SAFETY DATA SHEETS

This SDS packet was issued with item:

078907416

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078907627 078907628

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078907414 078907415 078907417 078907629 078907630

Allergan

T 800 678 1605

Allergan, plc.
100 Enterprise Dr.
Rockaway, NJ 07866
www.Allergan.com

Thank you for your recent request for information concerning Actavis Products and their Safety Data Sheets (SDS).

The intention of the enclosed information is to provide you with available data and information from published scientific and medical literature to assist you in your practice decisions. Some of this information may address off-label uses that are not currently approved by the U.S. Food and Drug Administration (FDA). If you did not request the enclosed information, please report to Allergan's Medical Information department.

An SDS does not exist for the following products and therefore we are unable to provide the documentation requested.

- Atenolol/Chlorthalidone Tablets
- Propranolol Tablets
- Doxycycline Hyclate Capsules
- Hydroxyzine Pamoate Capsules
- Metronidazole Tablets
- Primidone Tablets
- Buspirone Hydrochloride Tablets
- Minocycline Hydrochloride Capsules
- Cyclobenzaprine Hydrochloride Tablets
- Chlorzoxazone Tablets
- Diclofenac Sodium API
- Estradiol Tablets 0.5 mg 100, 1.0 mg 100, 1.0 mg 500, 2.0 mg 100, and 2.0 mg 500
- Metoclopramide Tablets, USP
- Lactulose Syrup / Lactulose Solution USP / EP Grade (No NDC provided)
- Lisinopril Tablets
- Methocarbamol Tablets 500 mg 500, Methocarbamol Tablets 500 mg 500, Methocarbamol Tablets 750 mg 100, and Methocarbamol Tablets 750 mg 100
- Simethicone and Artificial Tears Ointment (No NDC provided)
- Progesterone Capsules

The Occupational Safety and Health Administration (OSHA) exempts Safety Data Sheets (SDS) for drugs regulated by the U.S. Food and Drug Administration (FDA) that are in solid final form, including pills or tablets for direct administration to patients. In addition, drug products packaged by the chemical manufacturer intended for sale at a retail establishment to consumers (e.g., over-the-counter drugs) are exempt, as are drug products intended for personal use by employees at their work place (e.g., first aid supplies).[1]

The above information is being provided in response to your specific inquiry. Allergan, plc. makes no recommendation regarding unapproved uses. The intention is to provide a synopsis of relevant drug and medical information derived from readily available sources. The information provided may not represent all

available information on this topic. Any publication of the provided information or use beyond this intent is prohibited without written authorization from Allergan, plc. As is typical with published scientific and medical literature, some of the information presented in the enclosed or cited references may not conform to the approved labeling for the product(s) mentioned.

Please contact our Medical Communications Department at 1-800-678-1605 should you have any further questions. In addition, product prescribing information is available on the web at www.allergan.com.

Thank you for your interest in Allergan, plc. products.

Sincerely,

Global Medical Scientific Information
Allergan Medical Affairs
(800) 678-1605

Allergan

T 800 678 1605

Allergan, plc.
100 Enterprise Dr.
Rockaway, NJ 07866
www.Allergan.com

Reference:

1. Occupational Safety and Health Standards. Health Communication Statement [Subpart Z, Toxic and Hazardous Substances; 29 CFR 1910.1200(b)(6)(vii)]. Available at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10099. Accessed June 15, 2006.

WATSON Laboratories, Inc.
A Subsidiary of Watson Pharmaceuticals, Inc.

MATERIAL SAFETY DATA SHEET

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

1. PRODUCT IDENTIFICATION

TRADE/MATERIAL NAME: DOXYCYCLINE HYCLATE CAPSULES

Doxycycline Hyclate Capsules 50 mg 50, Doxycycline Hyclate Capsules 100 mg 50, and Doxycycline Hyclate Capsules 100 mg 500

DESCRIPTION: Doxycycline Hyclate Capsules
OTHER DESIGNATIONS: NDC# 00591-5535-50, 00591-5440-50, 00591-5440-05
CHEMICAL NAME: 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6methyl-1,11-dioxi-2-naphthacenecarboxamide Monohydrochloride, Compound with Ethyl Alcohol (2:1), Monohydrate
CHEMICAL FAMILY: Oxytetracycline Derivative
HOW SUPPLIED: 50 mg and 100 mg capsules
FORMULA: $(C_{22}H_{24}N_2O_8 \bullet HCl)_2 \bullet C_2H_6O \bullet H_2O$

PRODUCT USE:	Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER'S NAME:	**WATSON LABORATORIES INC.**
ADDRESS:	311 Bonnie Circle Corona, CA 92880
BUSINESS PHONE/GENERAL MSDS INFORMATION:	1-800-272-5525
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: 1-703-527-3887

2. COMPOSITION and INFORMATION ON INGREDIENTS

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CHEMICAL NAME	CAS #	EINECS #	% w/v	EU CLASSIFICATION FOR COMPONENTS
Doxycycline Hyclate	10592-13-9	234-198-7	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Cellulose	9004-34-6	232-674-9	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
FD & C Blue No. 1	3844-45-9	223-339-8	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Gelatin	9000-70-8	232-554-6	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Magnesium Stearate	557-04-0	209-150-3	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Silicon Dioxide	7631-86-9	231- 545 -4	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Sodium Lauryl Sulfate	151-21-3	205-788-1	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.
Titanium Dioxide	13463-67-7	236-675-5	Proprietary	HAZARD CLASSIFICATION: Not applicable. RISK PHRASES: Not applicable.

See Section 15 for full EU classification information of product and components.
NOTE: ALL Canadian WHMIS required information is included in appropriate sections based on the ANSI Z400.1-1998 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR. The MSDS is also prepared to include all European Union required information under EU Directives.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:

Product Description: This product is supplied as opaque, blue and white (50 mg) capsules and opaque, blue (100 mg) capsules.

Health Hazards: The chief health hazard associated with overexposures during normal use and handling is the potential for irritation of contaminated skin from opened or damaged capsules. Individuals who have had allergic reactions to products containing Doxycycline Hyclate, Tetracyclines, Sodium Lauryl Sulfate, or any of the other ingredients in this product, may experience allergic reactions after exposure to this product. Therapeutic use of Doxycycline Hyclate can cause adverse symptoms of the gastrointestinal system, blood, liver, kidneys, and skin.

Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, sodium oxides, titanium oxides, silicon oxides, magnesium oxides, and hydrogen chloride).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Inhalation of airborne dusts generated by opened or damaged capsules of this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or reaped skin contact may cause dermatitis (dry, red skin). Contact with the eyes of airborne dusts generated by opened or damaged capsules of this product may cause mild to moderate irritation, redness, and tearing.

SKIN ABSORPTION: This product is not known to be absorbed through intact skin.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for "Other Potential Health Effects".

HAZARDOUS MATERIAL IDENTIFICATION SYSTE

HEALTH HAZARD	(BLUE)	2*
FLAMMABLITY 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

INGESTION: Individuals who have had allergic reactions to products containing Doxycycline Hyclate, Tetracyclines, Sodium Lauryl Sulfate, or any of the other ingredients in this product may experience allergic reactions to this product.

INJECTION: Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms from prolonged or repeated exposure may include those described for "Other Potential Health Effects".

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included:

- Loss of appetite, nausea, vomiting, diarrhea, inflamed tongue, difficulty swallowing, inflammation of the small intestine and colon, inflammatory lesions in the anogenital region, inflamed esophagus, esophageal ulcerations, and hepatotoxicity.

(Section continued on next page)

3. HAZARD IDENTIFICATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses (continued):

- Maculopapular rash, erythematous rash, photosensitivity, and exfoliative dermatitis.
- Rise in BUN.
- Hives, angioneurotic edema, anaphylaxis, anaphylactoid purpura, serum sickness, inflamed pericardium, and worsening of systematic lupus erythematosus.
- Hemolytic anemia, neutropenia, eosinophilia, and thrombocytopenia.
- Bulging fontanels in infants and intracranial hypertension in adults.

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

ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin.

CHRONIC: Repeated skin contact may cause dermatitis (dry, red skin). In the event of chronic exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result. See Section 11 (Toxicological Information, for additional information).

TARGET ORGANS: ACUTE: Industrial Exposure: Skin, eyes. Therapeutic Doses: Gastrointestinal system. CHRONIC: Industrial Exposure: Skin. Therapeutic Doses: Gastrointestinal system, blood, liver, kidneys, skin.

4 FIRST-AID MEASURES

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

SKIN EXPOSURE: Basic hygiene should prevent any problems. If the product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes. Victims must seek immediate medical attention, especially if an adverse reaction occurs.

EYE EXPOSURE: If airborne dusts generated by opened or damaged capsules of this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids and then "roll" while flushing eyes. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: If airborne dusts generated by opened or damaged capsules of this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

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

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing Gastrointestinal system, blood, liver, kidneys, and skin conditions may be aggravated by chronic overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):

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

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

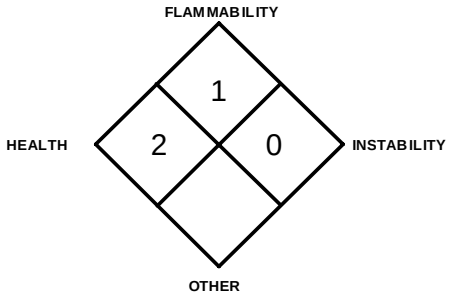
Water Spray: OK	Carbon Dioxide: OK
Dry Chemical: OK	Halon: OK
Foam: OK	Other: Any "ABC" Class

5. FIRE-FIGHTING MEASURES (Continued)

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, sodium oxides, titanium oxides, silicon oxides, magnesium oxides, and hydrogen chloride).

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



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

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

6. ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE: For small releases of this compound (1 bottle), take basic hygiene precautions. Lightweight gloves, a lab coat, and eye protection should be worn. Pick up or sweep up spilled capsules, place in a bag, and hold for waste disposal. Avoid generating airborne dusts of this product during cleanup. In case of a large spill, clear the affected area and protect people. Trained personnel using pre-planned procedures should respond to large or uncontrolled releases (a case of bottles). Proper protective equipment should be used, including lab gloves, full body gown, boots, and splash goggles. Respiratory protection should not be necessary. Pick up or sweep up spilled capsules. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces.

7. HANDLING and USE

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

- Work should be performed in an appropriate, designated area;
- Contaminated waste must be properly handled; and,
- If necessary, work areas must be regularly decontaminated.

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

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

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

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

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR									
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	AIHA WEELs		OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	TWA mg/m^3	STEL mg/m^3	mg/m^3
Doxycycline Hyclate	10592-13-9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Cellulose	9004-34-6	10	NE	10 (total dust) 5 (resp. frac.)	NE	10 (total dust) 5 (resp. frac.)	NE	NE	NE	NE	NE
FD & C Blue No. 1	3844-45-9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gelatin	9000-70-8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate: Limits are for Stearates	557-04-0	10	NE	NE	NE	NE	NE	NE	NE	NE	NE
Silicon Dioxide	7631-86-9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Lauryl Sulfate	151-21-3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Titanium Dioxide	13463-67-7	10	NE	15 (total dust)	NE	Lowest feasible concentration Limit of Quantitation 0.2		NE	NE	NE	NE

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently, there are international exposure limits for components of this product as follows:

CELLULOSE:

Australia: TWA = 10 mg/m^3, JAN 1993
Belgium: TWA = 10 mg/m^3, JAN 1993
France: VME = 10 mg/m^3, JAN 1999
The Netherlands: MAC-TGG = 10 mg/m^3, JAN 1999
Russia: TWA = 2 mg/m^3, STEL = 4 mg/m^3, Skin, JAN 1993
Switzerland: MAK-W = 6 mg/m^3, JAN 1999
United Kingdom: TWA 10 mg/m^3, STEL = 20 mg/m^3, Total Dust, SEP 2000
United Kingdom: TWA 4 mg/m3, Respirable Dust, SEO 2000
In Argentina, Bulgaria, Colombia, Jordan, New Zealand, Singapore, Vietnam check ACGIH TLV

TITANIUM DIOXIDE:

Arab Republic of Egypt: TWA 15 mg/m^3
Australia: TWA 10 mg/m^3
Belgium: TWA 10 mg/m^3
Denmark: TWA 6 mg/m^3
France: TWA 10 mg/m^3
Germany: TWA 6 mg/m^3
The Philippines: TWA 15 mg/m^3
Switzerland: TWA 6 mg/m^3
Turkey: TWA 15 mg/m^3
United Kingdom: TWA 10 mg/m^3 (total dust)
United Kingdom: TWA 5 mg/m^3 (respirable dust)
Bulgaria, Colombia, Jordan, Korea, New Zealand, Singapore, Vietnam check ACGIH TLV

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, and EU member states. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHAs Respiratory Protection Standard (1910.134-1998).

EYE PROTECTION: Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133, the European Standard EN166 and appropriate Standards of Canada for further information.

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

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

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not applicable for product.
FREEZING/MELTING POINT Not established.
EVAPORATION RATE (nBuAc = 1): Not established.
SOLUBILITY IN WATER: Not soluble.
VAPOR PRESSURE (air = 1): Not applicable for product.
SPECIFIC GRAVITY (water = 1): Not applicable.
ODOR THRESHOLD: Not established.
pH: Not established.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

9. PHYSICAL and CHEMICAL PROPERTIES (Continued)

APPEARANCE AND COLOR: This product is supplied as teal blue-colored capsules.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product is a distinguishing characteristic.

10. STABILITY and REACTIVITY

STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, sodium oxides, titanium oxides, silicon oxides, magnesium oxides, and hydrogen chloride).

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

HAZARDOUS POLYMERIZATION: Will not occur.

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

11. TOXICOLOGICAL INFORMATION

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing Doxycycline Hyclate, Tetracyclines, Sodium Lauryl Sulfate, or any of the other ingredients in this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following.

For Males And Females: Loss of appetite, nausea, vomiting, diarrhea, inflamed tongue, difficulty swallowing, inflammation of the small intestine and colon, inflammatory lesions in the anogenital region, inflamed esophagus, esophageal ulcerations, hepatotoxicity, maculopapular rash, erythematous rash, photosensitivity, exfoliative dermatitis, rise in BUN, hives, angioneurotic edema, anaphylaxis, anaphylactoid purpura, serum sickness, inflamed pericardium, worsening of systematic lupus erythematosus, hemolytic anemia, neutropenia, eosinophilia, thrombocytopenia, bulging fontanels in infants, and intracranial hypertension in adults.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue.

SENSITIZATION OF PRODUCT: Individuals who have had allergic reactions to products containing Doxycycline Hyclate, Tetracyclines, Sodium Lauryl Sulfate, or any of the other ingredients in this product may experience allergic reactions to this product.

TOXICITY DATA: Presented are LD_{50} Oral-Rat data currently available for Doxycycline Hyclate, the active component; no human data are available for the active component. Additional data are available for the other components of this product, but are not presented in this MSDS. Contact Watson Pharmaceuticals for more information.

DOXYCYCLINE HYCLATE:

LD_{50} (oral, rat) = 1700 mg/kg: Sense Organs and Special Senses (Eye): ptosis; Behavioral: muscle weakness; Lungs, Thorax, or Respiration: respiratory depression

SUSPECTED CANCER AGENT: Long-term studies in animals to evaluate carcinogenic potential of Doxycycline have not been conducted. However, there has been evidence of oncogenic activity in rats in studies with the related antibiotics, oxytetracycline (adrenal and pituitary tumors) and minocycline (thyroid tumors).

ACGIH lists Titanium Dioxide and Stearates such as Magnesium Stearate as a TLV-A4 (Not Classifiable as Human Carcinogen). IARC lists Titanium Dioxide as an IARC-3 compound (Unclassifiable as to Carcinogenicity in Humans). NIOSH lists Titanium Dioxide as an NIOSH-Ca (Potential occupational carcinogen, with no further categorization). The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system. Doxycycline Hyclate is rated as a Pregnancy Category D (POSITIVE EVIDENCE OR RISK, There is a risk to fetus after drug is administered, but under certain circumstances (e.g., treatment of life-threatening illnesses), the benefits can outweigh the risk). The reproductive effects described are related to therapeutic use of this product and are not reported to occur from industrial handling and exposure.

Mutagenicity: Although mutagenicity studies of Doxycycline have not been conducted, positive results in *in vitro* mammalian cell assays have been reported for related antibiotics (tetracycline, oxytetracycline).

Embryotoxicity: The components of this product are not reported to be embryotoxic to humans in therapeutic doses.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Teratogenicity: An expert review of published data on experiences with Doxycycline use during pregnancy by TERIS—the Teratogen Information System—concluded that therapeutic doses during pregnancy are unlikely to pose a substantial teratogenic risk (the quantity and quality of data were assessed as limited to fair), but the data are insufficient to state that there is no risk. A case-control study (18,515 mothers of infants with congenital anomalies and 32,804 mothers of infants with no congenital anomalies) shows a weak but marginally statistically significant association with total malformations and use of Doxycycline anytime during pregnancy. Sixty-three (0.19%) of the controls and fifty-six (0.3%) of the cases were treated with Doxycycline. This association was not seen when the analysis was confined to maternal treatment during the period of organogenesis (i.e., in the second and third months of gestation) with the exception of a marginal relationship with neural tube defect based on only two exposed cases. A small prospective study of eighty-one pregnancies describes forty-three pregnant women treated for 10 days with Doxycycline during early first trimester. All mothers reported their exposed infants were normal at 1 year of age.

Reproductive Toxicity: Doxycycline administered orally at dosage levels as high as 250 mg/kg/day had no apparent effect on the fertility of female rats.

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

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.

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

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of this product on aquatic plants or animals in the environment. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

13. DISPOSAL CONSIDERATIONS

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

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

14. TRANSPORTATION INFORMATION

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME:	Not Regulated
HAZARD CLASS NUMBER and DESCRIPTION:	Not Applicable
UN IDENTIFICATION NUMBER:	Not Applicable
PACKING GROUP:	Not Applicable
DOT LABEL(S) REQUIRED:	Not Applicable

EMERGENCY RESPONSE GUIDEBOOK NUMBER (2004): Not Applicable

MARINE POLLUTANT: No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

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

14. TRANSPORTATION INFORMATION (Continued)

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

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

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

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

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

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

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The Doxycycline Hyclate component of this product is on the Proposition 65 Lists, as a compound that cause development effects in humans when exposure is by internal use (orally). WARNING: This product contains a chemical known to the State of California to cause developmental toxicity.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE SKIN AND EYE IRRITATION. MAY CAUSE ALLERGIC REACTION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

CANADIAN REGULATIONS:

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

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

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: Class D2B (Materials Causing Other Toxic Effects)

EUROPEAN UNION REGULATIONS:

EU LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EU INFORMATION FOR COMPONENTS:

Cellulose: EU EINECS/ELINCS NUMBER: 232-674-9
EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

Doxycycline Hyclate: EU EINECS/ELINCS NUMBER: 234-198-7.
EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

FD & C Blue No. 1: EU EINECS/ELINCS NUMBER: 223-339-8
EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

Gelatin: EU EINECS/ELINCS NUMBER: 232-554-6
EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

Magnesium Stearate: EU EINECS/ELINCS NUMBER: 209-150-3
EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

15. REGULATORY INFORMATION (Continued)

EUROPEAN UNION REGULATIONS (continued):

EU INFORMATION FOR COMPONENTS (continued):

Silicon Dioxide: EU EINECS/ELINCS NUMBER: 231-545-4

EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

Sodium Lauryl Sulfate: EU EINECS/ELINCS NUMBER: 205-788-1

EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

Titanium Dioxide: EU EINECS/ELINCS NUMBER: 236-675-5

EU CLASSIFICATION: An official classification for this substance has not been published in Commission Directives.

16. OTHER INFORMATION

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

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

DATE OF PRINTING: February 15, 2005

DEFINITION OF TERMS

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

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

EXPOSURE LIMITS IN AIR:

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

DFG MAK 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 cause 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.

EXPOSURE LIMITS IN AIR (continued):

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.);

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

HEALTH HAZARD (continued):

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.]; **2** (Moderate Hazard-Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air, Including: Liquids having a flash-point at or above 37.8°C [100°F]; Solid materials in the form of course dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors.); **3** (Serious Hazard- Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] [e.g. OSHA Class IB and IC]; Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen [e.g. dry nitrocellulose and many organic peroxides]); **4** (Severe Hazard-Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C [73°F] and a boiling point below 37.8°C [100°F] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below [e.g. pyrophoric]).

PHYSICAL HAZARD:

0 (*Water Reactivity*: Materials that do not react with water. *Organic Peroxides*: Materials that are normally stable, even under fire conditions and will not react with water. *Explosives*: Substances that are Non-Explosive. Unstable *Compressed Gases*: No Rating. *Pyrophorics*: No Rating. *Oxidizers*: No "0" rating allowed. *Unstable Reactives*: Substances that will not polymerize, decompose, condense or self-react.); **1** (*Water Reactivity*: Materials that change or decompose upon exposure to moisture. *Organic Peroxides*: Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. *Explosives*: Division 1.5 & 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases*: Pressure below OSHA definition. *Pyrophorics*: No Rating. *Oxidizers*: Packaging Group III; Solids: any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. *Oxidizers*: 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.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD:

1 (continued): *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. *Reactives*: Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature); **3** (*Water Reactivity*: Materials that may form explosive reactions with water. *Organic Peroxides*: Materials that are capable of detonation or explosive reaction, but require a strong initiating source, or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives*: Division 1.2 – Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases*: Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics*: No Rating. *Oxidizers*: Packing Group I Solids: any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3.:2 potassium bromate/cellulose mixture. Liquids: Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives*: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.); **4** (*Water Reactivity*: Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides*: Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives*: Division 1.1 & 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases*: No Rating. *Pyrophorics*: Add to the definition of Flammability "4". *Oxidizers*: No "4" rating. *Unstable Reactives*: Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.).

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: **0** (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); **1** (materials that on exposure under fire conditions could cause irritation or minor residual injury); **2** (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury);**3** (materials that can on short exposure could cause serious temporary or residual injury); **4** (materials that under very short exposure could cause death or major residual injury).

DEFINITION OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY HAZARD: **0** Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand. **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 **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. **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. **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.

INSTABILITY HAZARD: **0** Materials that in themselves are normally stable, even under fire conditions. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures. **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. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction 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 & 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.

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:

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **ACGIH:** American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits. **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: EU is the European Union (formerly known as the **EEC,** European Economic Community). **EINECS:** This 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. **AUSTRALIAN: AICS** is the Australian Inventory of Chemical Substances. **NOHSC:** National Occupational Health & Safety Code.

300 Tice Boulevard
Woodcliff Lake NJ 07677
Phone (800) 828-9393
Fax (201) 391-5217

Par Pharmaceutical, Inc.

March 1, 2013

Marci Powell
Tel: 813-435-5161
Email: MarciPowell@globalsafetynet.com

Re: Material Safety Data Sheets

Dear Marci:

You have requested a Material Safety Data Sheet (MSDS) for Doxycycline Capsules, USP a Par Pharmaceutical product. While we understand the desire to provide workers with timely and accurate information concerning substances present in their workplace, we are unable to comply with your request because no MSDS is required for this product.

As you may be aware, the requirement for Material Safety Data Sheets is found in the Occupational Safety and Health Administration's Hazard Communication Standard, 29 CFR Part 1910-1200(b)(6)(VII) exempts from the entire Standard: "any drug… when it is in solid, final form for direct administration to the patient (e.g., tablets or capsules); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter-drugs)…"

OSHA has issued advice letters regarding this exemption. Pills are exempt if they are occasionally crushed, but are not designed to be crushed prior to administration (letter to Ms. Jan Harris, dated 09/13/93.) Unless a pill is designed to be dissolved or crushed, it is exempt (letter to Mr. Ronald Ray dated 06/11/99.)

As the product specified is exempt from the requirements of the Hazard Communication Standard, we have not prepared a Material Safety Data Sheet.

We refer you to the health information and materials transmitted to you as required by the FDA. We appreciate your business and trust that the foregoing adequately addresses your concerns.

Very truly yours,

Patricia A. Lipari
Director Sales Operations
Integrity, Customer Focus, Teamwork, Performance Driven