



SAFETY DATA SHEET

Revision date: 07-Oct-2013

Version: 4.0

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

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Contact E-Mail: pfizer-MSDS@pfizer.com

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International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Vibramycin (Doxycycline monohydrate) for oral suspension

Trade Name:	VIBRAMYCIN
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: Raspberry-flavored, dry powder
Signal Word: DANGER

Statement of Hazard: May damage 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.

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 Classification
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):

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2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Doxycycline monohydrate	17086-28-1	Not Listed	Repr. Cat.1;R61	1.72
Sucrose	57-50-1	200-334-9	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	*
FD & C Blue No. 1	3844-45-9	223-339-8	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Raspberry flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Simethicone emulsion	67762-90-7	Not Listed	Not Listed	*
D & C Red no. 28	18472-87-2	Not Listed	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: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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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.

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 breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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 monohydrate	
Pfizer OEL TWA-8 Hr:	250µg/m ³
Sucrose	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

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

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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

Physical State:

Powder

Color:

Blue

Odor:

Light raspberry

Molecular Formula:

Mixture

Molecular Weight:

Mixture

pH:

5 - 6.5 (1% slurry)

Polymerization:

Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under normal conditions of use.

Conditions to Avoid:

Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials:

As a precautionary measure, keep away from strong oxidizers

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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)

Propylparaben

Mouse Oral LD50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD50 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

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)

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

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

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11. TOXICOLOGICAL INFORMATION

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

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 (Not Classifiable)

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

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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.

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15. REGULATORY INFORMATION

OSHA Label:

DANGER

May damage the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Carboxymethylcellulose sodium

California Proposition 65

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

Australia (AICS):

Not Listed

Present

Present

Doxycycline monohydrate

California Proposition 65

Australia (AICS):

developmental toxicity initial date 10/1/91 internal use

Present

FD & C Blue No. 1

California Proposition 65

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

Australia (AICS):

EU EINECS/ELINCS List

Not Listed

Present

Present

223-339-8

Methylparaben

California Proposition 65

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

Australia (AICS):

EU EINECS/ELINCS List

Not Listed

Present

Present

202-785-7

Propylparaben

California Proposition 65

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

Australia (AICS):

EU EINECS/ELINCS List

Not Listed

Present

Present

202-307-7

Raspberry flavor

California Proposition 65

Not Listed

Simethicone emulsion

California Proposition 65

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

Australia (AICS):

Not Listed

Present

Present

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15. REGULATORY INFORMATION

Sucrose

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Microcrystalline cellulose

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

D & C Red no. 28

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

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

Reasons for Revision: Updated Section 2 - 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 15 - Regulatory Information. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 10 - Stability and Reactivity.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet