



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 2.5

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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: Doxycycline hyclate capsules**

Trade Name: Vibramycin(R)  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Doxycycline hyclate	24390-14-5	Not listed	50 or 100 mg ***
Magnesium stearate/sodium lauryl sulfate blend	MIXTURE	Not listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	*

**Additional Information:** \* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** 50 mg: White and light blue capsules; 100 mg: Light blue capsules  
**Signal Word:** WARNING

**Statement of Hazard:** Infants of mothers exposed during pregnancy may develop discoloration of the teeth  
May cause liver toxicity

**Additional Hazard Information:**  
**Short Term:** May cause allergic reactions in susceptible individuals. 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

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention.
<b>Ingestion:</b>	Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Inhalation:</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

## 5. FIRE FIGHTING MEASURES

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

## 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	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.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	IF TABLETS OR CAPSULES ARE CRUSHED AND/OR BROKEN, AVOID BREATHING DUST AND AVOID CONTACT WITH EYES, SKIN AND CLOTHING. Use adequate ventilation.
<b>Storage Conditions:</b>	Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

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Storage Temperature: 15 - 30 °C

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Doxycycline hyclate

Pfizer OEL TWA-8 Hr: 0.25 mg/m<sup>3</sup>

#### Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

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:** General room ventilation is adequate unless the process generates dust, mist or fumes.

#### Personal Protective Equipment:

**Hands:** Wear protective gloves when working with large quantities. Individuals with known sensitivity should wear protective gloves to avoid skin contact.

**Eyes:** Not required for the normal use of this product. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Wear protective clothing when working with large quantities. Individuals with known sensitivity should wear long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this material.

**Respiratory protection:** 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:

<b>Physical State:</b>	Capsule	<b>Color:</b>	Blue or blue/white
<b>Odor:</b>	Odorless	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** None known  
**Incompatible Materials:** Strong oxidizers

**Hazardous Decomposition Products:** No data available See Section 5 - under Hazardous combustion products.  
**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)**

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### Microcrystalline cellulose

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

### Doxycycline hyclate

Mouse Oral LD50 1900 mg/kg (hydrochloride)  
Rat Oral LD50 > 2000 mg/kg (hydrochloride)  
Rat Intravenous LD50 228 mg/kg (hydrochloride)  
Rat (weanling) Intraperitoneal LD50 262 mg/kg (hydrochloride)

**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 hyclate

30 Day(s) Rat Oral 500 mg/kg NOAEL None identified  
18 Month(s) Rat Oral 500 mg/kg/day NOAEL None identified  
1 Year(s) Dog Oral < 10 mg/kg/day NOEL 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 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 the material.

#### Chronic Effects/Carcinogenicity

No data available

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

#### Doxycycline hyclate

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 No effects at maximum dose

#### 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.

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**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.

**Additional Information:** FDA PREGNANCY CATEGORY D. Positive evidence of human fetal risk from marketing experience or human studies.

### 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.

**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



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<b>Doxycycline hyclate</b>	
California Proposition 65	developmental toxicity, initial date 10/1/91 (internal use)
Australia (AICS):	Present
<b>Microcrystalline cellulose</b>	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. 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**