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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2
Carcinogenicity: Category 2

EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3
Carcinogenic: 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
Other Hazards

Australian Hazard Classification (NOHSC):


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>
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<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
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<td>Carc. 2, H351; Repr. 2, H361d</td>
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</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.
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 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**
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
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
- Greece OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
- Lithuania OEL - TWA 5 mg/m³
- Sweden OEL - TWAs 4 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
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- 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
- ACGIH OELs - Notice of Intended Changes Listed
- 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
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Spain OEL - TWA**: 10 mg/m³
**Sweden OEL - TWAs**: 5 mg/m³
**Switzerland OEL - TWAs**: 3 mg/m³
**Vietnam OEL - TWAs**: 6 mg/m³

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).

- **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**: Capsule
- **Color**: Gray; Green
- **Odor**: No data available.
- **Odor Threshold**: No data available.
- **Molecular Formula**: Mixture
- **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

**Black Iron Oxide**

- **No data available**

**Corn Starch**

- **No data available**

**Metronidazole**

- **No data available**

**Gelatin**

- **No data available**

**Magnesium stearate**

- **No data available**
9. PHYSICAL AND CHEMICAL PROPERTIES

Titanium dioxide
No data available
D & C yellow No. 10
No data available
FD&C Green No. 3
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)

Black Iron Oxide
Rat Oral LD50 >1000 mg/kg

Metronidazole
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 3800mg/kg
Mouse Intraperitoneal LD 50 870mg/kg

Magnesium stearate
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)

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.

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

Reproductive & Fertility

Rabbit

Metalidazole

Eye Irritation

Rabbit

No effect

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

Carcinogen Status: See below
11. TOXICOLOGICAL INFORMATION

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

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

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

D & C yellow No. 10
- 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: Not Listed

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
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>EU EINECS/ELINCS List</th>
<th>CERCLA/SARA 313 Emission reporting</th>
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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 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information. Updated Section 7 - Handling and Storage.

Revision date: 02-May-2014

Prepared by: Product Stewardship Hazard Communication

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