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: **AMOXICILLIN TABLETS**
AMOXICILLIN CHEWABLE TABLETS
AMOXICILLIN CAPSULES
AMOXICILLIN FOR ORAL SUSPENSION

CHEMICAL NAME: For Active Ingredient: (2S,5R,6R)-6-[(R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate

THERAPEUTIC CLASS: Antibiotic
HOW SUPPLIED: Tablets, Chewable Tablets, Capsules, Powder for Suspension
PRODUCT USE: Pharmaceutical for Human Use

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME: **TEVA**
ADDRESS: 1090 Horsham Road
North Wales, PA 19454
BUSINESS PHONE: 215-591-3000 [08:00 AM --> 05:00 PM]
EUROPEAN CONTACT: **TEVA/TAPI**
ADDRESS: Sicor sri-Via Terrazzano
77-20017 Cho (MI), Italy
BUSINESS PHONE: +39 02 93197 306 [08:00 AM --> 05:00 PM]

EMERGENCY PHONE: United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
EMAIL: TevaSDSRequest@tevapharm.com
DATE OF PREPARATION: May 29, 2013
DATE OF REVISION: January 20, 2016

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EMERGENCY OVERVIEW: Product Description: This product supplied as tablets, chewable tablets, capsules and powder for oral suspension. **Health Hazards:** In the workplace, dusts from the product may cause irritation of contaminated skin or eyes. Non-therapeutic ingestion may be harmful. In therapeutic use, the most common adverse effects reported were diarrhea, rash, vomiting, and nausea. Long-term ingestion can cause severe diarrhea due to overgrowth of *clostridium difficile* bacteria. Long-term use can lead to super-infections from drug-resistant bacteria and fungal pathogens. Ingestion can cause serious allergic reactions in susceptible individuals. Hypersensitivity to penicillins may cause rash and serious, potentially fatal reactions including anaphylaxis. Some reports of sensitization effects via skin contact and inhalation are available. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects. **Flammability Hazards:** This product requires substantial pre-heating before ignition occurs. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** Negligible. **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 GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Amoxicillin Trihydrate (2S,5R,6R)-6-[(R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate	61336-70-7	For Freebase: 248-003-8	Proprietary	SELF CLASSIFICATION GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5, STOT (Gastrointestinal System) RE Cat. 2, Skin Sensitization Cat. 1B, Respiratory Sensitization Cat. 1B Hazard Codes: H303, H373, H317, H334 Hazard Symbol/Pictogram: GHS08
EXCIPIENTS - TABLETS				
Flavor	Mixture		Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Aluminum Oxide	1344-28-1	215-691-6	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Colloidal Silicon Dioxide	112945-52-5	Not Listed	Proprietary	SELF-CLASSIFICATION GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: Not Applicable.
Crospovidone	9003-39-8	Not Listed	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Gelatin	9000-70-8	232-554-6	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Hypromellose	9004-65-3	Not Listed	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Lactose Anhydrous	63-42-3	200-559-2	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Lactose Monohydrate	64044-51-5	Anhydrous: 200-559-2	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Magnesium Stearate	557-04-0	209-150-3	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Mannitol	87-78-1	201-770-2	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Methylparaben	99-76-3	202-785-7	Proprietary	SELF CLASSIFICATION EU/GHS 1272/2008: Classification: Reproductive Toxicity Cat. 2, Acute Oral Toxicity Cat. 4 Hazard Statement Codes: H361f, H302 Hazard Symbols/Pictograms: GHS07, GHS08
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Propylene Glycol	25322-68-3	NLP # 500-038-2	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Propylparaben	94-13-3	202-307-7	Proprietary	SELF CLASSIFICATION EU/GHS 1272/2008: Classification: Reproductive Toxicity Cat. 2 Hazard Statement Codes: H361f Hazard Symbols/Pictograms: GHS08
Sodium Benzoate	532-32-1	208-534-8	Proprietary	SELF CLASSIFICATION GHS & EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: None Applicable
Sodium Citrate	68-04-2	200-675-3	Proprietary	GHS & EU 1272/2008 Hazard Classification: Not Applicable
Sodium Lauryl Sulfate	151-21-3	205-788-1	Proprietary	SELF CLASSIFICATION GHS & EU 1272/2008 Classification: Flammable Solids Cat. 2, Acute Oral Toxicity Cat. 4 Hazard Codes: H228, H302 Hazard Symbol/Pictogram: GHS02, GHS07
Sodium Starch Glycolate	9063-38-1	Not Listed	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Sucrose	57-50-1	200-334-9	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.
Titanium Dioxide	13463-67-7	236-675-7	Proprietary	SELF-CLASSIFICATION GHS and EU 1272/2008 Classification: Carcinogenic Cat. 2 Hazard Codes: H351 Hazard Symbol/Pictogram: GHS08
Triacetin	102-76-1	203-051-9	Proprietary	SELF-CLASSIFICATION GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 4 Hazard Codes: H302 Hazard Symbol/Pictogram: GHS07
Xanthan Gum	11138-66-2	234-394-2	Proprietary	GHS & EU 1272/2008: Classification: Not applicable.

Note: Not all excipients in all formulations. No colorants, pigments or dyes included. See Section 16 for full classification information.

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

4. FIRST-AID MEASURES

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Take a copy of this SDS to health professional with victim.

SKIN OR EYE EXPOSURE: Flush affected area with water for 20 minutes.

INHALATION: Remove victim to fresh air.

INGESTION: CALL PHYSICIAN OR POISON CONTROL CENTER. Give victim up to three glasses of water. Do not induce vomiting.

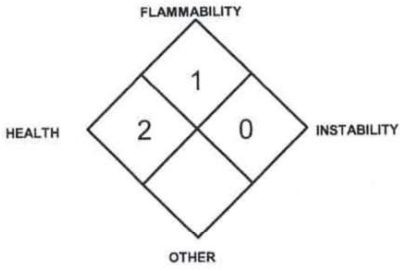
INJECTION: Flush injection site with water.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing renal conditions, or cholestatic jaundice/hepatic dysfunction and digestion system disorders, especially colitis may be aggravated upon 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. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated. Anticonvulsant therapy can be given if clinically indicated in event of seizures.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available.
AUTOIGNITION TEMPERATURE: Not available.
FLAMMABLE LIMITS (in air by volume, %): Not applicable.
FIRE EXTINGUISHING MEDIA: Carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon..
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.
SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides).
Explosion Sensitivity to Mechanical Impact: Not applicable.
Explosion Sensitivity to Static Discharge: Not sensitive.
SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Firefighters are recommended to wear Self-Contained Breathing Apparatus and full protective equipment. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING



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

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits should be kept in or near material handling areas. Avoid generating airborne dusts of this product during spill response procedures.
PROTECTIVE EQUIPMENT:

Small Spills: Nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection.

Large Spills: Double nitrile or other appropriate gloves, protective clothing (i.e., disposable Tyvek coveralls) and eye/face protection. When there is any danger of airborne aerosols being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter or Self-Contained Breathing Apparatus (SCBA).

METHODS FOR CLEAN-UP AND CONTAINMENT:

Small Spills: Clean with wet absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water.

Large Spills: Restrict access to the spill areas. Clean with wet absorbent pads and dispose of properly. Decontaminate the spill area using a bleach and detergent solution and rinse with clean water. Do not apply chemical in-activators as they may produce hazardous by-products.

All Spills: Place all spill residues in an appropriate, labeled container and seal. 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 material and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.
REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup.

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. Do not eat or drink while handling this material. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection).

CONDITIONS FOR SAFE STORAGE: Containers of this material must be properly labeled. Recommended Storage Temperature: 20-25°C (68-77°F). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This material is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear appropriate personal protective equipment.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used.

WORKPLACE EXPOSURE LIMITS/CONTROL PARAMETERS: There are no occupational exposure limits for these products. Information on exposure limits for the active ingredients can be obtained from Teva.

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), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

RESPIRATORY PROTECTION: None needed for normal handling of this product. For large spill response or tasks involving generation of aerosols, use the appropriate High Efficiency Particulate (HEPA) filter or Self-Contained Breathing Apparatus (SCBA).

EYE PROTECTION: Wear splash goggles or safety glasses as appropriate for the task.

HAND PROTECTION: Wear nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response.

SKIN PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.).

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product as a whole.

PHYSICAL FORM: Tablets, capsules, powder.
ODOR: Characteristic of penicillins
MOLECULAR WEIGHT: Mixture.
HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance may be a distinguishing characteristic of this product in event of accidental release.
COLOR: Multiple.
ODOR THRESHOLD: Not available.
MOLECULAR FORMULA: Mixture.

The following information is available for the Amoxicillin Trihydrate active ingredient:

FORM: Crystalline solid.
MOLECULAR WEIGHT: 419.45
ODOR: Characteristic of penicillins.
BOILING POINT @ 760 mmHg: 743.2°C (1369.7°F) [predict.]
VAPOR PRESSURE (air = 1) @ 25°C: 3.39E-23 mmHg [predict.]
EVAPORATION RATE (nBuAc = 1): Not applicable.
FLASH POINT: 403.3°C (757.9°F) [predicted]
SOLUBILITY IN WATER @ 25°C: Partially soluble in hot or cold water.
COEFFICIENT WATER/OIL DISTRIBUTION: Log P: 0.614 (predict.)
COLOR: White to off-white.
MOLECULAR FORMULA: $C_{16}H_{19}N_3O_5S \cdot 3H_2O$
ODOR THRESHOLD: Not available.
MELTING POINT: 194°C (381.2°F)
SPECIFIC GRAVITY (water = 1): Not available.
pH: 3 (1% aqueous solution)
DECOMPOSITION TEMPERATURE: Not available.
OTHER SOLUBILITIES: Not available.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Stable under normal conditions.
DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include carbon and nitrogen oxides. *Hydrolysis:* None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Incompatible with strong oxidizing agents, and strong acids.
POSSIBILITY OF HAZARDOUS REACTION/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 expected routes of occupational exposure to this product are via inhalation of dusts, eye and skin contact. Exposure may cause allergic reaction. Exposure may also cause effects described under 'Other Potential Health Effects'.

INHALATION: Dusts may irritate the nose and upper respiratory system. Symptoms may include sneezing, coughing, and nasal congestion.

CONTACT WITH SKIN or EYES: Mild irritation possible. Symptoms may include itching and redness and swelling.

SKIN ABSORPTION: No information.

INGESTION: May irritate the mouth, throat, and gastrointestinal system.

INJECTION: Not a likely route of exposure.

OTHER POTENTIAL HEALTH EFFECTS: In therapeutic use, the most common adverse effects reported are diarrhea, rash, vomiting, and nausea. Long-term ingestion can cause severe diarrhea due to overgrowth of *clostridium difficile* bacteria. Long-term use can lead to super-infections from drug-resistant bacteria and fungal pathogens. Ingestion can cause serious allergic reactions in susceptible individuals. Hypersensitivity to penicillins may cause rash and serious, potentially fatal reactions including anaphylaxis. Some reports of sensitization effects via skin contact and inhalation are available. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known. Body systems adversely affected during therapeutic use are provided below. More details can be obtained from Teva.

- Central Nervous System
- Gastrointestinal System
- Hemic and Lymphatic Systems
- Hypersensitivity Reactions
- Infections and Infestations
- Liver
- Miscellaneous
- Renal System

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
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

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Dusts from product may cause irritation if inhaled or to the eyes. Accidental ingestion may be harmful or cause allergic reaction.

Chronic: No chronic effects have been reported from workplace exposure. Chronic exposure may also lead to symptoms described under 'Other Potential Health Effects'.

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are:

Acute: Skin, eyes, respiratory system.

Chronic: Skin.

TOXICITY DATA: Details for the active ingredients can be obtained from Teva.

CARCINOGENIC POTENTIAL OF COMPONENTS: Long-term studies in animals have not been performed to evaluate carcinogenic potential. The components found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH are as follows:

CROSPOVIDONE: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

MAGNESIUM STEARATE (as a stearate): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

SUCROSE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

COLLOIDAL SILICON DIOXIDE: ACGIH TLV-A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans); IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

MAGNESIUM STEARATE (as a stearate): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

TITANIUM DIOXIDE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-2B (Possibly Carcinogenic to Humans); MAK-3A (Substances Which Cause Concern that They Could Be Carcinogenic for Man But Cannot Be Assessed Conclusively Because of Lack of Data. Substances for which the criteria for classification in Category 4 or 5 are fulfilled, but for which the database is insufficient for the establishment of a MAK value.); NIOSH-Ca (Potential Occupational Carcinogen with No Further Categorization); Notice of Intended Change: ACGIH TLV-A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans)

IRRITANCY OF PRODUCT: Dusts from this product may be irritating to the respiratory system or eyes.

SENSITIZATION TO THE MATERIAL: In therapeutic use, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy including amoxicillin. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. Possible symptoms of allergic reactions include swelling of face, difficulty breathing, hives, itching, sudden severe drop in blood pressure, headache, vaginal itching or discharge, fever, shortness of breath and joint pain.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of this product in pregnant women; however, when administered therapeutically, this product is not expected to cause fetal harm when administered to a pregnant woman. This product is rated by the FDA for therapeutic risk as **Pregnancy Risk Category B**. Refer to Definition of Terms for full Pregnancy Risk category definitions.

Mutagenicity: Negative in an Ames test.

Embryotoxicity/Teratogenicity: No evidence of fetal harm.

Reproductive Toxicity: No effect on fertility and reproductive performance in rats. Ampicillin-class antibiotics are excreted in human milk. Because there is potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

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

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: Currently, there is no specific information available on the potential mobility of this product.

PERSISTENCE AND BIODEGRADABILITY: Currently, there is no specific information on persistence and biodegradability of this product. Some biodegradation is expected.

BIO-ACCUMULATION POTENTIAL: Currently, no specific information is available on the bioconcentration potential of this product.

ECOTOXICITY: This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No aquatic toxicity data are available for components.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: The components of this product are not listed as having 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.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

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 of classification of 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.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

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

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for 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. CERCLA REPORTABLE QUANTITY (RQ): Not applicable.

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. TSCA INVENTORY STATUS: This product is a "drug" as defined by the Federal Food, Drug and Cosmetic Act (21 USC 321 et. Seq.); therefore, it is not a chemical substance under TSCA (40 CFR 720.3 (e)).

OTHER U.S. FEDERAL REGULATIONS: Regulations of the FDA are applicable to this product.

STATE REGULATIONS: Regulated Medical Waste.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component is listed on the California Proposition 65 Lists.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL/NDSL STATUS: This product is regulated by the Therapeutic Products Programme (TPP) of Health Canada; it is exempt from the requirements of CEPA.

OTHER CANADIAN REGULATIONS: None.

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

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.

ADDITIONAL EUROPEAN REGULATIONS:

SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: Formulated, finished medicinal products for human use, are subject to Directive 2001/83/EC and subsequent amendments to the directive.

CHEMICAL SAFETY ASSESSMENT: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **WARNING!** MAY BE HARMFUL IF SWALLOWED. MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. ACCIDENTAL INGESTION MAY CAUSE SEVERE ALLERGIC REACTIONS. MAY ALSO CAUSE SENSITIZATION VIA SKIN CONTACT AND INHALATION. REPEATED INGESTION MAY CAUSE SYSTEMIC EFFECTS. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES.

Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection.

FIRST-AID: If exposed, seek immediate medical attention. If swallowed, do not induce vomiting; give victim up to three glasses of water. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. If inhaled, remove to fresh air. If not breathing, give artificial respiration or oxygen if necessary.

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 spill debris in a suitable container.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

CLASSIFICATION FOR COMPONENTS:

FULL TEXT GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION:

Amoxicillin Trihydrate: This is a self-classification.

Classification: Acute Oral Toxicity Category 5, Specific Target Organ Toxicity (Gastrointestinal System) Repeated Exposure Category 2, Skin Sensitization Category 1B, Respiratory Sensitization Category 1B

Hazard Statements: H303: May be harmful if swallowed. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H373: May cause damage to gastrointestinal system through prolonged or repeated exposure.

Colloidal Silicon Dioxide, Sodium Benzoate: This is a self-classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if swallowed.

16. OTHER INFORMATION

CLASSIFICATION FOR COMPONENTS (continued):

FULL TEXT GHS & EU 1272/2008 (continued):

Methyl Paraben: This is a self-classification.
Classification: Reproductive Toxicity Category 2, Acute Oral Toxicity Category 4
Hazard Statements: H361f: Suspected of damaging fertility. H302: Harmful if swallowed.

Propyl Paraben: This is a self-classification.
Classification: Reproductive Toxicity Category 2
Hazard Statements: H361f: Suspected of damaging fertility.

Sodium Lauryl Sulfate: This is a self-classification.
Classification: Flammable Solids Category 2, Acute Oral Toxicity Category 4
Hazard Statements: H228: Flammable solid. H302: Harmful if swallowed.

Titanium Dioxide: This is a self-classification.
Classification: Carcinogenic Category 2
Hazard Statements: H351: Suspected of causing cancer.

Triacetin: This is a self-classification.
Classification: Acute Oral Toxicity Category 4
Hazard Statements: H302: Harmful if swallowed.

All Other Components: A classification is not applicable.

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.

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DEFINITIONS OF TERMS

A 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.

Ceiling Level (C). Skin absorption effects must also be considered.

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.

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).

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.];

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): **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 and 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 and 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.).

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_{50} for acute inhalation toxicity greater than 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 200 mg/L. Materials with an LD_{50} for acute dermal toxicity greater than 2000 mg/kg. Materials with an LD_{50} 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_{50} for acute inhalation toxicity greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} 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_{50} 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_{50} for acute inhalation toxicity greater than 3,000 ppm but less than or equal to 5,000 ppm.

DEFINITIONS OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): **2 (continued):** 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. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD_{50} 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_{50} for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Dusts and mists with an LC_{50} for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD_{50} 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_{50} for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. **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. **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.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD: **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 **N**ational **F**ire **P**rotection **A**ssociation (**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 and 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.

United States FDA Pharmaceutical Pregnancy Categories: Pregnancy Category A: Adequate and well-controlled human studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters). **Pregnancy 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. **Pregnancy Category C:** Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category D:** There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category X:** Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits. **Pregnancy Category N:** FDA has not classified this drug.

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. **O**ccupational **S**afety and **H**ealth **A**dministration (**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.

EUROPEAN and INTERNATIONAL:

The DFG: This is the Federal Republic of Germany's Occupation Health Agency, similar to the U.S. OSHA. **EU** is the European Community (formerly known as the **EEC,** European Economic Community). **EINECS:** This is the European Inventory of Now-Existing Chemical Substances. The **ARD** is the European Agreement Concerning the International Carriage of Dangerous Goods by Road and the **RID** are the International Regulations Concerning the Carriage of Dangerous Goods by Rail. **AICS** is the Australian Inventory of Chemical Substances.

SAFETY DATA SHEET

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

Product Identifier

Material Name: Clindamycin Hydrochloride Capsules

Trade Name: Cleocin; Dalacin; SOBELIN; DALACINE ; DALACIN C
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Serious Eye Damage/Eye Irritation: Category 2A
Skin Sensitization: Category 1

Label Elements

Signal Word: Warning
Hazard Statements:
H319 - Causes serious eye irritation
H317 - May cause an allergic skin reaction

Precautionary Statements:
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
P363 - Wash contaminated clothing before reuse

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Clindamycin Hydrochloride	21462-39-5	244-398-6	Eye Irrit. 2A (H319) Skin Sens.1 (H317)	20-30.2
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose	63-42-3	200-559-2	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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

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

Most Important Symptoms and Effects, Both Acute and Delayed

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

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO_2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon, nitrogen, sulfur, and chlorine.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Talc (non-asbestiform)	
ACGIH Threshold Limit Value (TWA)	2 mg/m^3
Australia TWA	2.5 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Belgium OEL - TWA	2 mg/m^3
Bulgaria OEL - TWA	1.0 fiber/cm3
	6.0 mg/m^3
	3.0 mg/m^3
Czech Republic OEL - TWA	2.0 mg/m^3
Denmark OEL - TWA	0.3 fiber/cm3
Finland OEL - TWA	0.5 fiber/cm3
Greece OEL - TWA	10 mg/m^3
	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	0.8 mg/m^3
Lithuania OEL - TWA	2 mg/m^3
	1 mg/m^3
Netherlands OEL - TWA	0.25 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m^3
	1.0 mg/m^3
Portugal OEL - TWA	2 mg/m^3
Romania OEL - TWA	2 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
	10 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Spain OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	2 mg/m^3
	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3
Corn Starch	
ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
Czech Republic OEL - TWA	4.0 mg/m^3
Greece OEL - TWA	10 mg/m^3
	5 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	4 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Slovakia OEL - TWA	4 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3
Clindamycin Hydrochloride	
Pfizer OEL TWA-8 Hr:	100 µg/m^3
Magnesium stearate	

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Capsule	**Color:**	Green (75 mg), Light blue / green (150 mg), light blue (300 mg)
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	No data available.
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Clindamycin Hydrochloride
No data available

Lactose
No data available

Talc (non-asbestiform)
No data available

Magnesium stearate
No data available

Corn Starch
No data available

Decomposition Temperature (°C):	No data available.
Evaporation Rate (Gram/s):	No data available

Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

Known Clinical Effects: Adverse effects associated with therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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

Clindamycin Hydrochloride

Rat Oral LD 50 2618 mg/kg
Rat Sub-tenon injection (eye) LD 50 279mg/kg
Rat Subcutaneous LD 50 891mg/kg
Mouse Oral LD 50 1479mg/kg
Mouse Intravenous LD 50 143mg/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

11. TOXICOLOGICAL INFORMATION

Clindamycin Hydrochloride

Eye Irritation	Rat	No effect
Eye Irritation	Rabbit	Moderate
Skin Irritation	Rat	No effect

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

Clindamycin Hydrochloride

6 Month(s)	Rat	Oral	600 mg/kg/day	NOAEL	No effects at maximum dose
6 Month(s)	Dog	Oral	600 mg/kg/day	LOAEL	Gastrointestinal system
1 Year(s)	Rat	Oral	300 mg/kg/day	NOAEL	No effects at maximum dose
1 Month(s)	Dog	Oral	300 mg/kg/day	NOAEL	No effects at maximum dose

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

Clindamycin Hydrochloride

Reproductive & Fertility	Rat	Oral	300 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Mouse	Oral	600 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	600 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	250 mg/kg/day	NOAEL	Not Teratogenic

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

Clindamycin Hydrochloride

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
In Vitro Micronucleus		Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Talc (non-asbestiform)
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

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

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Lactose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-559-2
Talc (non-asbestiform)	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9
Corn Starch	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

15. REGULATORY INFORMATION

Clindamycin Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	244-398-6

Magnesium stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.5; H303 - May be harmful if swallowed
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction

Data Sources:	Pfizer proprietary drug development information. Safety data sheets for individual ingredients.
Reasons for Revision:	Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.
Revision date:	31-Jul-2018
	Product Stewardship Hazard Communication
Prepared by:	Pfizer Global Environment, Health, and Safety Operations

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

End of Safety Data Sheet

Ibuprofen Tablets 200, 400, 600, 800mg

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 07/10/2012 Revision date: 06/11/2014 Supersedes: 07/10/2012 Version: 2.0

DR. REDDY'S
LIFE. RESEARCH. HOPE

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

1.1. Product identifier

Product form : Mixture

Product name. : Ibuprofen Tablets 200, 400, 600, 800mg

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Dr. Reddy's Laboratories Ltd.
8-2-337 Road No. 3, Banjara Hills
Hyderabad 500-034, - India
T +91-40-49002900 - F +91-40-49002999

1.4. Emergency telephone number

Emergency number : CHEMTREC (24 hrs., 7 days per week): United States: (800) 424-9300 CCN614136

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Acute Tox. 4 (Oral) H302

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :

GHS07

Signal word (GHS-US) : Warning

Hazard statements (GHS-US) : H302 - Harmful if swallowed

Precautionary statements (GHS-US) : P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+P312 - If swallowed, call a doctor if you feel unwell
P330 - If swallowed, rinse mouth
P501 - Dispose of contents/container in accordance with local and national regulations

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixture

Only components with health hazards above the applicable thresholds are shown. Specific composition withheld as trade secret.

Full text of H-phrases: see section 16

Name	Product identifier	%	GHS-US classification
Ibuprofen (main constituent)	(CAS No) 15687-27-1	80 – 90	Acute Tox. 4 (Oral), H302

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation	: If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
First-aid measures after skin contact	: Wash skin with mild soap and water.
First-aid measures after eye contact	: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion	: Rinse mouth. Call a POISON CENTER/doctor/physician if you feel unwell.

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

Symptoms/injuries after inhalation	: Inhalation may cause: irritation, coughing, shortness of breath.
Symptoms/injuries after skin contact	: No significant signs or symptoms indicative of any health hazard are expected to occur as a result of skin contact.
Symptoms/injuries after eye contact	: May cause slight irritation.
Symptoms/injuries after ingestion	: Harmful if swallowed. May be harmful if swallowed in large quantities. Follow all instructions given by your doctor or physician. Symptoms of overexposure may include: asthma, edema, hives, headache, and dizziness.

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

All treatments should be based on observed signs and symptoms of distress in the patient.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Carbon dioxide. Dry powder. Foam. Water spray.
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: No specific fire or explosion hazard.
Explosion hazard	: Product is not explosive.
Reactivity	: No dangerous reactions known.

5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection. Wear a self contained breathing apparatus. Wear fire/flame resistant/retardant clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid creating or spreading dust. Avoid contact with eyes and skin.

6.1.1. For non-emergency personnel

Protective equipment	: Wear suitable protective clothing and gloves. In case of inadequate ventilation wear respiratory protection.
Emergency procedures	: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment	: Wear suitable protective clothing and gloves. Chemical goggles or safety glasses.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Do not discharge into drains or the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Absorb and/or contain spill with inert material, then place in suitable container. Avoid generating dust.
Methods for cleaning up	: Minimize generation of dust. Take up in non-combustible absorbent material and shovel into container for disposal.

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Provide good ventilation in process area to prevent formation of dust. Use personal protective equipment as required.

Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Proper grounding procedures to avoid static electricity should be followed.
Storage conditions	: Keep only in the original container in a cool well ventilated place. Keep container closed when not in use. Do not store near food, foodstuffs, drugs, or potable water supplies.
Incompatible products	: Strong oxidizers. Strong bases. Strong acids.
Incompatible materials	: Sources of ignition.

7.3. Specific end use(s)

Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ibuprofen (15687-27-1)
Dr. Reddy's OEL 1300 µg/m³ (8-hr TWA)

8.2. Exposure controls

Appropriate engineering controls	: Avoid dispersal of dust in the air (ie, clearing dust surfaces with compressed air). Provide local exhaust or general room ventilation to minimize exposure to dust.
Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Wear dust impervious gloves.
Eye protection	: Chemical goggles or safety glasses.
Respiratory protection	: Where excessive dust may result, use approved respiratory protection equipment. Use an air-purifying respirator equipped with particulate filtering cartridges.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Tablets.
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 75 - 77 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: 3.3
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive. Dust may form explosive mixture in air.
Oxidising properties	: No oxidizing properties.
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Avoid creating or spreading dust. Keep away from sources of ignition.

10.5. Incompatible materials

Strong oxidizers. Strong bases. Strong acids. Alkali.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

Ibuprofen Tablets 200, 400, 600, 800mg	
ATE (oral)	500.000 mg/kg bodyweight

ibuprofen (15687-27-1)	
LD50 oral rat	636 mg/kg
LD50 oral mice	740 mg/kg
LD50 oral rabbit	1400 mg/kg
ATE (oral)	636.000 mg/kg bodyweight

Skin corrosion/irritation : Not classified
Ibuprofen - Non-irritating to the skin.

Serious eye damage/irritation : Not classified
Ibuprofen - Slightly irritating to the eyes.

Respiratory or skin sensitisation : Not classified
Ibuprofen - Non-sensitizing in the guinea pig.

Germ cell mutagenicity : Not classified
Ibuprofen - Not mutagenic in the Ames test. Weakly positive in the mouse micronucleus assay.

Carcinogenicity : Not classified
Ibuprofen – Not carcinogenic.

Reproductive toxicity : Not classified
Ibuprofen - Not teratogenic or embryotoxic in rats and rabbits. No effects on male or female fertility in rats.

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

Symptoms/injuries after inhalation : Inhalation may cause: irritation, coughing, shortness of breath.

Symptoms/injuries after skin contact : No significant signs or symptoms indicative of any health hazard are expected to occur as a result of skin contact.

Symptoms/injuries after eye contact : May cause slight irritation.

Symptoms/injuries after ingestion : Harmful if swallowed. May be harmful if swallowed in large quantities. Follow all instructions given by your doctor or physician. Symptoms of overexposure may include: asthma, edema, hives, headache, and dizziness.

SECTION 12: Ecological information

12.1. Toxicity

ibuprofen (15687-27-1)	
LC50 fishes 1	173 mg/l sunfish, bluegill
EC50 Daphnia 1	9.06 mg/l Skeletonema costatum

ibuprofen (15687-27-1)	
EC50 other aquatic organisms 1	20.5 mg/l

12.2. Persistence and degradability

ibuprofen (15687-27-1)	
Persistence and degradability	Not readily biodegradable. Moderately biodegradable.

12.3. Bioaccumulative potential

Ibuprofen Tablets 200, 400, 600, 800mg	
Log Pow	3.3

ibuprofen (15687-27-1)	
Log Pow	3.87 (calculated)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Sewage disposal recommendations : Do not dispose of waste into sewer.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Dispose of container in a licensed facility.

SECTION 14: Transport information

In accordance with DOT

Not considered a dangerous good for transport regulations

Additional information

Other information : No supplementary information available.

ADR

Transport document description : Not applicable

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

ibuprofen (15687-27-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

Ibuprofen Tablets 200, 400, 600, 800mg	
WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects

ibuprofen (15687-27-1)
Listed on the Canadian DSL (Domestic Substances List) inventory.

EU-Regulations

ibuprofen (15687-27-1)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances) substances.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 4 (Oral) H302

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC or 1999/45/EC

Xn; R22

15.2.2. National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

Indication of changes : GHS classification information. Revised sections: 1 - 16.

Data sources : ACGIH 2000.

European Chemicals Agency (ECHA) Registered Substances list. Accessed at http://echa.europa.eu/.

Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition.

National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition.

OSHA 29CFR 1910.1200 Hazard Communication Standard.

TSCA Chemical Substance Inventory. Accessed at http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html.

Abbreviations and acronyms : CLP: Classification, Labelling, Packaging.

ATE: Acute Toxicity Estimate.

CAS (Chemical Abstracts Service) number.

EC50: Environmental Concentration associated with a response by 50% of the test population.

GHS: Globally Harmonized System (of Classification and Labeling of Chemicals).

LD50: Lethal Dose for 50% of the test population.

OSHA: Occupational Safety & Health Administration.

TSCA: Toxic Substances Control Act.

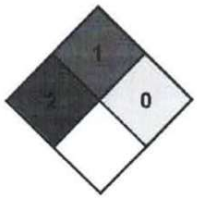
Full text of H-phrases: see section 16:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
H302	Harmful if swallowed

NFPA health hazard : 2 - Intense or continued exposure could cause temporary incapacitation or possible residual injury unless prompt medical attention is given.

NFPA fire hazard : 1 - Must be preheated before ignition can occur.

NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



SDS US (GHS HazCom 2012)

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