



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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CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Metronidazole Capsules

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	375 mg***
Corn Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*
Black Iron Oxide	1317-61-9	215-277-5	*
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Gelatin	9000-70-8	232-554-6	*
FD&C Yellow No. 10	Not assigned	Not listed	*
FD&C Green No. 3	2353-45-9	219-091-5	*

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: Grey; Green Capsules
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.

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EU Indication of danger: Harmful

EU Hazard Symbols:



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: Contain the source of the spill or leak if it is safe to do so. Vacuum or sweep material into appropriate container for disposal.

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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/m³

Corn Starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Black Iron Oxide

ACGIH Threshold Limit Value (TWA) = 1 mg/m³ TWA
Australia TWA = 1 mg/m³ TWA

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ 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:

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Physical State: Capsule
Molecular Formula: Mixture

Color: Gray ; Green
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
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

Magnesium stearate

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

Black Iron Oxide

Rat Oral LD50 >1000 mg/kg

Titanium dioxide

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

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

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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

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

Carcinogen Status: See below

FD&C Green No. 3

IARC: Group 3

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 low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected.

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

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

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

Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

Gelatin

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Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6
Black Iron Oxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-277-5
Titanium dioxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5
FD&C Green No. 3	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	219-091-5

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 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.

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

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End of Safety Data Sheet