



MATERIAL SAFETY DATA SHEET

Revision date: 16-Jan-2008

Version: 4.0

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Material Name: Doxycycline Hyclate Tablets

Trade Name: VIBRA-TABS; VIBRAMYCIN; BASSADO
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Salmon colored film-coated tablets
Signal Word: WARNING

Statement of Hazard: May cause harm to the unborn child.

Additional Hazard Information:

Short Term: May cause allergic reactions in susceptible individuals. Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
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.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Doxycycline hyclate	24390-14-5	Not listed	Repr.Cat1:R61	46.5
Magnesium stearate/sodium lauryl sulfate blend	MIXTURE	Not listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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.

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.

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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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Doxycycline hyclate

Pfizer OEL TWA-8 Hr: 250µg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA
Australia TWA	= 10 mg/m ³ TWA
Belgium OEL - TWA	= 10 mg/m ³ TWA
Estonia OEL - TWA	= 10 mg/m ³ TWA
France OEL - TWA	= 10 mg/m ³ VME
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 4 mg/m ³ TWA
Latvia OEL - TWA	= 2 mg/m ³ TWA
OSHA - Final PELs - TWAs:	= 15 mg/m ³ TWA total
	= 5 mg/m ³ TWA
Portugal OEL - TWA	= 10 mg/m ³ TWA
Romania OEL - TWA	= 10 mg/m ³ TWA
Spain OEL - TWA	= 10 mg/m ³ VLA-ED

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. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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:

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Physical State:	Tablet	Color:	Salmon colored
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

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

Hazardous Decomposition Products: None known
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.

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

Microcrystalline cellulose

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

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

Doxycycline hyclate

30 Day(s) Rat Oral 500 mg/kg NOEL None identified
18 Month(s) Rat Oral 50 mg/kg/day NOEL Thyroid, Bone
1 Year(s) Dog Oral < 10 mg/kg/day NOEL Liver

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

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Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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. Member State specific and Community specific provisions must be considered.

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
May cause harm to the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A



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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/ELINCS List	232-674-9

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet