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

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
### Other Hazards

**Australian Hazard Classification (NOHSC):**

No data available


**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

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

#### Non-Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple flavor, artificial</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Carmine lake</td>
<td>1328-60-5</td>
<td>215-527-3</td>
<td>Not Listed</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>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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Butylparaben</td>
<td>94-26-8</td>
<td>202-318-7</td>
<td>Not Listed</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>6706-59-8</td>
<td>Not Listed</td>
<td>Not Listed</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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Material Name:** Doxycycline calcium oral suspension syrup

**Revision date:** 12-Apr-2015

**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.
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
# Exposure Controls / Personal Protection

<table>
<thead>
<tr>
<th>Material Name: Doxycycline calcium oral suspension syrup</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium OEL - TWA</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
</tr>
</tbody>
</table>

Sodium hydroxide

- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Bulgaria OEL - TWA: 2.0 mg/m³
- Czech Republic OEL - TWA: 1 mg/m³
- Estonia OEL - TWA: 1 mg/m³
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

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

Exposure 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
Odor: Light raspberry
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available

Color: Red
Odor Threshold: No data available.
Molecular Weight: Mixture
## 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient:</td>
<td>No data available</td>
</tr>
<tr>
<td>Water, purified</td>
<td>No data available</td>
</tr>
<tr>
<td>Doxycycline calcium</td>
<td>No data available</td>
</tr>
<tr>
<td>Carmine lake</td>
<td>No data available</td>
</tr>
<tr>
<td>Apple flavor, artificial</td>
<td>No data available</td>
</tr>
<tr>
<td>Rasberry flavor</td>
<td>No data available</td>
</tr>
<tr>
<td>Butylparaben</td>
<td>No data available</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>No data available</td>
</tr>
<tr>
<td>Calcium chloride USP</td>
<td>No data available</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>No data available</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>No data available</td>
</tr>
<tr>
<td>Povidone</td>
<td>No data available</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>No data available</td>
</tr>
<tr>
<td>Simethicone emulsion</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>No data available</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>No data available</td>
</tr>
<tr>
<td>Doxycycline hydrochloride</td>
<td>No data available</td>
</tr>
<tr>
<td>Doxycycline monohydrate</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium metabisulfite USP</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density:</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability:</td>
<td></td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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
11. TOXICOLOGICAL INFORMATION

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)

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))
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  
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.

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.
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
developmental toxicity initial date 1/1/92 internal use
California Proposition 65 302-088-9
EU EINECS/ELINCS List Not Listed

Rasberry 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
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butylparaben</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>202-318-7</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>202-307-7</td>
</tr>
<tr>
<td>Sodium metabisulfite USP</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>231-673-0</td>
</tr>
<tr>
<td>Magnesium aluminum silicate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>215-478-8</td>
</tr>
<tr>
<td>Sorbitol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>200-338-0</td>
</tr>
<tr>
<td>Hydrogen chloride</td>
<td>1.0 %</td>
<td>5000 lb</td>
<td>2270 kg</td>
<td>500 lb</td>
<td></td>
</tr>
</tbody>
</table>

Revision date: 12-Apr-2015
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA - Section 302 Extremely Hazardous</th>
<th>Substances EPCRA RQs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone</td>
<td>5000 lb</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-595-7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA Hazardous Substances and their Reportable Quantities</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1000 lb</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Schedule 5</td>
<td>215-185-5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water, purified</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Present</td>
<td>231-791-2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex V - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin, USP</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>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</td>
<td>200-289-5</td>
</tr>
</tbody>
</table>
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
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