



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.3

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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Vibramycin (Doxycycline carrageenate) tablets

Trade Name: Vibramycin®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Microcrystalline cellulose	9004-34-6	232-674-9	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	*
Magnesium stearate	557-04-0	209-150-3	*
Doxycycline carrageenate	NOT ASSIGNED	Not listed	69.1

Ingredient	CAS Number	EU EINECS List	%
Crospovidone	9003-39-8	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Yellow tablets
Signal Word: WARNING

Statement of Hazard: Infants of mothers exposed during pregnancy may develop discoloration of the teeth.
May cause liver toxicity.
Short Term: Not expected to cause eye irritation. Not expected to cause skin irritation. Not acutely toxic (based on animal data). Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: May cause permanent discoloration of teeth if used during tooth development. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Photosensitivity has been reported in some individuals taking tetracyclines.

EU Indication of danger: Toxic to reproduction: Category 1

EU Hazard Symbols:

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EU Risk Phrases:

R61 - May cause harm to the unborn child.

Note:

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

4. FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with water for at least 15 minutes. Get medical attention.
Skin Contact:	Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
Ingestion:	Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
Fire Fighting Procedures:	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.
Fire / Explosion Hazards:	Not applicable

6. ACCIDENTAL RELEASE MEASURES

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

7. HANDLING AND STORAGE

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General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature. Protect from heat and moisture.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Silicon dioxide, colloidal NF

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO₂) mg/m³ TWA
= 20 mppcf TWA
Australia TWA = 2 mg/m³ TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Doxycycline carragenate

Pfizer OEL TWA-8 Hr: 0.25 mg/m³
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for doxycycline. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Rubber gloves
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablet	Color:	Yellow
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

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

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

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Doxycycline carragenate

Rat Oral LD50 > 2000 mg/kg

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.

Inhalation Acute Toxicity

Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

Ingestion Acute Toxicity

See Acute toxicity table

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

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Eye Irritation / Sensitization

Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

Skin Irritation / Sensitization

Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered. Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.

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

Doxycycline carragenate

30 Day(s) Rat No route specified 500 mg/kg/day NOEL None identified
18 Month(s) Rat Oral 500 mg/kg/day NOEL None identified
1 Year(s) Dog Oral 100 mg/kg/day LOEL Liver

Subchronic Effects

Rats administered doses of doxycycline hydrochloride up to 500 mg/kg/day for 30 days showed no toxic effects.

Chronic Toxicity

Chronic toxicity of doxycycline was evaluated in rats at oral doses up to 500 mg/kg/day for 18 months. Findings revealed no adverse effects on growth, food consumption, or survival. Yellow ultraviolet fluorescence of bone, teeth and/or kidneys was seen in rats at all levels. Chronic toxicity studies in dogs at oral doses up to 100 mg/kg/day for one year showed some functional and histopathological changes in the liver. However, effects were reversible after cessation of exposure to this material.

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

Doxycycline carragenate

Reproductive & Fertility-Females Rat Oral 250 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Monkey Oral 50 mg/kg/day NOEL Not Teratogenic

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Reproductive Effects	Fertility studies of doxycycline in female rats at oral doses up to 250 mg/kg/day showed no adverse effects.
Teratogenicity	No teratogenic effects were observed in monkeys at oral doses of doxycycline ranging from 1 to 50 mg/kg/day. Tetracyclines as a class are capable of crossing the placenta and causing permanent discoloration of the teeth. Liver Reproductive system
Mutagenicity	No data available however, positive results in in vitro mammalian cell assays have been reported for related antibiotics.
Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below
Crospovidone IARC:	Group 3
Silicon dioxide, colloidal NF IARC:	Group 3
At increase risk from exposure:	Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Toxic to reproduction: Category 1

EU Risk Phrases:
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S53 - Avoid exposure - obtain special instructions before use.

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OSHA Label:

WARNING

Infants of mothers exposed during pregnancy may develop discoloration of the teeth.
May cause liver toxicity.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Crospovidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Silicon dioxide, colloidal NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet