## 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>
<tr>
<td>Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300</td>
<td>+00 44 (0)1304 616161</td>
</tr>
<tr>
<td>Contact E-Mail: <a href="mailto:pfizer-MSDS@pfizer.com">pfizer-MSDS@pfizer.com</a></td>
<td>Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887</td>
</tr>
</tbody>
</table>

### 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:

![Skull and Crossbones](image)

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

### Australian Hazard Classification (NOHSC):
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 monohydrate</td>
<td>17086-28-1</td>
<td>Not Listed</td>
<td>Repr. Cat. 1; R61</td>
<td>1.72</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</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>Carboxymethylcellulose sodium</td>
<td>9004-32-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Blue No. 1</td>
<td>3844-45-9</td>
<td>223-339-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Rasberry flavor</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Simethicone emulsion</td>
<td>67762-90-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>D &amp; C Red no. 28</td>
<td>18472-87-2</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: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
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/m³

Sucrose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 rasberry
- **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.
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

**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))**
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.
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) Present
Australia (AICS): Present

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

FD & C Blue No. 1
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 223-339-8

Methylparaben
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

Propylparaben
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-307-7

Rasberry flavor
California Proposition 65 Not Listed

Simethicone emulsion
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
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 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