



# SAFETY DATA SHEET

Revision date: 13-Apr-2018

Version: 2.1

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## 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**  
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## 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

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### 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

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Metronidazole	443-48-1	207-136-1	Carc. 2 (H351) Repr. 2 (H361d)	65
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
FD&C Green No. 3	2353-45-9	219-091-5	Not Listed	*
Gelatin	9000-70-8	232-554-6	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 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.

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**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

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### 8. 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/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 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>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

#### Magnesium stearate

Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Metronidazole

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

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
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>
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>

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### 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/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). 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

<b>Physical State:</b>	Capsule	<b>Color:</b>	Gray ; Green
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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)**

**Black Iron Oxide**

No data available

**Corn Starch**

No data available

**Metronidazole**

No data available

**Gelatin**

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### 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

**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)**

**Black Iron Oxide**

Rat Oral LD50 >1000 mg/kg

**Metronidazole**

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 3800mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Mouse Intraperitoneal LD50 870mg/kg

#### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### 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

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### 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.



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### 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

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### 15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	207-136-1

#### 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

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**