



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 3.3

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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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 monohydrate) for oral suspension

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 monohydrate	17086-28-1	Not listed	1.72
Microcrystalline cellulose	9004-34-6	232-674-9	*
Sucrose	57-50-1	200-334-9	*

Ingredient	CAS Number	EU EINECS List	%
D&C red #28	18472-87-21	Not listed	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*
Methylparaben	99-76-3	202-785-7	*
Raspberry flavor	NOT ASSIGNED	Not listed	*
Simethicone emulsion	67762-90-7	Not listed	*
Propylparaben	94-13-3	202-307-7	*
FD & C Blue No. 1	3844-45-9	223-339-8	*

Additional Information:

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

3. HAZARDS IDENTIFICATION

Appearance: Raspberry-flavored, dry powder
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.

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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: 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. 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, and nitrogen oxides.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not available

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.

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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:

Minimize dust generation and accumulation. Use only in a well-ventilated area. Avoid contact with eyes, skin and clothing. Avoid breathing dust.

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:

<30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Doxycycline monohydrate

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

Sucrose

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

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. Local and general ventilation should be used as necessary, when handling this material in bulk.

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:

Not required for the normal use of this product. Wear protective clothing when working with large quantities.

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:

Powder

Color:

Blue

Odor:

Light raspberry

Molecular Formula:

Mixture

Molecular Weight:

Mixture

pH:

5 - 6.5 (1% slurry)

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10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: Oxidizers
Hazardous Decomposition Products: No data available
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 the individual ingredients.

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

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Intraperitoneal LD 50 200 mg/kg

Methylparaben

Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Carboxymethylcellulose sodium

Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Microcrystalline cellulose

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

Doxycycline monohydrate

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

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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

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)

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

Doxycycline monohydrate

30 Day(s) Rat Oral 500 mg/kg/day NOEL No effects at maximum dose
18 Month(s) Rat Oral 500 mg/kg/day NOAEL None identified
1 Year(s) Dog Oral 100 mg/kg/day LOEL Liver

Subchronic Effects

Rats administered oral doses 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 monohydrate

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

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.

FD & C Blue No. 1

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.

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

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

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b) XU

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Australia (AICS):	Present
EU EINECS List	232-674-9
Methylparaben	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7
Sucrose	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-334-9
Simethicone emulsion	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Propylparaben	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7
FD & C Blue No. 1	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	223-339-8

16. OTHER INFORMATION

Reasons for Revision: 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 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