MATERIAL SAFETY DATA SHEET

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

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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 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:

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. 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:

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

General Handling:

IF TABLETS OR CAPSULES ARE CRUSHED AND/OR BROKEN, AVOID BREATHING DUST AND AVOID CONTACT WITH EYES, SKIN AND CLOTHING. 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: 15 - 30 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Doxycycline hyclate

Pfizer OEL TWA-8 Hr: 0.25 mg/m³

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

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:

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

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.

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

Doxycycline hyclate

California Proposition 65	developmental toxicity, initial date 10/1/91 (internal use)
Australia (AICS):	Present

Microcrystalline cellulose

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