



MATERIAL SAFETY DATA SHEET

Revision date: 25-Jan-2007

Version: 1.0

Page 1 of 7

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

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

Material Name: Tinidazole Tablets

Trade Name: Fasigyn(R)
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	%
Tinidazole	19387-91-8	243-014-4	81.4
Microcrystalline cellulose	9004-34-6	232-674-9	*
Maize starch	9005-25-8	232-679-6	*
Magnesium Stearate	557-04-0	209-150-3	*
Sodium Lauryl Sulfate	151-21-3	205-788-1	*
Propylene glycol	57-55-6	200-338-0	*
Titanium dioxide	13463-67-7	236-675-5	*

Ingredient	CAS Number	EU EINECS List	%
Alginic acid	9005-32-7	232-680-1	*
Hypromellose	9004-65-3	Not listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White tablets
Signal Word: WARNING

Statement of Hazard: Suspected of causing cancer.
Suspected of damaging fertility.

Additional Hazard Information:

Short Term: Not acutely toxic (based on animal data) . May cause allergic reaction .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system Animal studies have shown a potential to cause adverse effects on the fetus. Structural similarity to known compounds indicate this material may cause cancer.

MATERIAL SAFETY DATA SHEET

Material Name: Tinidazole Tablets
Revision date: 25-Jan-2007

Page 2 of 7
Version: 1.0

Known Clinical Effects: Clinical use of tinidazole has been associated with severe allergic reactions, headaches, and GI effects (bitter belching, nausea, vomiting, and anorexia). These effects are generally dose and sensitivity dependent.

EU Indication of danger: Carcinogenic: Category 3
Toxic to Reproduction; Category 3

EU Hazard Symbols:



EU Risk Phrases:

R40 - Limited evidence of a carcinogenic effect.
R62 - Possible risk of impaired fertility.
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 product or its ingredients 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. 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: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Tinidazole Tablets
Revision date: 25-Jan-2007

Page 3 of 7
Version: 1.0

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.

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.

Storage Conditions:

Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tinidazole

Pfizer OEL TWA-8 Hr: 0.4 mg/m³

Microcrystalline cellulose

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

Maize 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

Propylene glycol

Australia TWA = 10 mg/m³ TWA
= 150 ppm TWA
= 474 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.

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.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Tinidazole Tablets
Revision date: 25-Jan-2007

Page 4 of 7
Version: 1.0

Respiratory protection: 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:

Physical State:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable at ambient temperatures
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Polymerization: Will not occur

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)

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Alginic acid

Rat Oral LD 50 >5 gm/kg

Sodium Lauryl Sulfate

Rat Oral LD 50 1288 mg/kg
Rat Intraperitoneal LD 50 210 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 mg/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Titanium dioxide

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

Tinidazole

Rat (F) Oral LD50 2710 mg/kg
Mouse (F) Oral LD50 4190 mg/kg
Rat Intravenous LD50 > 250 mg/kg
Mouse Intravenous LD50 > 250 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: Tinidazole Tablets
Revision date: 25-Jan-2007

Page 5 of 7
Version: 1.0

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)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

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

Magnesium Stearate

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

Sodium Lauryl Sulfate

3 Day(s) Rat Oral 75 mg/kg LOAEL Liver, Blood

Tinidazole

1 Month(s) Rat Oral 500 mg/kg/day NOAEL Male reproductive system
6 Month(s) Rat Oral 300 mg/kg/day NOAEL Male reproductive system

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

Tinidazole

Reproductive & Fertility Rat Oral 300 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Mouse Oral 300 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 100 mg/kg/day NOAEL Not Teratogenic
Reproductive & Fertility-Males Mouse Oral 200 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat No route specified 2000 mg/kg LOEL Maternal Toxicity, Fetotoxicity

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

Tinidazole

Bacterial Mutagenicity (Ames) *Salmonella* Positive
Sister Chromatid Exchange Human Lymphocytes Positive
In Vivo Micronucleus Mouse Positive

Carcinogen Status: See below

Titanium dioxide

IARC: Group 2B
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

MATERIAL SAFETY DATA SHEET

Material Name: Tinidazole Tablets
Revision date: 25-Jan-2007

Page 6 of 7
Version: 1.0

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: Carcinogenic: Category 3
Toxic to Reproduction; Category 3

EU Risk Phrases:
R40 - Limited evidence of a carcinogenic effect.
R62 - Possible risk of impaired fertility.

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 causing cancer.
Suspected of damaging fertility.

Canada - WHMIS: Classifications

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



Tinidazole

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	243-014-4

Microcrystalline cellulose

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

MATERIAL SAFETY DATA SHEET

Material Name: Tinidazole Tablets
Revision date: 25-Jan-2007

Page 7 of 7
Version: 1.0

EU EINECS List	232-674-9
Alginic acid	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-680-1
Maize 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
Sodium Lauryl Sulfate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1
Hypromellose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
Propylene glycol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0
Titanium dioxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

16. OTHER INFORMATION

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

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet