



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
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1-212-573-2222

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Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Metronidazole Tablets

**Trade Name:** Flagyl  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antibiotic agent, antiprotozoal agent.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Metronidazole	443-48-1	207-136-1	250 or 500 mg***
Titanium dioxide	13463-67-7	236-675-5	*
CELLULOSE (FIBRE DE PAPIER)	9004-34-6	232-674-9	*

Ingredient	CAS Number	EU EINECS List	%
Polyethylene glycol	25322-68-3	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
FD & C Blue No. 2, Aluminum lake	16521-38-3	240-589-3	*

**Additional Information:** \* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Blue Tablets  
**Signal Word:** WARNING

**Statement of Hazard:** Suspected of damaging the unborn child.  
Suspected of causing cancer.

**Additional Hazard Information:**  
**Short Term:** The active ingredient is not acutely toxic. Not an eye irritant (based on components).  
**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.  
**EU Indication of danger:** Harmful

**EU Hazard Symbols:**

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## EU Risk Phrases:

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

## Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 4. FIRST AID MEASURES

- Eye Contact:** Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
- Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
- Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

## 5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Not applicable

## 6. ACCIDENTAL RELEASE MEASURES

- Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- 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.
- Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- 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.

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### 7. HANDLING AND STORAGE

**General Handling:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. Use with adequate ventilation.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Metronidazole

Pfizer OEL TWA-8 Hr: 3200 ug/m<sup>3</sup>

#### Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

#### CELLULOSE (FIBRE DE PAPIER)

OSHA - Final PELs - TWAs: = 15 mg/m<sup>3</sup> TWA total  
= 5 mg/m<sup>3</sup> TWA  
ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA  
Australia TWA = 10 mg/m<sup>3</sup> TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Analytical Method:** Analytical method available for Metronidazole. Contact Pfizer Inc for further information.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels.

#### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Tablets	<b>Color:</b>	Blue
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

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**Conditions to Avoid:** Not determined  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

#### Metronidazole

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

#### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

#### CELLULOSE (FIBRE DE PAPIER)

Rabbit Dermal LD 50 > 2000 mg/kg  
Rat Inhalation LC 50 > 5.05 mg/L/4 hours  
Rat Oral LD 50 > 5000 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)

#### Polyethylene glycol

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

#### Metronidazole

Eye Irritation Rabbit No effect

#### CELLULOSE (FIBRE DE PAPIER)

Eye Irritation Rabbit  
Skin Irritation Rabbit  
Skin Sensitization - GPMT Guinea Pig

### 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

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Embryo / Fetal Development    Mouse    Intraperitoneal    40 mg/kg    LOAEL    Fetotoxicity

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

#### **Metronidazole**

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

**Carcinogen Status:**                      See below

#### **Metronidazole**

**IARC:**    Group 2B  
**NTP:**    Reasonably Anticipated To Be A Carcinogen  
**OSHA:**                                        Present

#### **Titanium dioxide**

**IARC:**    Group 2B  
**OSHA:**                                        Present

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:**                This formulation has not been tested as a whole, the following apply to component substance(s): No harmful effects to aquatic organisms are expected. This material has potential to bioaccumulate and long term adverse effects to aquatic organisms are possible.

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

#### **Metronidazole**

Mysid Shrimp    OECD    LC-50    96 Hours    >180 mg/L  
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.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:**                      Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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## 15. REGULATORY INFORMATION

EU Symbol: Xn  
EU Indication of danger: Harmful

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

EU Safety Phrases:  
S22 - Do not breathe dust.  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:  
WARNING  
Suspected of damaging the unborn child.  
Suspected of causing cancer.

### Canada - WHMIS: Classifications

WHMIS hazard class:  
Class D, Division 2, Subdivision A



#### Metronidazole

California Proposition 65	Listed; Cancer
Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons:	Present Schedule 4
EU EINECS List	207-136-1

#### Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS): EU EINECS List	Present 236-675-5

#### Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

#### Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

#### FD & C Blue No. 2, Aluminum lake

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS): EU EINECS List	Present 240-589-3

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### CELLULOSE (FIBRE DE PAPIER)

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - 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.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**