



# 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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CHEMTREC (24 hours): 1-800-424-9300

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

**Material Name: Doxycycline hyclate for injection (IV only)**

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

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Doxycycline hyclate	24390-14-5	Not listed	17
Ascorbic acid (Vitamin C)	50-81-7	200-066-2	*

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

## 3. HAZARDS IDENTIFICATION

Appearance: Light-yellow crystalline powder for reconstitution  
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 effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. May cause permanent discoloration of teeth if used during tooth development. Photosensitivity has been reported in some individuals taking tetracyclines.

EU Indication of danger: Toxic to reproduction: Category 1

EU Hazard Symbols:



EU Risk Phrases:  
R63 - Possible risk of harm to the unborn child.

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**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. If irritation occurs or persists, get medical attention.

**Skin Contact:** Wash skin with soap and water. Remove contaminated clothing and shoes. 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:** May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-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:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 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

**General Handling:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize dust generation and accumulation. Avoid breathing dust. Use adequate ventilation.

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

**Storage Temperature:** Store as directed by product packaging.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Doxycycline hyclate

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

**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. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab fume hood.

#### Personal Protective Equipment:

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**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>	Crystalline powder	<b>Color:</b>	Light yellow
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**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:** There are no data for this formulation. The information included in this section describes the potential hazards of various forms of the active ingredient and/or of a chemically-related material.

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

##### Ascorbic acid (Vitamin C)

Rat Oral LD 50 11.9 g/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)



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<b>Acute Toxicity Comments:</b>	A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
<b>Inhalation Acute Toxicity</b>	Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.
<b>Ingestion Acute Toxicity</b>	See Acute toxicity table.
<b>Eye Irritation / Sensitization</b>	Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.
<b>Skin Irritation / Sensitization</b>	Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

### 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. Dogs receiving 20 to 21 daily intravenous doses at a dose level of 5 mg/kg at a rate of 1 mg/kg/min showed no signs of drug toxicity. At doses of 10 mg, dogs showed evidence of thrombosis with recanalization.

#### **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.

### 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 evidence of teratogenicity was observed for doxycycline in mice, rats, rabbits, and monkeys. 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.

#### **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.

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### 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:**  
R63 - Possible risk of harm to the unborn child.

**EU Safety Phrases:**  
S22 - Do not breathe dust.  
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



#### **Doxycycline hyclate**

**California Proposition 65**

**Australia (AICS):**

developmental toxicity, initial date 10/1/91 (internal use)

Present

#### **Ascorbic acid (Vitamin C)**

**Inventory - United States TSCA - Sect. 8(b)**

**Australia (AICS):**

**EU EINECS List**

Present

Present

200-066-2

### 16. OTHER INFORMATION

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**Reasons for Revision:**

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. 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**