



SAFETY DATA SHEET

Revision date: 12-Apr-2015

Version: 3.1

Page 1 of 14

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

Product Identifier

Material Name: Doxycycline calcium oral suspension syrup

Trade Name: Vibramycin

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A

EU Classification:

EU Indication of danger: Toxic to reproduction: Category 1

EU Risk Phrases:

R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger

Hazard Statements: H360D - May damage the unborn child

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 2 of 14
Version: 3.1



Other Hazards

No data available

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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 | GHS Classification | % |
|-----------------------------|------------|-----------------------|---------------------------|---|------|
| Calcium chloride USP | 10035-04-8 | Not Listed | Not Listed | Eye Irrit. 2 (H319) | * |
| Doxycycline calcium | 94088-85-4 | 302-088-9 | Repr.Cat.1;R61 | Repr. 1A (H360D) | 1 |
| Sodium metabisulfite USP | 7681-57-4 | 231-673-0 | Xn; R22 R31 Xi; R41 | Acute Tox. 4 (H302) Eye Dam. 1 (H318) | <1.0 |
| Magnesium aluminum silicate | 1327-43-1 | 215-478-8 | Not Listed | Not Listed | * |
| Hydrogen chloride | 7647-01-0 | 231-595-7 | T; R23 C; R35 | STOT SE 3 (H335) Skin Corr. 1A (H314) Press. Gas Acute Tox. 3 (H331) | ** |
| Sodium hydroxide | 1310-73-2 | 215-185-5 | C; R35 | Skin Corr. 1A (H314) | ** |
| Glycerin, USP | 56-81-5 | 200-289-5 | Not Listed | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|--------------------------|--------------|-----------------------|-------------------|--------------------|---|
| Apple flavor, artificial | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Carmine lake | 1328-60-5 | 215-527-3 | Not Listed | Not Listed | * |
| Raspberry flavor | NOT ASSIGNED | Not Listed | Not Listed | Not Listed | * |
| Simethicone emulsion | 67762-90-7 | Not Listed | Not Listed | Not Listed | * |
| Butylparaben | 94-26-8 | 202-318-7 | Not Listed | Not Listed | * |
| Propylparaben | 94-13-3 | 202-307-7 | Not Listed | Not Listed | * |
| Sorbitol | 6706-59-8 | Not Listed | Not Listed | Not Listed | * |
| Propylene glycol | 57-55-6 | 200-338-0 | Not Listed | Not Listed | * |
| Povidone | 9003-39-8 | Not Listed | Not Listed | Not Listed | * |
| Water, purified | 7732-18-5 | 231-791-2 | Not Listed | Not Listed | * |

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 3 of 14
Version: 3.1

Additional Information: ** to adjust pH
 * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 4 of 14
Version: 3.1

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

Precautions for Safe Handling

Minimize generating airborne mists and vapors. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Doxycycline calcium

Pfizer OEL TWA-8 Hr: 0.25 mg/m³

Sodium metabisulfite USP

ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
Belgium OEL - TWA 5 mg/m³
Denmark OEL - TWA 5 mg/m³
France OEL - TWA 5 mg/m³
Greece OEL - TWA 5 mg/m³
Ireland OEL - TWAs 5 mg/m³
Portugal OEL - TWA 5 mg/m³
Spain OEL - TWA 5 mg/m³
Switzerland OEL - TWAs 5 mg/m³
Vietnam OEL - TWAs 5 mg/m³

Propylene glycol

Australia TWA 150 ppm
474 mg/m³
10 mg/m³
Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³
Latvia OEL - TWA 7 mg/m³
Lithuania OEL - TWA 7 mg/m³

Hydrogen chloride

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
7.5 mg/m³
Austria OEL - MAKs 5 ppm
8 mg/m³

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
 Revision date: 12-Apr-2015

Page 5 of 14
 Version: 3.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|--------------------------------|--------------------------------|
| Belgium OEL - TWA | 5 ppm 8 mg/m ³ |
| Bulgaria OEL - TWA | 5 ppm 8.0 mg/m ³ |
| Cyprus OEL - TWA | 5 ppm 8 mg/m ³ |
| Czech Republic OEL - TWA | 8 mg/m ³ |
| Estonia OEL - TWA | 5 ppm 8 mg/m ³ |
| Germany - TRGS 900 - TWAs | 2 ppm 3 mg/m ³ |
| Germany (DFG) - MAK | 2 ppm 3.0 mg/m ³ |
| Greece OEL - TWA | 5 ppm 7 mg/m ³ |
| Hungary OEL - TWA | 8 mg/m ³ |
| Ireland OEL - TWAs | 5 ppm 8 mg/m ³ |
| Italy OEL - TWA | 5 ppm 8 mg/m ³ |
| Japan - OELs - Ceilings | 5 ppm 7.5 mg/m ³ |
| Latvia OEL - TWA | 5 ppm 8 mg/m ³ |
| Lithuania OEL - TWA | 5 ppm 8 mg/m ³ |
| Luxembourg OEL - TWA | 5 ppm 8 mg/m ³ |
| Malta OEL - TWA | 5 ppm 8 mg/m ³ |
| Netherlands OEL - TWA | 8 mg/m ³ |
| Poland OEL - TWA | 5 mg/m ³ |
| Portugal OEL - TWA | 5 ppm 8 mg/m ³ |
| Romania OEL - TWA | 5 ppm 8 mg/m ³ |
| Slovakia OEL - TWA | 5 ppm 8.0 mg/m ³ |
| Slovenia OEL - TWA | 5 ppm 8 mg/m ³ |
| Spain OEL - TWA | 5 ppm 7.6 mg/m ³ |
| Switzerland OEL - TWAs | 2 ppm 3.0 mg/m ³ |
| Vietnam OEL - TWAs | 5 mg/m ³ |
| Sodium hydroxide | |
| ACGIH Ceiling Threshold Limit: | 2 mg/m ³ |
| Australia PEAK | 2 mg/m ³ |
| Austria OEL - MAKs | 2 mg/m ³ |
| Bulgaria OEL - TWA | 2.0 mg/m ³ |
| Czech Republic OEL - TWA | 1 mg/m ³ |
| Estonia OEL - TWA | 1 mg/m ³ |

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 6 of 14
Version: 3.1

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------------|-----------------------|
| France OEL - TWA | 2 mg/m ³ |
| Greece OEL - TWA | 2 mg/m ³ |
| Hungary OEL - TWA | 2 mg/m ³ |
| Japan - OELs - Ceilings | 2 mg/m ³ |
| Latvia OEL - TWA | 0.5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 2 mg/m ³ |
| Poland OEL - TWA | 0.5 mg/m ³ |
| Slovakia OEL - TWA | 2 mg/m ³ |
| Slovenia OEL - TWA | 2 mg/m ³ |
| Sweden OEL - TWAs | 1 mg/m ³ |
| Switzerland OEL - TWAs | 2 mg/m ³ |

Glycerin, USP

| | |
|---------------------------|----------------------|
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Czech Republic OEL - TWA | 10 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| Finland OEL - TWA | 20 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Germany (DFG) - MAK | 50 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Poland OEL - TWA | 10 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL - TWAs | 50 mg/m ³ |

Analytical Method:

Analytical method available for Doxycycline. Contact Pfizer Inc for further information.

Exposure Controls

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:

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:

Syrup

Color:

Red

Odor:

Light raspberry

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

No data available.

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 7 of 14
Version: 3.1

9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Water, purified

No data available

Doxycycline calcium

No data available

Carmin lake

No data available

Apple flavor, artificial

No data available

Raspberry flavor

No data available

Butylparaben

No data available

Propylparaben

No data available

Calcium chloride USP

No data available

Glycerin, USP

No data available

Magnesium aluminum silicate

No data available

Povidone

No data available

Propylene glycol

No data available

Simethicone emulsion

No data available

Hydrogen chloride

No data available

Sodium hydroxide

No data available

Sorbitol

No data available

Doxycycline hydrochloride

No data available

Doxycycline monohydrate

No data available

Sodium metabisulfite USP

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 8 of 14
Version: 3.1

Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information in this section describes the hazards of various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.
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.

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

Doxycycline calcium

Mouse Oral LD50 1900 mg/kg (hydrochloride)
Rat Oral LD50 > 2000mg/kg (hydrochloride)

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Calcium chloride USP

Rat Oral LD50 1000 mg/kg
Mouse Oral LD50 1940mg/kg

Glycerin, USP

Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m³
Rat Dermal LD 50 > 21.9 g/kg

Povidone

Rat Oral LD50 100 g/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 9 of 14
Version: 3.1

11. TOXICOLOGICAL INFORMATION

Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/kg

Hydrogen chloride

Rat Sub-tenon injection (eye) LC50 1H 3,124 ppm
Mouse Inhalation LC50 1H 1,108ppm
Mouse Oral LD50 900mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Doxycycline hydrochloride

Rat Oral LD50 1700 mg/kg
Mouse Oral LD50 1890mg/kg
Dog Oral LD50 > 500mg/kg
Rat IV LD50 137mg/kg
Rat Subcutaneous LD50 700mg/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)

Glycerin, USP

Eye Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Skin Irritation / Sensitization

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)

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

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 & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 10 of 14
Version: 3.1

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

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

Povidone

IARC: Group 3 (Not Classifiable)

Hydrogen chloride

IARC: Group 3 (Not Classifiable)

Sodium metabisulfite USP

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.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L
Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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.

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 11 of 14
Version: 3.1

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Apple flavor, artificial

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Calcium chloride USP

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |

Carmine lake

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| EU EINECS/ELINCS List | 215-527-3 |

Doxycycline calcium

| | |
|------------------------------------|---|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | developmental toxicity initial date 1/1/92 internal use |
| EU EINECS/ELINCS List | 302-088-9 |

Raspberry flavor

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |

Simethicone emulsion

| | |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
 Revision date: 12-Apr-2015

Page 12 of 14
 Version: 3.1

15. REGULATORY INFORMATION

| | |
|--|--------------------|
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |
| Butylparaben | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 202-318-7 |
| Propylparaben | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 202-307-7 |
| Sodium metabisulfite USP | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| EU EINECS/ELINCS List | 231-673-0 |
| Magnesium aluminum silicate | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 215-478-8 |
| Sorbitol | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| EU EINECS/ELINCS List | Not Listed |
| Propylene glycol | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 200-338-0 |
| Hydrogen chloride | |
| CERCLA/SARA 313 Emission reporting | 1.0 % |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 5000 lb 2270 kg |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs | 500 lb |

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
 Revision date: 12-Apr-2015

Page 13 of 14
 Version: 3.1

15. REGULATORY INFORMATION

| | |
|---|------------|
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 5000 lb |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| | Schedule 6 |
| EU EINECS/ELINCS List | 231-595-7 |

Povidone

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | Not Listed |

Sodium hydroxide

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 1000 lb |
| | 454 kg |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 5 |
| | Schedule 6 |
| EU EINECS/ELINCS List | 215-185-5 |

Water, purified

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| 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 | 231-791-2 |

Glycerin, USP

| | |
|--|--|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex V - Exemptions from the obligations of Register: | Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern |
| EU EINECS/ELINCS List | 200-289-5 |

SAFETY DATA SHEET

Material Name: Doxycycline calcium oral suspension syrup
Revision date: 12-Apr-2015

Page 14 of 14
Version: 3.1

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child

C - Corrosive
Xn - Harmful
Xi - Irritant
Toxic to reproduction: Category 1
T - Toxic

R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.
R23 - Toxic by inhalation.
R35 - Causes severe burns.
R31 - Contact with acids liberates toxic gas.
R41 - Risk of serious damage to eyes.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage.

Revision date: 12-Apr-2015

Product Stewardship Hazard Communication

Prepared by: 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