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

Product Identifier

Material Name: Metronidazole Capsules
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

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

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
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Black Iron Oxide</td>
<td>1317-61-9</td>
<td>215-277-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Metronidazole</td>
<td>443-48-1</td>
<td>207-136-1</td>
<td>Carc. 2 (H351) Repr. 2 (H361d)</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FD&amp;C Green No. 3</td>
<td>2353-45-9</td>
<td>219-091-5</td>
<td>Not Listed</td>
</tr>
<tr>
<td></td>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</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 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 firefighting 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: Contain the source of the spill or leak if it is safe to do so. Vacuum or sweep material into appropriate container for disposal.

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. 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 drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
# Exposure Controls / Personal Protection

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

**Corn Starch**
- **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
- **Czech Republic OEL - TWA**: 4.0 mg/m³
- **Germany OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWAs**: 10 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Slovakia OEL - TWA**: 4 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Switzerland OEL - TWAs**: 3 mg/m³

**Magnesium stearate**
- **Lithuania OEL - TWA**: 5 mg/m³
- **Sweden OEL - TWAs**: 5 mg/m³

**Metronidazole**
- **Netherlands OEL - TWA**: 0.00012 mg/m³

**Titanium dioxide**
- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Australia TWA**: 10 mg/m³
- **Austria OEL - MAKs**: 5 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Bulgaria OEL - TWA**: 10.0 mg/m³
- **Denmark OEL - TWA**: 6 mg/m³
- **Estonia OEL - TWA**: 5 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Greece OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWAs**: 10 mg/m³
- **Latvia OEL - TWA**: 10 mg/m³
- **Lithuania OEL - TWA**: 5 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Poland OEL - TWA**: 10.0 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Romania OEL - TWA**: 10 mg/m³
- **Russia OEL - TWA**: 10 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Sweden OEL - TWAs**: 5 mg/m³
- **Switzerland OEL - TWAs**: 3 mg/m³
- **Vietnam OEL - TWAs**: 6 mg/m³
- **Vietnam OEL - TWAs**: 5 mg/m³
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.

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

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection:
Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Capsule</th>
<th>Color:</th>
<th>Gray ; Green</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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)
Black Iron Oxide
No data available
Corn Starch
No data available
Metronidazole
No data available
Gelatin
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Magnesium stearate**
No data available

**Titanium dioxide**
No data available

**D & C yellow No. 10**
No data available

**FD&C Green No. 3**
No data available

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>No data available</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>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>D &amp; C yellow No. 10</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>3 g/kg</td>
</tr>
<tr>
<td>FD&amp;C Green No. 3</td>
<td>Mouse</td>
<td>Oral</td>
<td>LD50</td>
<td>3800mg/kg</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metronidazole</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black Iron Oxide</td>
<td>Rat</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt;1000 mg/kg</td>
</tr>
</tbody>
</table>

Material Name: Metronidazole Capsules
Titanium dioxide
D & C yellow No. 10
FD&C Green No. 3
Revision date: 13-Apr-2018
Version: 2.1
Page 6 of 10
11. TOXICOLOGICAL INFORMATION

Mouse Intraperitoneal LD 50 870mg/kg

Magnesium stearate
Rat Oral LD50  > 2000 mg/kg
Rat Inhalation LC50  > 2000 mg/m³

Titanium dioxide
Rat Oral LD50  > 7500 mg/kg
Rat Subcutaneous LD50  50 mg/kg

D & C yellow No. 10
Rat Oral LD50  2000 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

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

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
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

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

Metronidazole
Not specified Rat Oral Tumors
Not specified Mouse Oral Tumors
11. TOXICOLOGICAL INFORMATION

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)

FD&C Green No. 3
- IARC: Group 3 (Not Classifiable)

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

Black Iron Oxide

- 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: 215-277-5

Corn Starch

- 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 IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 232-679-6

FD&C Green No. 3

- 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: 219-091-5

Gelatin

- 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: 232-554-6

Magnesium stearate

- 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: 209-150-3

Metronidazole

- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Carcinogen 1/1/1988
- Australia (AICS): Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Standard for the Uniform Scheduling</th>
<th>Schedule 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>for Drugs and Poisons:</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>207-136-1</td>
</tr>
</tbody>
</table>

Titanium dioxide

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65           | carcinogen 9/2/2011 airborne, unbound particles of respirable size |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                  | Present   |
| EU EINECS/ELINCS List               | 236-675-5 |

16. OTHER INFORMATION

Text of CLP/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

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 13-Apr-2018

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