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

<table>
<thead>
<tr>
<th>Pfizer Inc</th>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Pharmaceuticals Group</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>235 East 42nd Street</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>New York, New York 10017</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>1-212-573-2222</td>
<td>United Kingdom</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Pfizer Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramsgate Road</td>
</tr>
<tr>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td>CT13 9NJ</td>
</tr>
<tr>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

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

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

---

**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:**

![T Hazard Symbol](image)

**EU Risk Phrases:** R61 - May cause harm to the unborn child.

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.
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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxycycline hyclate</td>
<td>24390-14-5</td>
<td>Not Listed</td>
<td>Repr.Cat 1;R61</td>
<td>50-60</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-677-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Ethylcellulose</td>
<td>9004-57-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6 Lake</td>
<td>Not assigned</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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/m³

Titanium dioxide
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Australia TWA: 10 mg/m³
- Austria OEL - MAKs: 5 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Denmark OEL - TWA: 6 mg/m³
- Estonia OEL - TWA: 5 mg/m³
- France OEL - TWA: 10 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- Latvia OEL - TWA: 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- OSHA - Final PELS - TWAs: 15 mg/m³
- Poland OEL - TWA: 10.0 mg/m³
- Portugal OEL - TWA: 10 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Talc (non-asbestiform)</strong></td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Propylene glycol</strong></td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>474 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>470 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td><strong>Sodium lauryl sulfate</strong></td>
<td></td>
</tr>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td><strong>Magnesium Stearate</strong></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td><strong>Talc (non-asbestiform)</strong></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1.0 fiber/cm³</td>
</tr>
<tr>
<td></td>
<td>6.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>0.3 fiber/cm³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>0.5 fiber/cm³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
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<tr>
<td>Lithuania OEL - TWA</td>
<td>0.8 mg/m³</td>
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<td></td>
<td>1 mg/m³</td>
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<tr>
<td>Netherlands OEL - TWA</td>
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<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
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<td>Poland OEL - TWA</td>
<td>4.0 mg/m³</td>
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<tr>
<td></td>
<td>1.0 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

<table>
<thead>
<tr>
<th></th>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>Australia TWA</th>
<th>Belgium OEL - TWA</th>
<th>Estonia OEL - TWA</th>
<th>France OEL - TWA</th>
<th>Ireland OEL - TWAs</th>
<th>Latvia OEL - TWA</th>
<th>OSHA - Final PELS - TWAs:</th>
<th>Portugal OEL - TWA</th>
<th>Spain OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>2 mg/m³</td>
<td>15 mg/m³</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4 mg/m³</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


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: Tablet

Odor: Odorless

Molecular Weight: Mixture

Color: Salmon colored

Molecular Formula: Mixture

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

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.
11. TOXICOLOGICAL INFORMATION

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

**Doxycycline hyclate**
- Mouse Oral LD$_{50}$ 1900 mg/kg (hydrochloride)
- Rat Oral LD$_{50}$ > 2000 mg/kg (hydrochloride)
- Rat Intravenous LD$_{50}$ 228 mg/kg (hydrochloride)
- Rat (weanling) Intraperitoneal LD$_{50}$ 262 mg/kg (hydrochloride)

**Talc (non-asbestiform)**
- Rat Oral LD$_{50}$ > 1600 mg/kg

**Titanium dioxide**
- Rat Oral LD$_{50}$ > 7500 mg/kg
- Rat Subcutaneous LD$_{50}$ 50 mg/kg

**Hydroxypropyl methylcellulose**
- Rat Oral LD$_{50}$ > 10,000 mg/kg

**Microcrystalline cellulose**
- Rat Oral LD$_{50}$ > 5000 mg/kg
- Rabbit Dermal LD$_{50}$ > 2000 mg/kg

**Sodium lauryl sulfate**
- Rat Oral LD$_{50}$ 1288 mg/kg

**Propylene glycol**
- Mouse Oral LD$_{50}$ 22,000 mg/kg
- Rat Oral LD$_{50}$ 20,000 mg/kg
- Rabbit Dermal LD$_{50}$ 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
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) Salmonella 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
Oncorhynchus mykiss (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.
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: developmental toxicity initial date 10/1/91 internal use
Australia (AICS): Present

Titanium dioxide
California Proposition 65: carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 236-675-5

Hydroxypropyl methylcellulose
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 4

Ethylcellulose
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
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 Schedule 6
  for Drugs and Poisons:
  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.

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