



# SAFETY DATA SHEET

Revision date: 02-May-2014

Version: 2.0

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## 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:**  
**International CHEMTREC (24 hours): +1-703-527-3887**

**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

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**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
Hazardous Substance. Non-Dangerous Goods.

**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

### Hazardous

| Ingredient                 | CAS Number | EU EINECS/ELINCS List | EU Classification                       | GHS Classification               | %    |
|----------------------------|------------|-----------------------|---|----------------------------------|------|
| Metronidazole              | 443-48-1   | 207-136-1             | Carc. Cat. 3, R40;<br>Repr. Cat. 3, R63 | Carc. 2, H351;<br>Repr. 2, H361d | 63.5 |
| Microcrystalline cellulose | 9004-34-6  | 232-674-9             | Not Listed                              | Not Listed                       | *    |
| Titanium dioxide           | 13463-67-7 | 236-675-5             | Not Listed                              | Not Listed                       | *    |

| Ingredient                       | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|----------------------------------|------------|-----------------------|-------------------|--------------------|---|
| FD & C Blue No. 2, Aluminum lake | 16521-38-3 | 240-589-3             | Not Listed        | Not Listed         | * |
| Hydroxypropyl cellulose          | 9004-64-2  | Not Listed            | Not Listed        | Not Listed         | * |
| Hydroxypropyl methylcellulose    | 9004-65-3  | Not Listed            | Not Listed        | Not Listed         | * |
| Polyethylene glycol              | 25322-68-3 | Not Listed            | Not Listed        | Not Listed         | * |
| Stearic acid                     | 57-11-4    | 200-313-4             | Not Listed        | Not Listed         | * |

### 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.

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**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:** No data available

**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 CO<sub>2</sub>, 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 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.

**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 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

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**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

Netherlands OEL - TWA 0.00012 mg/m<sup>3</sup>

#### Microcrystalline cellulose

|                                   |                      |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup> |
| Australia TWA                     | 10 mg/m <sup>3</sup> |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup> |
| Estonia OEL - TWA                 | 10 mg/m <sup>3</sup> |
| France OEL - TWA                  | 10 mg/m <sup>3</sup> |
| Ireland OEL - TWAs                | 10 mg/m <sup>3</sup> |
|                                   | 4 mg/m <sup>3</sup>  |
| Latvia OEL - TWA                  | 2 mg/m <sup>3</sup>  |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup> |
| Portugal OEL - TWA                | 10 mg/m <sup>3</sup> |
| Romania OEL - TWA                 | 10 mg/m <sup>3</sup> |
| Russia OEL - TWA                  | 6 mg/m <sup>3</sup>  |
| Spain OEL - TWA                   | 10 mg/m <sup>3</sup> |
| Switzerland OEL - TWAs            | 3 mg/m <sup>3</sup>  |
| Vietnam OEL - TWAs                | 10 mg/m <sup>3</sup> |
|                                   | 5 mg/m <sup>3</sup>  |

#### Polyethylene glycol

|                           |   |
|---------------------------|---|
| Austria OEL - MAKs        | 1000 mg/m <sup>3</sup>                                  |
| Germany - TRGS 900 - TWAs | 1000 mg/m <sup>3</sup>                                  |
| Germany (DFG) - MAK       | 1000 mg/m <sup>3</sup> average molecular weight 200-600 |
| Slovakia OEL - TWA        | 1000 mg/m <sup>3</sup>                                  |
| Slovenia OEL - TWA        | 1000 mg/m <sup>3</sup>                                  |
| Switzerland OEL - TWAs    | 1000 ppm  |

#### Titanium dioxide

|   |                        |
|---|------------------------|
| ACGIH Threshold Limit Value (TWA)       | 10 mg/m <sup>3</sup>   |
| ACGIH OELs - Notice of Intended Changes | Listed                 |
| Australia TWA                           | 10 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                      | 5 mg/m <sup>3</sup>    |
| Belgium OEL - TWA                       | 10 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                      | 10.0 mg/m <sup>3</sup> |
| Denmark OEL - TWA                       | 6 mg/m <sup>3</sup>    |
| Estonia OEL - TWA                       | 5 mg/m <sup>3</sup>    |
| France OEL - TWA                        | 10 mg/m <sup>3</sup>   |
| Greece OEL - TWA                        | 10 mg/m <sup>3</sup>   |
|   | 5 mg/m <sup>3</sup>    |
| Ireland OEL - TWAs                      | 10 mg/m <sup>3</sup>   |
|   | 4 mg/m <sup>3</sup>    |
| Latvia OEL - TWA                        | 10 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA                     | 5 mg/m <sup>3</sup>    |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                           |                        |
|---------------------------|------------------------|
| OSHA - Final PELs - TWAs: | 15 mg/m <sup>3</sup>   |
| Poland OEL - TWA          | 10.0 mg/m <sup>3</sup> |
| Portugal OEL - TWA        | 10 mg/m <sup>3</sup>   |
| Romania OEL - TWA         | 10 mg/m <sup>3</sup>   |
| Russia OEL - TWA          | 10 mg/m <sup>3</sup>   |
| Spain OEL - TWA           | 10 mg/m <sup>3</sup>   |
| Sweden OEL - TWAs         | 5 mg/m <sup>3</sup>    |
| Switzerland OEL - TWAs    | 3 mg/m <sup>3</sup>    |
| Vietnam OEL - TWAs        | 6 mg/m <sup>3</sup>    |
|                           | 5 mg/m <sup>3</sup>    |

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.

#### Metronidazole

**Pfizer Occupational Exposure Band (OEB):** OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

#### 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:

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 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

|                           |                    |                          |                    |
|---------------------------|--------------------|--------------------------|--------------------|
| <b>Physical State:</b>    | Tablets            | <b>Color:</b>            | Blue               |
| <b>Odor:</b>              | No data available. | <b>Odor Threshold:</b>   | No data available. |
| <b>Molecular Formula:</b> | Mixture            | <b>Molecular Weight:</b> | Mixture            |

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

#### Metronidazole

No data available

#### Polyethylene glycol

No data available

#### Microcrystalline cellulose

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### 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 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

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### 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 > 5000mg/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

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### 11. TOXICOLOGICAL INFORMATION

|                            |       |                 |           |       |                 |
|----------------------------|-------|-----------------|-----------|-------|-----------------|
| Embryo / Fetal Development | Mouse | Intraperitoneal | 9 mg/kg   | LOAEL | Fetotoxicity    |
| Embryo / Fetal Development | Rat   | Oral            | 200 mg/kg | NOEL  | Not Teratogenic |
| Embryo / Fetal Development | Mouse | Intraperitoneal | 40 mg/kg  | LOAEL | Fetotoxicity    |

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Metronidazole

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Positive  
*In Vitro* Sister Chromatid Exchange Hamster Negative  
*In Vivo* Unscheduled DNA Synthesis Rabbit Negative  
*In Vivo* Micronucleus Rat Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative

##### Stearic acid

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Unscheduled DNA Synthesis *E. coli* Negative

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

##### Metronidazole

Not specified Rat Oral Tumors  
Not specified Mouse Oral Tumors

##### Stearic acid

26 Week(s) Rat Subcutaneous 0.5 mg/kg/week NOAEL Not carcinogenic  
52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOAEL Tumors

Carcinogen Status: See below

##### 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.



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**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 |
|------------------------------------|------------|

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**15. REGULATORY INFORMATION**

|  |   |
|--|---|
| California Proposition 65  | Not Listed  |
| Inventory - United States TSCA - Sect. 8(b)                        | Present   |
| Australia (AICS):  | Present   |
| EU EINECS/ELINCS List  | Not Listed  |
| <b>Hydroxypropyl methylcellulose</b>                               |   |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed  |
| 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  |
| EU EINECS/ELINCS List  | Not Listed  |
| <b>Metronidazole</b>   |   |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed  |
| California Proposition 65  | carcinogen initial date 1/1/88  |
| Australia (AICS):  | Present   |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 4  |
| EU EINECS/ELINCS List  | 207-136-1   |
| <b>Microcrystalline cellulose</b>                                  |   |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed  |
| California Proposition 65  | Not Listed  |
| Inventory - United States TSCA - Sect. 8(b)                        | Present   |
| Australia (AICS):  | Present   |
| REACH - Annex XVII - Restrictions on Certain Dangerous Substances: | Use restricted. See item 9[f]. powder   |
| EU EINECS/ELINCS List  | 232-674-9   |
| <b>Polyethylene glycol</b>   |   |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed  |
| 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 3  |
| EU EINECS/ELINCS List  | Not Listed  |
| <b>Stearic acid</b>  |   |
| 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  | 200-313-4   |
| <b>Titanium dioxide</b>  |   |
| CERCLA/SARA 313 Emission reporting                                 | Not Listed  |
| 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   |

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### 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

Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**