

# Material Safety Data Sheet

Issuing Date: 10/12/2021

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Version 2

## 1. PRODUCT AND COMPANY INFORMATION

<b>Product ID:</b>	PF1414/P
<b>Product Name</b>	Minoxidil 20mg/ml topical solution
<b>Product Type</b>	Finished Product - Consumer (Retail) and Professional Use
<b>Recommended Use</b>	Personal Beauty Care Product
<b>Synonyms</b>	Rogaine, Loniten, Minoximen, Theroxidil, Alopexil, Alostil, Tricoxidil, Lonolox,Prexidil
<b>Manufacturer</b>	Laropharm Sos. Alexandriei nr.145A – C.P.:B07 – Bragadiru, Ilfov Romania
<b>E-mail Address</b>	office@laropharm.ro
<b>Emergency Telephone</b>	(021)315 94 32 (021)369 32 02

## 2. HAZARDS IDENTIFICATION





### 2.1. Classification of the substance or mixtures

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable, Acute Toxine, Skin Irritation, Eye Irritation

### 2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

GHS Classification	Category 2	Acute Toxicity-Oral Category 4	Toxic to Reproduction Category 2	Chronic Aquatic-Toxicity Category 2
GHS Pictograms				
Signal Word	Danger Warning			
Hazard Statement	H225: Highly flammable liquid and vapour H302: Harmful if Swallowed; H315: Causes skin irritation; H319: Causes serious eye irritation; H335: May cause respiratory irritation; H351: Suspected of causing cancer; H361: Suspected of damaging fertility or the unborn child.			
Precautionary Statement Prevention	P203 P210 P233 P240 P241 P242 P243 P261 P264 P264+P265 P270 P271 P280			
Precautionary Statement Response	P303 + P361 + P353 P301+P317 P302+P352 P304+P340 P305+P351+P338 P318 P319 P321 P330 P332+P317 P337+P317 P362+P364 P370 + P378			
Precautionary Statement Storage	P403 + P235 P403+P233 P405			
Precautionary Statement Disposal	P501			

Code	Statement
P203	Obtain, read and follow all safety instructions before use.
P210	Keep away from heat/ sparks/open flames/hot surfaces. — No smoking.
P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting/.../equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge
P261	Avoid breathing dust/fume/gas/mist/vapors/spray.
P264	Wash hands thoroughly after handling.
P265	Do not touch eyes.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection. <i>Condition for use:</i> Manufacturer/supplier to specify type of equipment. — Specify protective gloves and eye/face protection.
P301+P317	IF SWALLOWED: Get emergency medical help.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P303 + P361 + P353	IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P318	If exposed or concerned, get medical advice.
P319	Get medical help if you feel unwell.
P321	Specific treatment.
P330	Rinse mouth.
P332+P317	IF SKIN irritation occurs: Get emergency medical help.
P337+P317	If eye irritation persists: Get emergency medical help.

P362+P364	Take off contaminated clothing. And wash it before reuse.
P370 + P378	In case of fire: Use ... for extinction. <i>Condition for use:</i> Manufacturer/supplier to specify appropriate media. — if water increases risk.
P403 + P235	Store in a well-ventilated place. Keep cool.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to.... <i>Condition for use:</i> .....in accordance with local/regional/national/ international regulation (to be specified).

**General hazards** This is a personal care or cosmetic product that is safe for consumers and other users under normal and reasonably foreseeable use.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous ingredients

Chemical Name	CAS-No	Weight g/bottle
Minoxidil	38304-91-5	1.20
Ethanol	64-17-5	36.0 ml
Propylene glycol	57-55-6	9.0
Purified water	N.A.	q.s.ad.60.00 ml

### 4. FIRST AID MEASURES

<b>General advice</b>	No hazards which require special first aid measures. When symptoms persist or in all cases of doubt seek medical advice.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. If symptoms persist, call a physician. <b>Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician.</b>
<b>Skin contact clothing</b>	<b>IMMEDIATELY flood affected skin with water while removing and isolating all contaminated.</b> Gently wash all affected skin areas thoroughly with soap and water. If skin problems occur, discontinue use. If symptoms persist, call a physician.
<b>Ingestion</b>	<b>Do not induce vomiting.</b> Clean mouth with water and afterwards drink plenty of water. If the victim is convulsing or unconscious, do not give anything by mouth, though, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. If symptoms persist, call a physician.
<b>Inhalation</b>	<b>IMMEDIATELY leave the contaminated area; take deep breaths of fresh air.</b> If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital.
<b>Protection of first-aiders</b>	Use personal protective equipment. Remove all sources of ignition.
<b>Most important symptoms/effects, acute and delayed</b>	None known.
<b>Notes to Physician</b>	Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

**Flammable properties**

Flammable liquid.

**Flash point**

Chemical Name	Criteria
Ethanol	Flash point < 23°C and initial boiling point ≤ 35°C
Propylene glycol	Flash point < 23°C and initial boiling point > 35°C
Purified water	Flash point ≥ 23°C and ≤ 60°C (1)

**Suitable extinguishing media**

**Small fire:** Dry chemical, CO<sub>2</sub> or water spray **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray.

**Extinguishing media which shall not be used for safety reasons**

No information available

**Special hazard**

The release of the following substances is possible in a fire: Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke). Nitrous oxides. May form explosive mixtures with air.

**Special protective equipment for fire-fighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions**

Wear appropriate personal protective clothing and eye protection to prevent skin and eye contact. Work clothing that becomes wet should be immediately removed due to its flammability hazard.

**Advice for emergency responders**

Use personal protective equipment.

**Environmental precautions**

Do not discharge product into natural waters without pre-treatment or adequate dilution. Should not be released into the environment.

**Methods for containment**

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

**Methods for cleaning up**

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Use non-sparking tools and equipment. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). If necessary, employ water fog to disperse the vapors. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## 7. HANDLING AND STORAGE

**Advice on safe handling**

Keep out of the reach of children. Observe label precautions. Keep away from open flames, hot surfaces and sources of ignition. Do not inhale. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke in work area.

**Technical measures/Storage conditions**

Keep out of the reach of children. Store in original containers, protected from direct sunlight, tightly closed in a dry, cool and well-ventilated place. Keep away from open flames, hot surfaces and sources of ignition. Keep away from direct sunlight.

**Notes**

Minoxidil is photolabile, developing a yellow discoloration. Photodegradation is reported to occur at a high rate at lower concentrations and at acidic pH.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Measures** Adequate mechanical ventilation. Fumehood, eye wash station and safety shower.

### Personal Protective Equipment

**Eye Protection** Wear appropriate protective eyeglasses or chemical safety goggles as described by and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

**Hand Protection** Wear appropriate gloves to prevent skin exposure

**Skin and Body Protection** Wear appropriate protective clothing to minimize contact with skin.

**Respiratory Protection** 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.

**Thermal hazards** Not applicable.

**Hygiene measures** None under normal use conditions.

**Environmental exposure controls** See section 6 for more information.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State @20°C** Liquid  
**Appearance** Clear to yellow  
**Odor** Alcohol

<u>Property</u>	<u>Values</u>	<u>Note</u>
pH value	7.5-9.0	
Melting/freezing point	248°C	
Boiling point/boiling range	78 °C / 172 °F	
Flash point	<= 22 °C / <= 72 °F	
Evaporation rate	No information available	
flammability (solid, gas)	No information available	
Flammability Limits in Air		
Upper flammability limit	No information available	
Lower Flammability Limit	No information available	
Vapor pressure	No information available	
Vapor density	No information available	
Relative density	0.900-0.930	
Water solubility	No information available	
Solubility in other solvents	No information available	
Partition coefficient: n-octanol/water	1.24(20°C)	
Autoignition temperature	No information available	.
Decomposition temperature	259-261 °C	.
Viscosity of Product	No information available	
Bulk Density	No information available	
Oxidizing properties	No information available	

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	None under normal use conditions.
<b>Stability</b>	Stable under normal conditions.
<b>Hazardous polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous Reactions</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and gases may occur.
<b>Conditions to Avoid</b>	Keep away from open flames, hot surfaces and sources of ignition. Extremes of temperature and direct sunlight.
<b>Materials to avoid</b>	Strong oxidants
<b>Hazardous Decomposition Products</b>	None under normal use.

## 11. TOXICOLOGICAL INFORMATION

### Product Information

<b>Acute Toxicity</b>	No known effect based on information supplied.
<b>Inhalation</b>	
<b>Skin contact</b>	
<b>Ingestion</b>	
<b>Eye contact</b>	
<b>Chronic Toxicity</b>	No known effect based on information supplied.
<b>Inhalation</b>	
<b>Skin contact</b>	
<b>Ingestion</b>	
<b>Eye contact</b>	

<b>Respiratory or skin sensitization</b>	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.
<b>Germ cell mutagenicity</b>	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.
<b>Carcinogenicity</b>	<b>OSHA</b> MINOXIDIL is not listed. <b>NTP</b> MINOXIDIL is not listed. <b>IARC</b> MINOXIDIL is not listed. <b>California</b> This product does not contain any chemicals known <b>Proposition 65</b> to the State of California to cause cancer, birth defects, or any other reproductive harm.

<b>Reproductive toxicity</b>	<p>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.</p> <p>Developmental toxicity/ teratogenicity: There was no evidence of teratogenic effects in rats and rabbits.</p> <p>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.</p>
<b>Neurological Effects</b>	No known effect.
<b>Developmental toxicity</b>	No known effect.
<b>Teratogenicity</b>	No known effect.
<b>Signs and symptoms of exposure</b>	<p>Symptoms related to the physical, chemical, and toxicological characteristics  Chest pain. Fast or irregular heartbeat. Skin redness. Headache. Weakness. Dizziness. Blurred vision. Swelling of feet or lower legs. Bloating. Nausea. Vomiting. Weight gain. Decreased sexual desire.</p> <p>Delayed and immediate effects of exposure  Low blood pressure. Pulmonary hypertension.  Medical conditions aggravated by exposure  Heart problems. Blood disorders. Pheochromocytoma. Kidney impairment.</p>
<b>Potential health effects</b>	<p>Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.</p> <p>Ingestion: Harmful if swallowed</p> <p>Skin: May be harmful if absorbed through skin. Cause skin irritation.</p> <p>Eyes: Causes serious eye irritation.</p>

Chemical Name	CAS-No	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethanol	64-17-5	10470 mg/kg bw (OECD 401; standard acute method; rat)	> 15800 mg/kg bw (Rabbit)	116.9 mg/L air (Similar to OECD 403; standard acute method; rat; 4 h)
Propylene glycol	57-55-6	22000 mg/kg (rat)	> 2000 mg/kg bw (Guideline not indicated; fixed dose procedure; rabbit)	> 317.042 mg/L (Guideline not indicated; rabbit; 2 h)



## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Chemical Name	CAS-No	Toxicity to algae	Toxicity to fish	Toxicity to Microorganisms	Toxicity to daphnia and other aquatic invertebrates	Toxicity to other organisms
Ethanol	64-17-5	275 mg/L (Similar to OECD 201; Chlorella vulgaris; static; freshwater; growth rate)	14200 mg/L (US EPA method E03-05; Pimephales promelas; flow-through; freshwater)	IC50: > 1000 mg/L (OECD 209; activated sludge from domestic and industrial sewage treatment plants; static; freshwater)	5012 mg/L (Guideline: ASTM E729-80; Ceriodaphnia dubia; static; freshwater)	> 100 mg/L (Guideline not indicated; Lumbriculus variegatus; static; freshwater; 96 h)
Propylene glycol	57-55-6	19300 (OECD 201; Skeletonema costatum; static; saltwater; growth rate)	40613 mg/L (Guideline: Environment Canada (1990); Oncorhynchus mykiss; static; freshwater)	-	18800 mg/L (Guideline: US EPA FIFRA 72-3 (TSCA 797.1950); Americamysis bahia; static; saltwater; mortality)	6983 mg/kg sediment dw (Guideline: OSPARCOM guidelines; Corophium volutator; short-term toxicity static; saltwater; 10 d)
Chemical Name	CAS-No	Toxicity to algae	Toxicity to fish	Toxicity to Microorganisms	Toxicity to daphnia and other aquatic invertebrates	Toxicity to other organisms
Ethanol	64-17-5		7900 mg/L (Read across data on Methanol; guideline not indicated; Oryzias latipes; static; freshwater)		2 mg/L (Guideline not indicated; Ceriodaphnia dubia; semi-static; freshwater)	> 79 mg/L (Guideline not indicated; Rana temporaria; static; freshwater; 48 h)
Propylene glycol	57-55-6	< 5300 mg/L (OECD 201; Skeletonema costatum; static; saltwater; growth rate)		NOEC: > 20000 mg/L (Guideline not indicated; Pseudomonas putida; freshwater; 18 h)	13020 mg/L (EPA 600/4-89/001; Ceriodaphnia sp.; semi-static; freshwater)	1368.77 mg/kg sediment dw (Guideline: OSPARCOM guidelines; Corophium volutator; short-term toxicity; static; saltwater; 10 d)

### Persistence and degradability

Chemical Name	Ready Test Results	Persistence and degradability
Ethanol	84 % (Guideline not indicated; aerobic; sewage, domestic, non-adapted; O <sub>2</sub> consumption; 20 d; meets 10-d window criterion)	83 % (Read across data on Methanol; guideline not indicated; anaerobic; natural water / sediment; 3 d)
Propylene glycol	81.7 % (OECD 301 F; aerobic; activated sludge, domestic (adaptation not specified); CO <sub>2</sub> evolution; meets 10-d window criterion)	95.8 % (OECD 306; aerobic; natural water; DOC removal; 64 d)

**Bioaccumulative potential**

Chemical Name	Bioconcentration factor (BCF)
Ethanol	< 10
Propylene glycol	0.09 (Calculated value)

**Mobility**

Chemical Name	KOC Values
Ethanol	1 (Read across data on Methanol; calculated value (PCKOCWIN v1.66 calculation, EPA for EPI suite, 2000); adsorption; soil)
Propylene glycol	2.9 (Calculated value; TGD (non-hydrophobics) method)

**Other adverse effects** No information available.

### 13. DISPOSAL CONSIDERATIONS

**Waste from Residues / Unused Products** **Household:** Do not discharge product into natural waters without pre-treatment or adequate dilution. **Non-household:** Should not be released into the environment. Dispose of in accordance with local regulations.

**Contaminated packaging** Dispose of in accordance with local regulations.

**Other disposal recommendations** **Non-household:** Products covered by this MSDS, in their original form, when disposed from a commercial facility as waste, are ignitable hazardous waste. Disposal should be in accordance with Local, State and Federal regulations.

### 14. TRANSPORT INFORMATION

**14.1 UN number**

ADR/RID: 1170 IMDG: 1170 IATA: 1170

**14.2 UN proper shipping name**

ADR/RID: ETHANOL SOLUTION IMDG: ETHANOL SOLUTION IATA: ETHANOL SOLUTION

**14.3 Transport hazard class(es)**

ADR/RID: 3 IMDG: 3 IATA: 3

**14.4 Packaging group**

ADR/RID: II IMDG: II IATA: II

**14.5 Environmental hazards**

ADR/RID: no IMDG Marine pollutant: no IATA: no

**14.6 Special precautions for user**

No data available

## 15. REGULATORY INFORMATION

### 15.1. EU-Regulations

Safety, health and environmental regulations / legislation specific for the substance or mixture in question

There is no date

### 15.2. National regulations

Chemical safety assessment for this product, in order to maintain a chemical safety assessment according to REACH Regulation (EC) No. 1272/2008 and **REACH Regulation(EC) No. 2020/878**.

## 16. OTHER INFORMATION

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### **Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of MSDS**