastrointestinal system) through prolonged or repeated exposure by ingestion.
- Precautionary Statements:
  - Prevention: P260: Do NOT breathe dust. P264: Wash thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection.
  - Response: P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. P337 + P313: If eye irritation persists: Get medical advice/attention. P312: Call a POISON CENTER or doctor if you feel unwell.
  - Storage: None
  - Disposal: P501: Dispose of contents/containers in accordance with all local, regional, national and international regulations.
- Hazard Symbol/Pictograms: GHS07, GHS08

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION:

CLINDAMYCIN HYDROCHLORIDE: The following is a Self-Classification.

- Classification: Acute Oral Toxicity Category 5, Eye Irritation Category 2A, Specific Target Organ Toxicity (Ingestion) Repeated Exposure Category 2
- Hazard Statement Codes: H303: May be harmful if swallowed. H319: Causes serious eye irritation. H373: May cause damage to organs (gastrointestinal system) through prolonged or repeated exposure by ingestion.

16. OTHER INFORMATION (Continued)

CLASSIFICATION FOR COMPONENTS (continued):

FULL TEXT GLOBAL HARMONIZATION (continued):

ETHYL ALCOHOL:

Classification: Flammable Liquid Category 2

Hazard Statements: H225: Highly flammable liquid and vapor.

ALL OTHER COMPONENTS:

An official classification for these substances has not been published.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721-1961 • (800) 441-3365
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DEFINITIONS OF TERMS

For information on medical terms used in this SDS consult an on-line database such as Medline Plus: http://www.nlm.nih.gov/medlineplus/druginformation.html.
A large number of abbreviations and acronyms appear on a SDS. 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.

ACGIH - American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed humans. 2: Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed mammals. 3A: Substances which 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 which 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 which 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.

NIOSH RELs: NIOSH's Recommended Exposure Limits.

PEL-Permissible Exposure Limit: 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 a there is a danger of cutaneous absorption.

STEL-Short Term Exposure Limit: 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: 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.

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. PII or Draize = "0". *Eye Irritation*: Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = "0". *Oral Toxicity LD_{50} Rat*: < 5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: < 2000 mg/kg. *Inhalation Toxicity 4-hrs LC_{50} Rat*: < 20 mg/L.); 1 (Slight Hazard: Minor reversible injury may occur; slightly or mildly irritating. *Skin Irritation*: Slightly or mildly irritating. *Eye Irritation*: Slightly or mildly irritating. *Oral Toxicity LD_{50} Rat*: > 500-5000 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 1000-2000 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 2-20 mg/L); 2 (Moderate Hazard: Temporary or transitory injury may occur. *Skin Irritation*: Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. *Eye Irritation*: Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, ≤ 25. *Oral Toxicity LD_{50} Rat*: > 50-500 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 200-1000 mg/kg. *Inhalation Toxicity LC_{50} 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 destroy dermal tissue, cause skin burns, 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_{50} Rat*: > 1-50 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: > 20-200 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: > 0.05-0.5 mg/L.); 4 (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. *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_{50} Rat*: ≤ 1 mg/kg. *Dermal Toxicity LD_{50} Rat or Rabbit*: ≤ 20 mg/kg. *Inhalation Toxicity LC_{50} 4-hrs Rat*: ≤ 0.05 mg/L)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

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 require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur, including: 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] (e.g. OSHA Class IIIB, or; 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 in air, including: 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; Solids and semisolids 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, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] (e.g. OSHA Class IB and IC); 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]; 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 which will burn readily, including: 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] (e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below [e.g. 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. *Unstable Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No "0" rating allowed. *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. *Explosives*: Division 1.5 & 1.6 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. 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 explosive hazard. 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 – Explosive substances where the explosive effect 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*: Packing Group II 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. *Unstable Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential 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 1.2 – 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*: Packing Group I 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 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-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 to cause significant heat generation or explosion.).

DEFINITIONS 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 whose LC_{50} for acute inhalation toxicity is greater than 10,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 200 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 2000 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 2000 mg/kg. Materials that are essentially non-irritating to the respiratory tract, eyes and skin. 1 (materials that, under emergency conditions, can cause significant irritation): Gases and vapors whose LC_{50} for acute inhalation toxicity is greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 10 mg/L but less than or equal to 200 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 500 mg/kg but less than or equal to 2000 mg/kg. Materials that cause slight to moderate irritation to the respiratory tract, eyes and skin. 2 (materials that, under emergency conditions, can cause temporary incapacitation or residual injury): Gases and vapors whose LC_{50} for acute inhalation toxicity is greater than 3,000 ppm but less than or equal to 5,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 2 mg/L but less than or equal to 10 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 200 mg/kg but less than or equal to 1000 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} 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. 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. 3 (materials that, under emergency conditions, can cause serious or permanent injury): Gases and vapors whose LC_{50} for acute inhalation toxicity is greater than 1,000 ppm but less than or equal to 3,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials whose LD_{50} for acute dermal toxicity is greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials whose LD_{50} for acute oral toxicity is greater than 5 mg/kg but less than or equal to 50 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials that are respiratory irritants. Cryogenic gases that cause frostbite and irreversible tissue damage. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials that are corrosive to the skin. 4 (materials that, under emergency conditions, can be lethal): Gases and vapors whose LC_{50} for acute inhalation toxicity less than or equal to 1,000 ppm. Dusts and mists whose LC_{50} for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD_{50} for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD_{50} for acute oral toxicity is less than or equal to 5 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC_{50} for acute inhalation toxicity, if its LC_{50} is less than or equal to 1000 ppm.

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 according with Annex D. 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. 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 *Recommendation 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 percent 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 a 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). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. Most ordinary combustible materials. 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 in air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5 percent 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 (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 a 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 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD (continued): 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 percent 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 estimated 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 estimated 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 estimated 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 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. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures.

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 vapors to form an ignitable mixture with air. Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition. LEL - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. UEL - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

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. Definitions of some terms used in this section are: LD_{50} - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; LC_{50} - Lethal Concentration (gases) which kills 50% of the exposed animals; ppm concentration expressed in parts of material per million parts of air or water; mg/m^3 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. Other measures of toxicity include TDLo, the lowest dose to cause a symptom and TCLo the lowest concentration to cause a symptom; TDo, LDLo, and LDo, or TC, TCo, LCLo, and LCo, the lowest dose (or concentration) to cause lethal or toxic effects. Cancer Information: The sources are: IARC - the International Agency for Research on Cancer; NTP - the National Toxicology Program, RTECS - the Registry of Toxic Effects of Chemical Substances, OSHA and CAL/OSHA. 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.

REPRODUCTIVE TOXICITY INFORMATION:

A mutagen is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical which 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 which causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance which interferes in any way with the reproductive process.

ECOLOGICAL INFORMATION:

EC is the effect concentration in water. BCF = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. TL_m = median threshold limit; Coefficient of Oil/Water Distribution is represented by log K_{ow} or log K_{oc} and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

ACGIH: American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

This section explains the impact of various laws and regulations on the material. EPA is the U.S. Environmental Protection Agency, NIOSH is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (OSHA). WHMIS is the Canadian Workplace Hazardous Materials Information System. DOT and TC are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic/Non-Domestic Substances List (DSL/NDSL); the U.S. Toxic Substance Control Act (TSCA); Marine Pollutant status according to the DOT; the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund); and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label; OSHA - U.S. Occupational Safety and Health Administration.