

## SAFETY DATA SHEET

### 1. IDENTIFICATION

**Product identifier:** Minoxidil MENS 5% Topical Solution

**Synonym:** 380 (30 day) & 798 (90 day)

**Manufacturer Name:** Perrigo Company.  
**US Address:** 515 Eastern Avenue  
Allegan, MI 49010 USA

**Manufacturing Site Address:** Perrigo Israel Pharmaceutical Ltd  
Tzvi Burnstein 1  
Yeruham 80500, Israel

**Telephone number:** +1 269-673-8451

**Emergency phone number:** 888-464-2986 (U.S. calls)  
+1 760-476-3962 Code 333304 (International calls)

**Email Address:** SDSRequest@perrigo.com

**Recommended use:** Human drug – Hair regrowth treatment for men

**Restrictions on use:** Use only as directed.

### 2. HAZARD(S) IDENTIFICATION

#### Classification:

Physical	Health
Flammable Liquid Category 3	Carcinogen Category 2

#### Label Elements: Warning!



#### Hazard statement(s)

Flammable liquid and vapor  
Suspected of causing cancer.

#### Precautionary statement(s)

Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Keep away from heat, sparks, open flames and hot surfaces. No smoking.  
Keep container tightly closed.  
Ground and bond container and receiving equipment

#### Precautionary statement(s)

Use explosion-proof electrical, ventilating and lighting equipment.  
Use only non-sparking tools.  
Take precautionary measures against static discharge.  
Wear protective gloves and eye protection.  
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
IF exposed or concerned: Get medical attention.  
In case of fire: Use water spray, carbon dioxide or alcohol-resistant foam to extinguish.  
Store in a well-ventilated place. Keep cool.  
Store locked up.  
Dispose in accordance with local and national regulations.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Propylene Glycol	57-55-6	Proprietary
Ethanol	64-17-5	Proprietary
Water	7732-18-5	Proprietary
Minoxidil	38304-91-5	5%

The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. FIRST-AID MEASURES

**Inhalation:** Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

**Skin contact:** Remove contaminated clothing. Wash skin with soap and water. If irritation develops and persists, get medical attention. Launder clothing before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

**Most important symptoms/effects, acute and delayed:** May cause eye irritation. Ingestion may cause gastrointestinal irritation and nervous system effects. Inhalation of ethanol vapors may cause dizziness and drowsiness.

**Indication of immediate medical attention and special treatment, if necessary:** Immediate medical attention is not normally required.

### 5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.

**Specific hazards arising from the chemical:** Flammable liquid and vapor. Vapors are heavier than air and can flow to remote ignition sources and flash back. Vapors may be explosive in confined areas. Vapors will collect in low areas. Vapors may be ignited by static sparks. Flames may be invisible in daylight.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8. Eliminate all ignition sources and ventilate the area with explosion-proof equipment. Prevent entry into basements or confined areas.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Stop spill at the source if it is safe to do so. Absorb with an inert material. Use non-sparking tools and equipment. Collect into a suitable container for disposal.

## 7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid eye and skin contact. Avoid breathing vapors. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and laundry before re-use. Keep product away from heat, sparks and all other sources of ignition. Electrically bond and ground transfer equipment. Use appropriately rated electrical equipment in areas where this material is handled and stored. Keep containers closed when not in use.

**Conditions for safe storage, including any incompatibilities:** Store as indicated on product packaging. Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Keep containers closed when not in use. Store away from oxidizers.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure guidelines:

Propylene Glycol	10 mg/m <sup>3</sup> TWA AIHA WEEL
Ethanol	1000 ppm TWA OSHA PEL 1000 ppm STEL ACGIH TLV
Water	None Established
Minoxidil	70 ug/m <sup>3</sup> TWA PERRIGO OEL

**Appropriate engineering controls:** Use with adequate general or local exhaust ventilation to minimize exposures levels. Use explosion-proof equipment where required.

### Individual protection measures:

**Respiratory protection:** None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor or supplied air respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

**Skin protection:** Impervious gloves recommended if contact with the drug product is possible.

**Eye protection:** Chemical safety goggles recommended if contact with the drug product is possible.

**Other:** None known.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance (physical state, color, etc.):** Clear, colorless liquid

**Odor:** Alcohol odor

<b>Odor threshold:</b> 100 ppm (Ethanol)	<b>pH:</b> 8.6
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined
<b>Flash point:</b> 40.6°C (105°F) (Closed Cup)	<b>Evaporation rate:</b> Same as water
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> 3%	<b>UEL:</b> 19%
<b>Vapor pressure:</b> 59.3 mmHg @ 25°C (ethanol)	<b>Vapor density:</b> 1.59 (ethanol)
<b>Relative density:</b> Not determined	<b>Solubility(ies):</b> Soluble
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available

**Decomposition temperature:** Not available

**Viscosity:** Not determined

## 10. STABILITY AND REACTIVITY

**Reactivity:** Not reactive under normal conditions of use.

**Chemical stability:** Stable.

**Possibility of hazardous reactions:** Reaction with strong oxidizers will generate heat and cause fire.

**Conditions to avoid:** Avoid heat, sparks, flames, and all other sources of ignition.

**Incompatible materials:** Avoid oxidizing agents, acids and bases.

**Hazardous decomposition products:** Thermal decomposition may yield carbon oxides.

## 11. TOXICOLOGICAL INFORMATION

### Acute effects of exposure:

**Inhalation:** Inhalation of vapors may cause minor irritation of the mucous membranes and upper respiratory tract and central nervous system effects such as dizziness, drowsiness and headache.

**Ingestion:** Swallowing may cause gastrointestinal irritation and nervous system effects such as drowsiness and drunkenness.

**Skin contact:** No adverse effects are expected. Minor irritation is possible

**Eye contact:** Contact may cause mild irritation with redness and tearing.

**Chronic Effects:** None known.

**Sensitization:** Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

**Germ Cell Mutagenicity:** None of the components have been shown to cause germ cell mutagenicity.

Minoxidil was not mutagenic in the Salmonella (Ames) test, the DNA damage alkaline elution assay, the in vitro rat hepatocyte unscheduled DNA synthesis (UDS) assay, the rat bone marrow micronucleus assay, or the mouse bone marrow micronucleus assay. An equivocal result was recorded in an in vitro cytogenetic assay using Chinese hamster cells at long exposure times, but a similar assay using human lymphocytes was negative.

**Reproductive Toxicity:** Orally administered minoxidil has been associated with evidence of increased fetal resorption in rabbits, but not rats, when given at dosages 5 times the maximum recommended human oral antihypertensive dosage. There was no evidence of teratogenic effects of orally administered minoxidil in rats or rabbits. There was no evidence of teratogenic effects in rats receiving subcutaneous minoxidil dosages of 80 mg/kg daily (about 2000 times the maximal systemic human exposure achieved with daily administration of topical minoxidil); however, maternal toxicity was observed with this dosage. Evidence of developmental toxicity was observed in rats receiving sc dosages exceeding 80 mg/kg daily. Ethanol is known to cause developmental toxicity when intentionally ingested during pregnancy.

**Carcinogenicity:** Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1).

In the 2 year dermal study in mice an increased incidence of mammary adenomas and adenocarcinomas in the females at all dose levels (8, 25, and 80 mg/kg/day) was attributed to increased prolactin activity. In the 2 year dermal study in rats there were significant increased incidence of pheochromocytomas in males and females and preputial gland adenomas in males. There was no evidence of epithelial hyperplasia or tumorigenesis at the site of topical application of minoxidil in either species in the 2 year dermal carcinogenesis studies. No evidence of carcinogenicity was detected in rats or rabbits treated topically with minoxidil for 1 year.

**Acute Toxicity Values:** Acute Oral Toxicity Estimate (ATE) calculated: 26,316 mg/kg

Ethanol: LD50 oral rat 7060 mg/kg; LC50 inhalation rat 20000 ppm/10 hr.

Propylene Glycol: LD50 oral rat 22,000 mg/kg, LD50 dermal rabbit >2000 mg/kg

Minoxidil: Oral rat LD50 1321 mg/kg

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity values:** No data is available

**Persistence and degradability:** No data is available

**Bioaccumulative potential:** No data is available

**Mobility in soil:** No data is available.

**Other adverse effects:** None known.

## 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

## 14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
<b>DOT</b>	UN1170	Ethanol Solution	3	III	No
<b>TDG</b>	UN1170	Ethanol Solution	3	III	No
<b>IMDG</b>	UN1170	Ethanol Solution	3	III	No
<b>IATA</b>	UN1170	Ethanol Solution	3	III	No

**Note:** Not Regulated in non-bulk packages for US and Canadian ground transportation per the combustible liquid exception.

**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):** Not applicable – product is transported only in packaged form.

**Special precautions:** None known.

## 15. REGULATORY INFORMATION

**Safety, health, and environmental regulations specific for the product in question.**

**CERCLA:** This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

**SARA Hazard Category (311/312):** Fire Hazard, Chronic Health

**EPA SARA 313:** This product contains the following chemicals regulated under SARA Title III, section 313:  
None

**EPA TSCA Inventory:** This product is a drug and not subject to TSCA.

**CANADA:**

**Canadian CEPA:** This product is a drug and not subject to CEPA regulations.

## 16. OTHER INFORMATION

**NFPA Rating:** Health = 1      Flammability = 2      Instability = 0  
**HMIS Rating:** Health = 1\*      Flammability = 2      Physical Hazard = 0

**SDS Revision History:** Update Address

**Date of preparation:** January 24, 2016

**Disclaimer:** This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).