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

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
Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Doxycycline calcium oral suspension syrup

Trade Name: Vibramycin(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxycycline calcium</td>
<td>94088-85-4</td>
<td>302-088-9</td>
<td>1</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>1327-43-1</td>
<td>215-478-8</td>
<td>*</td>
</tr>
<tr>
<td>Calcium chloride USP</td>
<td>10035-04-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>*</td>
</tr>
<tr>
<td>Sodium metabisulfite USP</td>
<td>7681-57-4</td>
<td>231-673-0</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>6706-69-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Rasberry flavor</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Butylparaben</td>
<td>94-26-8</td>
<td>202-318-7</td>
<td>*</td>
</tr>
<tr>
<td>Simethicone emulsion</td>
<td>67762-90-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>*</td>
</tr>
<tr>
<td>Carmine no. 40 - FCC</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Apple flavor, artificial</td>
<td>NOT ASSIGNED</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Raspberry-apple flavored syrup
Signal Word: WARNING
Statement of Hazard: Infants of mothers exposed during pregnancy may develop discoloration of the teeth
May cause allergic reaction in sensitive individuals
May cause liver toxicity

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 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 Risk Phrases: R63 - Possible risk of harm to the unborn child.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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 spill with absorbent material. 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: Use with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage Conditions: Keep container tightly closed when not in use. Store in a cool, dry place away from direct sunlight.

Storage Temperature: <30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Doxycycline calcium
Pfizer OEL TWA-8 Hr: 0.25 mg/m³

Hydrogen chloride
ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
  Australia PEAK = 5 ppm Peak
  = 7.5 mg/m³ Peak

Glycerin, USP
OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
  = 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA): = 10 mg/m³ TWA
  Australia TWA = 10 mg/m³ TWA

Sodium hydroxide
OSHA - Final PELS - TWAs: 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
  Australia PEAK = 2 mg/m³ Peak

Sodium metabisulfite USP
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
  Australia TWA = 5 mg/m³ TWA

Propylene glycol
Australia TWA = 10 mg/m³ TWA
  = 150 ppm TWA
  = 474 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


Engineering Controls: Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:
# Hand Protection
Rubber gloves

# Eye Protection
Wear safety glasses or goggles if eye contact is possible.

# Skin Protection
Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

# 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.

## Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Syrup</th>
<th>Color: Red</th>
<th>Molecular Formula: Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>Light raspberry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Stability and Reactivity

- **Stability:** Stable
- **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.
- **Incompatible Materials:** Strong oxidizers
- **Hazardous Decomposition Products:** No data available See Section 5 - under Hazardous combustion products.
- **Polymerization:** Will not occur

## 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)

- **Hydrogen chloride**
  - Rat Inhalation LC50 1H 3,124 ppm
  - Mouse Inhalation LC50 1H 1,108 ppm
  - Mouse Oral LD50 900 mg/kg

- **Sodium hydroxide**
  - Mouse IP LD50 40 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

- **Povidone**
  - Rat Oral LD50 100 g/kg

- **Propylparaben**
  - Mouse Oral LD 50 6332 mg/kg
  - Mouse Intraperitoneal LD 50 200 mg/kg

- **Glycerin, USP**
Inhalation Acute Toxicity
Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

Ingestion Acute Toxicity
See Acute toxicity table.

Irritation / Sensitization: (Study Type, Species, Severity)

Eye Irritation / Sensitization
Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. The potential for irritation should be considered.

Skin Irritation / Sensitization
Tetracyclines are known to cause local irritation upon intramuscular and intravenous administration. 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

Subchronic Effects
Chronic Toxicity
Rats administered oral doses up to 500 mg/kg/day for 30 days showed no toxic effects. Chronic toxicity was evaluated in rats at oral doses up to 500 mg/kg/day for 18 months. Findings revealed no adverse effects on growth, food consumption, or survival. Yellow ultraviolet fluorescence of bone, teeth and/or kidneys was seen in rats at all levels. Chronic studies in dogs at oral doses up to 100 mg/kg/day for one year showed some functional and histopathological changes in the liver. However, effects were reversible after cessation of exposure to the material.

Chronic Effects/Carcinogenicity
No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.

Reproductive Effects
Fertility studies of doxycycline in female rats at oral doses up to 250 mg/kg/day showed no adverse effects.

Teratogenicity
No teratogenic effects were observed in monkeys at oral doses of doxycycline HCl ranging from 1 to 50 mg/kg/day. Tetracyclines as a class are capable of crossing the placenta and causing permanent discoloration of the teeth. Liver Reproductive system
Mutagenicity: No data available; however, positive results in in vitro mammalian cell assays have been reported for related antibiotics.

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

Hydrogen chloride
IARC: Group 3

Povidone
IARC: Group 3

Sodium metabisulfite USP
IARC: Group 3

At increase risk from exposure: Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.

Additional Information: FDA PREGNANCY CATEGORY D. Positive evidence of human fetal risk from marketing experience or human studies.

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)

Glycerin, USP
Onchorhyncus 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.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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: R63 - Possible risk of harm to the unborn child.
EU Safety Phrases:

S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Infants of mothers exposed during pregnancy may develop discoloration of the teeth
May cause allergic reaction in sensitive individuals
May cause liver toxicity

Canada - WHMIS: Classifications

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

Doxycycline calcium
- California Proposition 65: developmental toxicity, initial date 1/1/92 (internal use)
- EU EINECS List: 302-088-9

Butylparaben
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS List: 202-318-7

Hydrogen chloride
- CERCLA/SARA 313 Emission Reporting: = 1.0 % de minimis concentration
  acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  = 2270 kg final RQ
  = 5000 lb final RQ
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs:
  = 500 lb TPQ gas only
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs:
  = 5000 lb EPCRA RQ gas only
- Inventory - United States TSCA - Sect. 8(b): T
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- EU EINECS List: 231-595-7

Simethicone emulsion
- Inventory - United States TSCA - Sect. 8(b): XU
- Australia (AICS): Present

Magnesium aluminum silicate
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS List: 215-478-8

Calcium chloride USP
16. OTHER INFORMATION

Reasons for Revision:
Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures.
Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by:
Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet