1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Metronidazole Tablets
Trade Name: Flagyl
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent, antiprotozoal agent.

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 2
Carcinogenicity: Category 2

EU Classification:
EU Indication of danger: Carcinogenic: Category 3
Toxic to Reproduction: Category 3

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning
Hazard Statements:
H351 - Suspected of causing cancer
H361d - Suspected of damaging the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
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

PZ00294
SAFETY DATA SHEET

Material Name: Metronidazole Tablets
Revision date: 02-May-2014

Other Hazards
Australian Hazard Classification (NOHSC):

No data available

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>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>Metronidazole</td>
<td>443-48-1</td>
<td>207-136-1</td>
<td>Carc. Cat. 3, R40; Repr. Cat. 3, R63</td>
<td>Carc. 2, H351; Repr. 2, H361d</td>
<td>63.5</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>FD &amp; C Blue No. 2, Aluminum lake</td>
<td>16521-38-3</td>
<td>240-589-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>57-11-4</td>
<td>200-313-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
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**

<table>
<thead>
<tr>
<th>Symptoms and Effects of Exposure:</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Conditions Aggravated by Exposure:</td>
<td>None known</td>
</tr>
</tbody>
</table>

**Indication of the Immediate Medical Attention and Special Treatment Needed**

<table>
<thead>
<tr>
<th>Notes to Physician:</th>
<th>None</th>
</tr>
</thead>
</table>

**5. FIRE FIGHTING MEASURES**

**Extinguishing Media:**
Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

<table>
<thead>
<tr>
<th>Hazardous Combustion Products:</th>
<th>Formation of toxic gases is possible during heating or fire.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fire / Explosion Hazards:</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Measures for Cleaning / Collecting:</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Consideration for Large Spills:</td>
<td>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>

**7. HANDLING AND STORAGE**

**Precautions for Safe 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.

**Conditions for Safe Storage, Including any Incompatibilities**

PZ00294
Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Metronidazole

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>OEL Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands OEL - TWA</td>
<td>0.00012 mg/m³</td>
</tr>
</tbody>
</table>

Microcrystalline cellulose

<table>
<thead>
<tr>
<th>Source</th>
<th>OEL Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

Polyethylene glycol

<table>
<thead>
<tr>
<th>Source</th>
<th>OEL Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>1000 mg/m³ average molecular weight 200-600</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>1000 ppm</td>
</tr>
</tbody>
</table>

Titanium dioxide

<table>
<thead>
<tr>
<th>Source</th>
<th>OEL Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>ACGIH OELs - Notice of Intended Changes</td>
<td>Listed</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

PZ00294
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Exposure Controls

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.

Personal Protective Equipment:

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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablets  
Odor: No data available.  
Molecular Formula: Mixture  
Solvent Solubility: No data available  
Water Solubility: No data available  
pH: No data available.  
Melting/Freezing Point (°C): No data available  
Boiling Point (°C): No data available.  
Partition Coefficient: (Method, pH, Endpoint, Value) No data available

Metronidazole

Pfizer Occupational Exposure Band (OEB): OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

Physical State: Tablets  
Color: Blue  
Odor Threshold: No data available.  
Molecular Weight: Mixture

Solvent Solubility: No data available  
Water Solubility: No data available  
pH: No data available.  
Melting/Freezing Point (°C): No data available  
Boiling Point (°C): No data available.  
Partition Coefficient: (Method, pH, Endpoint, Value) No data available

Metronidazole

Polyethylene glycol

No data available

Microcrystalline cellulose
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Hydroxypropyl methylcellulose
No data available

Hydroxypropyl cellulose
No data available

Stearic acid
No data available

Titanium dioxide
No data available

FD & C Blue No. 2, Aluminum lake
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

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 included in this section describes the potential hazards of the individual ingredients.

Long Term: Animal studies indicate that this material may cause adverse effects on the developing fetus.

Known Clinical Effects: Clinical use of this drug has caused nausea, dizziness, and effects on blood forming organs.

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

Metronidazole
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 3800mg/kg
Mouse Intraperitoneal LD 50 870mg/kg
### 11. TOXICOLOGICAL INFORMATION

**Microcrystalline cellulose**
- Rat, Oral LD50 > 5000 mg/kg
- Rabbit, Dermal LD50 > 2000 mg/kg

**Hydroxypropyl methylcellulose**
- Rat, Oral LD50 > 10,000 mg/kg

**Stearic acid**
- Rat, Oral LD50 > 4640 mg/kg
- Rabbit, Dermal LD50 > 5000 mg/kg

**Titanium dioxide**
- Rat, Oral LD50 > 7500 mg/kg
- Rat, Subcutaneous LD50 50 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)**

**Metronidazole**
- Eye Irritation, Rabbit, No effect

**Polyethylene glycol**
- Eye Irritation, Rabbit, Mild
- Skin Irritation, Rabbit, Mild

**Microcrystalline cellulose**
- Skin Irritation, Rabbit, Non-irritating
- Eye Irritation, Rabbit, Non-irritating

**Stearic acid**
- Skin Irritation, Rabbit, Moderate
- Eye Irritation, Rabbit, Mild

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

**Metronidazole**
- 2 Year(s), Mouse, Oral, 600 mg/kg, LOAEL
- 80 Week(s), Rat, Oral, 30 mg/kg, LOAEL
- 34 Day(s), Rat, Oral, = 34 g/kg, LOAEL, Kidney, Ureter, Bladder
- 4 Month(s), Dog, Oral, 75 mg/kg, LOAEL
- 1 Year(s), Non-human Primate, Oral, 150 mg/kg, LOAEL

**Stearic acid**
- 30 Week(s), Rat, Oral 300 ppm, LOAEL, Adipose tissue

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Metronidazole**
- Reproductive & Fertility, Rat, Oral, 400 mg/kg, LOAEL, Fertility
- Reproductive & Fertility, Rabbit, Oral, 200 mg/kg, NOAEL, Fertility, Developmental toxicity, Fetotoxicity
## 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Genetic Toxicity</th>
<th>Study Type, Cell Type/Organism, Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Metronidazole</strong></td>
<td><em>In Vitro</em> Bacterial Mutagenicity (Ames) <em>Salmonella</em> Positive</td>
</tr>
<tr>
<td></td>
<td><em>In Vitro</em> Sister Chromatid Exchange <em>Hamster</em> Negative</td>
</tr>
<tr>
<td></td>
<td><em>In Vivo</em> Unscheduled DNA Synthesis <em>Rabbit</em> Negative</td>
</tr>
<tr>
<td></td>
<td><em>In Vivo</em> Micronucleus <em>Rat</em> Negative</td>
</tr>
<tr>
<td></td>
<td><em>In Vitro</em> Chromosome Aberration <em>Human Lymphocytes</em> Negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Study Type, Cell Type/Organism, Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stearic acid</strong></td>
<td><em>In Vitro</em> Bacterial Mutagenicity (Ames) <em>Salmonella</em> Negative</td>
</tr>
<tr>
<td></td>
<td>Unscheduled DNA Synthesis <em>E. coli</em> Negative</td>
</tr>
</tbody>
</table>

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Study Type, Cell Type/Organism, Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Metronidazole</strong></td>
<td>Not specified <em>Rat</em> Oral Tumors</td>
</tr>
<tr>
<td></td>
<td>Not specified <em>Mouse</em> Oral Tumors</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Study Type, Cell Type/Organism, Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stearic acid</strong></td>
<td>26 Week(s) <em>Rat</em> Subcutaneous 0.5 mg/kg/week NOAEL Not carcinogenic</td>
</tr>
<tr>
<td></td>
<td>52 Week(s) <em>Mouse</em> Subcutaneous 0.05 mg/kg/week LOAEL Tumors</td>
</tr>
</tbody>
</table>

### Carcinogen Status:

**Metronidazole**
- IARC: Group 2B (Possibly Carcinogenic to Humans)
- NTP: Reasonably Anticipated To Be A Human Carcinogen

**Titanium dioxide**
- IARC: Group 2B (Possibly Carcinogenic to Humans)
- OSHA: Listed

## 12. ECOLOGICAL INFORMATION

### Environmental Overview:

The following information is available for the individual ingredients.

### Toxicity:

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

**Metronidazole**
- *Mysidopsis bahia* (Mysid Shrimp) OECD LC-50 96 Hours >180 mg/L
- *Cyprinodon variegatus* (Sheepshead Minnow) OECD LC-50 96 Hours >1060 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.
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

FD & C Blue No. 2, Aluminum lake
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 240-589-3

Hydroxypropyl cellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</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>Microcrystalline cellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Stearic acid</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
</tr>
</tbody>
</table>

- **CERCLA/SARA 313 Emission reporting**
- **California Proposition 65**
- **Inventory - United States TSCA - Sect. 8(b)**
- **Australia (AICS):**
- **EU EINECS/ELINCS List**
15. REGULATORY INFORMATION

EU EINECS/ELINCS List  236-675-5

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Carcinogenic: Category 3
Toxic to Reproduction: Category 3

R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. 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 10 - Stability and Reactivity. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information.

Revision date: 02-May-2014

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