



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 2.1

Page 1 of 7

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

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

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

### Material Name: Minoxidil Tablets

Trade Name: LONITEN  
Chemical Family: Mixture  
Intended Use: Pharmaceutical product used as antihypertensive

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Minoxidil	38304-91-5	253-874-2	2.5 or 10 mg***
Microcrystalline cellulose	9004-34-6	232-674-9	*
Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*
Silica colloidal, Ph. Eur.	112945-52-5	Not listed	*

**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:** White tablets  
**Signal Word:** WARNING

**Statement of Hazard:** Harmful if swallowed.  
Suspected of causing cancer.  
Suspected of damaging fertility.

**Additional Hazard Information:**  
**Short Term:** Not a skin irritant (based on animal data) . May be harmful if swallowed.  
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, developing fetus, heart.

## MATERIAL SAFETY DATA SHEET

Material Name: Minoxidil Tablets  
Revision date: 02-Jan-2007

Page 2 of 7  
Version: 2.1

**Known Clinical Effects:** The most common side effects with topical use of minoxidil are itching and other skin irritations of the treated area. Adverse effects associated with the therapeutic use of minoxidil for hypertension include salt and water retention, accumulation of fluid around the heart, changes in heart rhythm, and excessive hair growth. Due to intended use, dangerous lowering of blood pressure can occur.

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

**EU Hazard Symbols:**



**EU Risk Phrases:**

R22 - Harmful if swallowed.  
R40 - Limited evidence of a carcinogenic effect  
R62 - Possible risk of impaired fertility.

**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 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.

**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 determined

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

# MATERIAL SAFETY DATA SHEET

Material Name: Minoxidil Tablets  
Revision date: 02-Jan-2007

Page 3 of 7  
Version: 2.1

**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.

## 7. HANDLING AND STORAGE

**General Handling:** If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Minoxidil

Pfizer OEL TWA-8 Hr: 0.07 mg/m<sup>3</sup>

### Microcrystalline cellulose

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

### Starch

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

### Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m<sup>3</sup> TWA except stearates of toxic metals  
Australia TWA = 10 mg/m<sup>3</sup> TWA

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

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

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

### 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.

# MATERIAL SAFETY DATA SHEET

Material Name: Minoxidil Tablets  
Revision date: 02-Jan-2007

Page 4 of 7  
Version: 2.1

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

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

## 10. STABILITY AND REACTIVITY

Stability: Stable  
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)

#### Minoxidil

Rat Oral LD50 1321 mg/kg  
Mouse Oral LD50 2457 mg/kg  
Rat Intravenous LD50 49 mg/kg

#### Lactose

Rat Oral LD50 > 10 g/kg

#### Magnesium stearate

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

#### Starch

Mouse IP LD50 6600 mg/kg

#### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal 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)

#### Minoxidil

Skin Irritation Guinea Pig Non-irritating

#### Microcrystalline cellulose

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

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

#### Minoxidil

13 Week(s) Mouse Dermal 80 mg/kg/day LOAEL Male reproductive system  
13 Week(s) Rat Dermal 80 mg/kg/day LOAEL Male reproductive system

## MATERIAL SAFETY DATA SHEET

Material Name: Minoxidil Tablets  
Revision date: 02-Jan-2007

Page 5 of 7  
Version: 2.1

1 Month(s) Dog Oral 0.05 mg/kg/day LOAEL Heart  
1 Month(s) Monkey Oral 20 mg/kg/day LOAEL Heart  
1 Month(s) Rat Oral 300 mg/kg/day LOAEL Heart

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

#### **Minoxidil**

Embryo / Fetal Development Rat Oral 80 mg/kg/day NOAEL Not teratogenic, Embryotoxicity, Fetotoxicity  
Reproductive & Fertility Rat Oral 3 mg/kg/day LOAEL Fertility, Embryotoxicity  
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL No effects at maximum dose  
Embryo / Fetal Development Rat Subcutaneous 11 mg/kg/day NOAEL Not Teratogenic  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Fetotoxicity

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

#### **Minoxidil**

*In Vivo* Micronucleus Rat Negative  
Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Unscheduled DNA Synthesis Rat Hepatocyte Negative  
Micronucleus Mouse Bone Marrow Negative  
*In Vitro* Cytogenetics Human Lymphocytes Negative

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### **Minoxidil**

2 Year(s) Mouse Female Oral 10 mg/kg/day LOAEL Malignant tumors  
2 Year(s) Mouse Female Dermal 8 mg/kg/day LOAEL Malignant tumors, Mammary gland  
22 Month(s) Rat Oral 30 mg/kg/day NOAEL Not carcinogenic, Heart  
2 Year(s) Rat Oral NOAEL Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

**Silica colloidal, Ph. Eur.**  
**IARC:** Group 3

## **12. ECOLOGICAL INFORMATION**

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

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

#### **Minoxidil**

*Pimephales promelas* (Fathead Minnow) OECD LC50 96 Hours > 97 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.

### Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

# MATERIAL SAFETY DATA SHEET

Material Name: Minoxidil Tablets  
Revision date: 02-Jan-2007

Page 6 of 7  
Version: 2.1

## Minoxidil

Activated sludge OECD EC-50 > 1000 mg/L

### 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  
Carcinogenic: Category 3  
Toxic to Reproduction; Category 3

**EU Risk Phrases:**  
R22 - Harmful if swallowed.  
R40 - Limited evidence of a carcinogenic effect  
R62 - Possible risk of impaired fertility.

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

**OSHA Label:**  
WARNING  
Harmful if swallowed.  
Suspected of causing cancer.  
Suspected of damaging fertility.

#### Canada - WHMIS: Classifications

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



## Minoxidil

Australia (AICS):

Present

# MATERIAL SAFETY DATA SHEET

Material Name: Minoxidil Tablets  
Revision date: 02-Jan-2007

Page 7 of 7  
Version: 2.1

---

<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 2
<b>EU EINECS List</b>	Schedule 4 253-874-2
<b>Microcrystalline cellulose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	232-674-9
<b>Lactose</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	200-559-2
<b>Silica colloidal, Ph. Eur.</b>	
<b>Australia (AICS):</b>	Present
<b>Starch</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	XU
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	232-679-6
<b>Magnesium stearate</b>	
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS List</b>	209-150-3

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.

**Prepared by:** Corporate Occupational Toxicology & Hazard Assessment

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.

**End of Safety Data Sheet**