SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME MINOXIDIL, USP
PRODUCT CODE 0574
SUPPLIER
MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855
661 Route 3, Unit C, Plattsburgh, NY, 12901
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063
MEDISCA Pharmaceutique Inc.
Tel.: 1.800.665.6334 | Fax.: 514.338.1693
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2
MEDISCA Australia Pty Ltd
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047
Unit 7, Heritage Business Park
5-9 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300
NSW Poisons Information Centre: 131 126

USES Cardiovascular drug

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION
Acute Toxicity - Oral (Category 4)
Toxic to Reproduction (Category 2)
Chronic Aquatic Toxicity (Category 2)

PICTOGRAM

WARNING

SIGNAL WORD Warning

HAZARD STATEMENT(S)
Harmful if swallowed.
Causes serious eye irritation
Causes skin irritation.
Suspected of damaging fertility or the unborn child.
Suspected mutagen and carcinogen.
Toxic to aquatic life with long lasting effects.

AUSTRALIA-ONLY HAZARDS
Not Applicable.

PRECAUTIONARY STATEMENT(S)
Prevention Wash thoroughly after handling
Do not eat, drink or smoke when using this product.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves, protective clothing, eye protection, face protection.
Avoid release to the environment.
SAFETY DATA SHEET

Response

IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF ON SKIN (HAIR): Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.
IF EXPOSED OR CONCERNED: Get medical advice/attention. Collect spillage.

Storage

Store locked up

Disposal

Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

Health Hazard 2
Flammability 0
Reactivity 0
Personal Protection E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME 2,4-Pyrimidinediamine, 6-(1-piperidinyl)-, 3-oxide.
BOTANICAL NAME Not applicable
SYNONYM Alostil, Lonolox, Rogaine
CHEMICAL FORMULA C₉H₁₅N₅O
CAS NUMBER 38304-91-5
ALTERNATE CAS NUMBER Not applicable
MOLECULAR WEIGHT 209.2515

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minoxidil</td>
<td>38304-91-5</td>
<td>100</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES

Chemical family: Pyrimidine oxide.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

SYMPTOMS AND EFFECTS

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.
SAFETY DATA SHEET

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT
On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

STORAGE CONDITIONS
Store in original container, tightly sealed container, protected from direct sunlight, in a dry, and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Preserve in well-closed containers. Protect from light.

NOTES
Minoxidil is photolabile, developing a yellow discoloration. Photodegradation is reported to occur at a higher rate at lower concentrations and at acidic pH. However, minoxidil's overall stability was reported to be greatest at pH 4.5.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Chemical Name: Minoxidil</th>
<th>CAS #: 38304-91-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>Ceiling</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³
### PERSONAL PROTECTIVE EQUIPMENT

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fume hood, eye wash station, and safety shower.

### NOTES

USP: ELV: Industrial: TWA: 0.07 mg/m³

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL STATE</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>White to off-white, crystalline powder.</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Soluble in alcohol and in propylene glycol; sparingly soluble in methanol; slightly soluble in water; practically insoluble in chloroform, in acetone, in ethyl acetate, and in hexane.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td><strong>ODOR THRESHOLD</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>BOILING POINT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>FREEzing POINT</strong></td>
<td>(259-261)°C, (498.2-501.8)°F (decomposes)</td>
</tr>
<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
<td>~0.5</td>
</tr>
<tr>
<td><strong>EVAPORATION RATE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOR DENSITY (AIR = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>RELATIVE DENSITY (WATER = 1)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>(259-261)°C, (498.2-501.8)°F</td>
</tr>
</tbody>
</table>

### SECTION 10: STABILITY AND REACTIVITY

**REACTIVITY:** Not established

**STABILITY:** Stable under recommended storage conditions

**MATERIALS TO AVOID:** Strong oxidants

**HAZARDOUS DECOMPOSITION PRODUCTS:** Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

**HAZARDOUS POLYMERIZATION:** Will not occur

**POSSIBILITY OF HAZARDOUS REACTION:** Not established

**CONDITIONS TO AVOID:** Moisture, sunlight and extreme temperatures. Light sensitive.
### SECTION 11: TOXICOLOGICAL INFORMATION

#### ACUTE TOXICITY
- **Oral:** Rat: LD50: (mg/kg): 1321
- **Dermal:** Rabbit LD50: (mg/kg): Not available
- **Inhalation:** Rat: LD50: (mg/L/4hr): Not available

#### SKIN CORROSION/IRRITATION
Based on available data, the classification criteria are not met.

#### SERIOUS EYE DAMAGE/EYE IRRITATION
Based on available data, the classification criteria are not met.

#### RESPIRATORY OR SKIN SENSITIZATION
- Respiratory sensitization: Due to lack of data the classification is not possible.
- Skin sensitization: Based on available data, the classification criteria are not met.
  - Sensitization study (1-3%)
  - Result: Non-sensitizing.
  - Species: Guinea pig
  - Organ: Skin.

#### GERM CELL MUTAGENICITY
Based on available data, the classification criteria are not met. Suspected mutagen: The Toolbox profiler in vitro mutagenicity (Ames test) alerts by ISS gives an alert for mutagenicity.

#### CARCINOGENICITY
- **OSHA**
  - MINOXIDIL is not listed.
- **NTP**
  - MINOXIDIL is not listed.
- **IARC**
  - MINOXIDIL is not evaluated.
- **California**
  - Proposition 65
  - This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

#### ADDITIONAL CARCINOGENICITY INFORMATION
Based on available data, the classification criteria are not met. Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotoxic and nongenotoxic) alerts by ISS gives an alert for carcinogenicity. Oral: Carcinogenicity studies were conducted dermally and orally (diet), in mice and rats. They were positive.

Dermal: In the two-year study by the dermal route in rats, there were significant increases of incidents of pheochromocytomas in males and females and preputial gland adenomas in males. No evidence of carcinogenicity was found in rats and rabbits treated topically with minoxidil for one year.

#### REPRODUCTIVE TOXICITY
- Toxicity to reproduction: In a study in which male and female rats received one or five times the maximum recommended human oral antihypertensive dose of minoxidil (multiples based on a 50 kg patient) there was a dose-dependent reduction in conception rate.
- Developmental toxicity/teratogenicity: There was no evidence of teratogenic effects in rats and rabbits.
- Subcutaneous administration of minoxidil to pregnant rats at 80 mg/kg/day was maternally toxic but not teratogenic. Higher subcutaneous doses produced evidence of developmental toxicity. There are no adequate and well controlled studies in pregnant women.

#### SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Due to lack of data the classification is not possible.

#### SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Due to lack of data the classification is not possible.

#### ASPIRATION HAZARDS
Based on available data, the classification criteria are not met.

#### SIGNS AND SYMPTOMS OF EXPOSURE
- Symptoms related to the physical, chemical, and toxicological characteristics
- Delayed and immediate effects of exposure
  - Low blood pressure. Pulmonary hypertension.
- Medical conditions aggravated by exposure

#### POTENTIAL HEALTH EFFECTS
- **Inhalation**
  - May be harmful if inhaled. May cause respiratory tract irritation.
- **Ingestion**
  - Harmful if swallowed.
## SECTION 12: ECOLOGICAL INFORMATION

### TOXICITY
- EC50: 48 Hr: Crustacea (Daphnia): (mg/L): 1.52*
- LC50: 96 Hr: Fish: (mg/L): 84.12*
- IC50: 72 Hr: Algae: (mg/L): Not available

### PERSISTENCE AND DEGRADABILITY
Suspected persistent in the environment. The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

### BIOACCUMULATIVE POTENTIAL
- LogPow: 1.24 (20°C)

### MOBILITY IN SOIL
Slightly soluble in water.
- Water solubility: 2200 mg/L
- Henry's Law Constant: 2.12E-16 atm-m³/mole (25°C)

### OTHER ADVERSE EFFECTS
This product is not intended to be released into the environment

### NOTES
*Danish QSAR database

## SECTION 13: DISPOSAL考慮

### WASTE DISPOSAL
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

## SECTION 14: TRANSPORT INFORMATION

### UNITED STATES & CANADA
- UN PROPER SHIPPING NAME: Not dangerous good
- UN NUMBER: Not applicable
- CLASS: Not applicable
- PACKING GROUP: Not applicable

### AUSTRALIA
- UN PROPER SHIPPING NAME: Not dangerous good
- UN NUMBER: Not applicable
- CLASS: Not applicable
- PACKING GROUP: Not applicable

### ENVIRONMENTAL HAZARDS
- Not available

### SPECIAL SHIPPING INFORMATION
- Not applicable

## SECTION 15: REGULATORY INFORMATION

Last Revision: 05/2017
MINOXIDIL, USP
# SAFETY DATA SHEET

## AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
</tr>
</thead>
<tbody>
<tr>
<td>MINOXIDIL 38304-91-5</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
<td>N/L</td>
</tr>
</tbody>
</table>

MINOXIDIL = Not Listed; X = Listed

## SECTION 16: OTHER INFORMATION

Available upon request

## REFERENCES

CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA - Mine Safety and Health Administration; ACGIH - American Conference of Governmental Industrial Hygienists; IDHL - Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL - Recommended Exposure Limit

## LAST REVISION

05/2017

## SUPERSEDES

10/2014

## DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.