



MATERIAL SAFETY DATA SHEET

Revision date: 21-Feb-2007

Version: 1.0

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

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

Material Name: Metronidazole Extended Release Tablets

Trade Name: Flagyl(R) ER
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	71.5
Titanium dioxide	13463-67-7	236-675-5	*
Magnesium Stearate	557-04-0	209-150-3	*
Silicon dioxide, NF	7631-86-9	231-545-4	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*

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	*
Lactose	63-42-3	200-559-2	*
Polysorbate 80	9005-65-6	Not listed	*
Simethicone emulsion	67762-90-7	Not listed	*
Methacrylic acid copolymer	25086-15-1	Not listed	*

Additional Information: * Proprietary
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) .

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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:



EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect
R63 - Possible risk of harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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:

Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact:

Wash skin with soap and water. If irritation occurs or persists, get 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.

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.

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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.

7. HANDLING AND STORAGE

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Magnesium Stearate

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

Silicon dioxide, NF

OSHA - Final PELs - Table Z-3 Mineral D: (80)/(% SiO₂) mg/m³ TWA
= 20 mppcf TWA
Australia TWA = 2 mg/m³ TWA

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA
ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA
Australia TWA = 2.5 mg/m³ TWA containing no asbestos fibers
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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.

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Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

Engineering Controls: Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section.

Personal Protective Equipment:

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: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

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9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablets	Color:	Blue
Molecular Formula:	Mixture	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: The information included in this section describes the potential hazards of the individual ingredients.

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

Lactose

Rat Oral LD50 > 10 g/kg

Polysorbate 80

Rat Intravenous LD 50 1790 mg/kg
Mouse Oral LD 50 25 g/kg

Silicon dioxide, NF

Rat Oral LD50 10 g/kg

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Titanium dioxide

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

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

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Eye Irritation Rabbit No effect

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

Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOEL Liver

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2 Year(s) Mouse Oral 600 mg/kg LOEL
80 Week(s) Rat Oral 30 mg/kg LOEL
34 Day(s) Rat Oral = 34 g/kg LOEL Kidney, Ureter, Bladder
4 Month(s) Dog Oral 75 mg/kg LOEL
1 Year(s) Non-human Primate Oral 150 mg/kg LOEL

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

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Reproductive & Fertility Rat Oral 400 mg/kg LOEL Fertility
Reproductive & Fertility Rabbit Oral 200 mg/kg NOEL Fertility, Developmental toxicity, Fetotoxicity
Embryo / Fetal Development Mouse Intraperitoneal 9 mg/kg LOEL Fetotoxicity
Embryo / Fetal Development Rat Oral 200 mg/kg NOEL Not Teratogenic
Embryo / Fetal Development Mouse Intraperitoneal 40 mg/kg LOEL Fetotoxicity

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

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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

Silicon dioxide, NF

IARC: Group 3

Talc (non-asbestiform)

IARC: Group 3

Titanium dioxide

IARC: Group 2B
OSHA: Present

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IARC: Group 2B
NTP: Reasonably Anticipated To Be A Carcinogen
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.

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

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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.

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



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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

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):	Present
EU EINECS List	240-589-3

Titanium dioxide

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

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Magnesium Stearate

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

Polysorbate 80

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

Silicon dioxide, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-545-4

Simethicone emulsion

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

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

Methacrylic acid copolymer

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

Present

16. OTHER INFORMATION

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet