# MATERIAL SAFETY DATA SHEET

**Revision date:** 02-Jan-2007
**Version:** 2.1

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

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**Material Name:** Minoxidil Tablets

**Trade Name:** LONITEN

**Chemical Family:** Mixture

**Intended Use:** Pharmaceutical product used as antihypertensive

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>112945-52-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

**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.
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.
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/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

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

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


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.
9. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>White</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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/m³

- **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
Minoxidil

Reproductive & 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)
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

Australia (AICS):
Present
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