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

Product Identifier

Material Name: Minoxidil Tablets

Trade Name: LONITEN; LONOLOX; LONNOTEN; LONOTEN

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antihypertensive

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+0044 (0)1304 616161

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

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2
Carcinogenicity: Category 2

Label Elements

Signal Word: Warning

Hazard Statements:
H351 - Suspected of causing cancer
H361f - Suspected of damaging fertility

Precautionary Statements:
P201 - Obtain special instructions before use
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minoxidil</td>
<td>38304-91-5</td>
<td>253-874-2</td>
<td>Acute Tox.4 (H302)</td>
<td>2.0-8.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc.2 (H351)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.2 (H361f)</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>112945-52-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Maize starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
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</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known
5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
- Hazardous Combustion: Formation of toxic gases is possible during heating or fire.
- Products:
- Fire / Explosion Hazards: Not determined

Advice for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
- 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.
- Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities
- Storage Conditions: Store as directed by product packaging.
- Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters: Refer to available public information for specific member state Occupational Exposure Limits.

Minoxidil
- Pfizer OEL TWA-8 Hr: 50µg/m³

Microcrystalline cellulose
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Controls**

**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. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

---

**MINOXIDIL TABLETS**

---

<table>
<thead>
<tr>
<th>Material Name</th>
<th>OEL</th>
<th>MAK</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maize starch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<tr>
<td>OSHA - Final PELS - TWAs:</td>
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<td></td>
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</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
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</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
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<tr>
<td>Vietnam OEL - TWAs</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
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<tr>
<td>Silica colloidal, Ph. Eur.</td>
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<tr>
<td>Austria OEL - MAKs</td>
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</tr>
<tr>
<td>Germany (DFG) - MAK</td>
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<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>4 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maize starch</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
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<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
<td>4 mg/m³</td>
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<tr>
<td>OSHA - Final PELS - TWAs:</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
<td></td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
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<tr>
<td>Magnesium stearate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td><strong>Solvent Solubility:</strong></td>
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<tr>
<td><strong>Water Solubility:</strong></td>
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<tr>
<td><strong>pH:</strong></td>
<td>No data available</td>
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<tr>
<td><strong>Melting/Freezing Point (°C):</strong></td>
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<tr>
<td><strong>Boiling Point (°C):</strong></td>
<td>No data available</td>
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<tr>
<td><strong>Partition Coefficient:</strong></td>
<td><strong>Method, pH, Endpoint, Value</strong></td>
</tr>
<tr>
<td>Minoxidil</td>
<td>Predicted 7.4  Log D 1.606</td>
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<tr>
<td>Microcrystalline cellulose</td>
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<tr>
<td>Lactose NF, monohydrate</td>
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<tr>
<td>Silica colloidal, Ph. Eur.</td>
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</tr>
<tr>
<td>Magnesium stearate</td>
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<tr>
<td><strong>Decomposition Temperature (°C):</strong></td>
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<tr>
<td><strong>Evaporation Rate (Gram/s):</strong></td>
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<td><strong>Vapor Pressure (kPa):</strong></td>
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<td><strong>Vapor Density (g/ml):</strong></td>
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<tr>
<td><strong>Relative Density:</strong></td>
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<tr>
<td><strong>Viscosity:</strong></td>
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<tr>
<td><strong>Flammability:</strong></td>
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</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
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<td>Flammability (Solids):</td>
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<tr>
<td>Flash Point (Liquid) (°C):</td>
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<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
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</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
   Oxidizing Properties: No data available
   Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
   Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
   Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May be harmful if swallowed. (based on animal data)
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.

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

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

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

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)
11. TOXICOLOGICAL INFORMATION

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
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 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:

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

Minoxidil
Pimephales promelas (Fathead Minnow)  OECD  LC50  96 Hours  > 97 mg/L

MINOXIDIL TABLETS
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: (Inoculum, Method, End Point, Result)

Minoxidil
Activated sludge OECD EC-50 > 1000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Minoxidil
Predicted 7.4 Log D 1.606

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Minoxidil
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
Schedule 4
15. REGULATORY INFORMATION

EU EINECS/ELINCS List  253-874-2

Microcrystalline cellulose
  CERCLA/SARA 313 Emission reporting  Not Listed
  California Proposition 65  Not Listed
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS): Present
  EU EINECS/ELINCS List  232-674-9

Silica colloidal, Ph. Eur.
  CERCLA/SARA 313 Emission reporting  Not Listed
  California Proposition 65  Not Listed
  Australia (AICS): Present
  EU EINECS/ELINCS List  Not Listed

Maize starch
  CERCLA/SARA 313 Emission reporting  Not Listed
  California Proposition 65  Not Listed
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS): Present
  REACH - Annex IV - Exemptions from the obligations of Register:
  EU EINECS/ELINCS List  232-679-6

Lactose NF, monohydrate
  CERCLA/SARA 313 Emission reporting  Not Listed
  California Proposition 65  Not Listed
  Australia (AICS): Present
  EU EINECS/ELINCS List  Not Listed

Magnesium stearate
  CERCLA/SARA 313 Emission reporting  Not Listed
  California Proposition 65  Not Listed
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS): Present
  EU EINECS/ELINCS List  209-150-3

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.2; H361f - Suspected of damaging fertility

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Revision date: 08-Apr-2019

MINOXIDIL TABLETS
SAFETY DATA SHEET

Material Name: Minoxidil Tablets
Revision date: 08-Apr-2019

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet