



# SAFETY DATA SHEET

Revision date: 08-Apr-2019

Version: 4.0

Page 1 of 10

## 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  
+00 44 (0)1304 616161  
Emergency telephone number:  
International Chemtrec (24 hours): +1-703-527-3887

**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



## SAFETY DATA SHEET

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

Page 2 of 10  
Version: 4.0

**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

#### Hazardous

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

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*

**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

## SAFETY DATA SHEET

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

Page 3 of 10  
Version: 4.0

### Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**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/m<sup>3</sup>

### Microcrystalline cellulose

## SAFETY DATA SHEET

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

Page 4 of 10  
Version: 4.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup> 4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>

#### Silica colloidal, Ph. Eur.

Austria OEL - MAKs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Switzerland OEL - TWAs	4 mg/m <sup>3</sup>

#### Maize starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup> 4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

#### Magnesium stearate

Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### 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.

## SAFETY DATA SHEET

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

Page 5 of 10  
Version: 4.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Tablets	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available.
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### Minoxidil

Predicted 7.4 Log D 1.606

#### Microcrystalline cellulose

No data available

#### Lactose NF, monohydrate

No data available

#### Silica colloidal, Ph. Eur.

No data available

#### Magnesium stearate

No data available

**Decomposition Temperature (°C):** No data available.

<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

## SAFETY DATA SHEET

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

Page 6 of 10  
Version: 4.0

### 10. STABILITY AND REACTIVITY

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

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
<b>Short Term:</b>	May be harmful if swallowed. (based on animal data)
<b>Long Term:</b>	Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, developing fetus, heart.
<b>Known Clinical Effects:</b>	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	2457mg/kg
Rat	Intravenous	LD50	49mg/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/m <sup>3</sup>

**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)

## SAFETY DATA SHEET

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

Page 7 of 10  
Version: 4.0

### 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

<i>In Vivo</i> Micronucleus	Rat	Negative
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
Micronucleus	Mouse Bone Marrow	Negative
<i>In Vitro</i> 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

<i>Pimephales promelas</i> (Fathead Minnow)	OECD	LC50	96 Hours	> 97 mg/L
---	------	------	----------	-----------

## SAFETY DATA SHEET

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

Page 8 of 10  
Version: 4.0

**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**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling</b>	Schedule 2
<b>for Drugs and Poisons:</b>	Schedule 4



## SAFETY DATA SHEET

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

Page 9 of 10  
Version: 4.0

### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	253-874-2
<b>Microcrystalline cellulose</b>	
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
<b>Silica colloidal, Ph. Eur.</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Maize starch</b>	
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:	Present
EU EINECS/ELINCS List	232-679-6
<b>Lactose NF, monohydrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Magnesium stearate</b>	
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

## SAFETY DATA SHEET

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

**Page 10 of 10**  
**Version: 4.0**

---

**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**