



# MATERIAL SAFETY DATA SHEET

Revision date: 16-Aug-2013

Version: 5.0

Page 1 of 10

## 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

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

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
International CHEMTREC (24 hours): +1-703-527-3887

### 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: DANGER

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:

<b>Australian Hazard Classification (NOHSC):</b>	R61 - May cause harm to the unborn child. Hazardous Substance. Non-Dangerous Goods.
--	--

## MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 2 of 10  
Version: 5.0

### 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 hyclate	24390-14-5	Not Listed	Repr.Cat 1;R61	50-60
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Ethylcellulose	9004-57-3	Not Listed	Not Listed	*
FD&C Yellow No. 6 Lake	Not assigned	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:** Formation of toxic gases is possible during heating or fire.

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

## MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 3 of 10  
Version: 5.0

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

### 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. 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). 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 hyclate

Pfizer OEL TWA-8 Hr:	250µg/m <sup>3</sup>
----------------------	----------------------

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	6 mg/m <sup>3</sup>
Estonia OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>

# MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 4 of 10  
Version: 5.0

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
<b>Propylene glycol</b>	
Australia TWA	150 ppm 474 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Ireland OEL - TWAs	150 ppm 470 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Latvia OEL - TWA	7 mg/m <sup>3</sup>
Lithuania OEL - TWA	7 mg/m <sup>3</sup>
<b>Sodium lauryl sulfate</b>	
Pfizer OEL TWA-8 Hr:	0.3 mg/m <sup>3</sup>
<b>Magnesium Stearate</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
<b>Talc (non-asbestiform)</b>	
ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	2.5 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 fiber/cm <sup>3</sup> 6.0 mg/m <sup>3</sup> 3.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	2.0 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Denmark OEL - TWA	0.3 fiber/cm <sup>3</sup>
Finland OEL - TWA	0.5 fiber/cm <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup> 2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup> 0.8 mg/m <sup>3</sup>
Lithuania OEL - TWA	2 mg/m <sup>3</sup> 1 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.25 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m <sup>3</sup> 1.0 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Spain OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	2 mg/m <sup>3</sup> 1 mg/m <sup>3</sup>

## MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 5 of 10  
Version: 5.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Microcrystalline cellulose

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

<b>Analytical Method:</b>	Analytical method available for doxycycline. Contact Pfizer Inc for further information.
<b>Engineering Controls:</b>	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.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Tablet	<b>Color:</b>	Salmon colored
<b>Odor:</b>	Odorless	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
-----------------------------	---

## MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 6 of 10  
Version: 5.0

### 11. TOXICOLOGICAL INFORMATION

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

##### **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)

##### **Talc (non-asbestiform)**

Rat Oral LD50 > 1600 mg/kg

##### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD50 50 mg/kg

##### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 mg/kg

##### **Microcrystalline cellulose**

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

##### **Sodium lauryl sulfate**

Rat Oral LD50 1288 mg/kg

##### **Propylene glycol**

Mouse Oral LD50 22,000 mg/kg  
Rat Oral LD50 20,000 mg/kg  
Rabbit Dermal LD50 20,800 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

##### **Sodium lauryl sulfate**

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild Moderate  
Skin Sensitization - GPMT Guinea Pig Negative  
Skin Sensitization - LLNA Mouse Negative

##### **Propylene glycol**

Skin Irritation Rabbit Mild  
Eye Irritation Rabbit Mild

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

##### **Magnesium Stearate**

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

## MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 7 of 10  
Version: 5.0

### 11. TOXICOLOGICAL INFORMATION

#### 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

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

#### Sodium lauryl sulfate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
-------------------------------	-------------------	----------

#### Carcinogen Status:

See below

#### Talc (non-asbestiform)

IARC:	Group 3 (Not Classifiable)
-------	----------------------------

#### Titanium dioxide

IARC:	Group 2B (Possibly Carcinogenic to Humans)
OSHA:	Listed

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

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

#### Sodium lauryl sulfate

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	3.6 mg/L
--	------	----------	----------

### 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.

## MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 8 of 10  
Version: 5.0

### 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:  
DANGER  
May cause harm to the unborn child.

#### Canada - WHMIS: Classifications

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



#### Doxycycline hyclate

California Proposition 65  
Australia (AICS):

developmental toxicity initial date 10/1/91 internal use  
Present

#### Titanium dioxide

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS/ELINCS List

carcinogen initial date 9/2/11 airborne, unbound particles of respirable size  
Present  
Present  
236-675-5

#### Hydroxypropyl methylcellulose

California Proposition 65  
Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
Standard for the Uniform Scheduling  
for Drugs and Poisons:

Not Listed  
Present  
Present  
Schedule 4

#### Ethylcellulose

California Proposition 65  
Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):

Not Listed  
Present  
Present



## MATERIAL SAFETY DATA SHEET

Material Name: Doxycycline Hyclate Tablets  
Revision date: 16-Aug-2013

Page 9 of 10  
Version: 5.0

### 15. REGULATORY INFORMATION

#### Propylene glycol

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

#### Sodium lauryl sulfate

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 6
EU EINECS/ELINCS List	205-788-1

#### FD&C Yellow No. 6 Lake

California Proposition 65	Not Listed
---------------------------	------------

#### Magnesium Stearate

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

#### Talc (non-asbestiform)

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

#### 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

### 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 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. Updated Section 5 - Fire Fighting Measures. Updated Section 15 - Regulatory Information.

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

## MATERIAL SAFETY DATA SHEET

**Material Name: Doxycycline Hyclate Tablets**  
**Revision date: 16-Aug-2013**

**Page 10 of 10**  
**Version: 5.0**

---

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**