



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • Loprox® Shampoo (ciclopirox) 1%

Product Code • 399207010104; NDC 99207-010-10

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Loprox Shampoo is indicated for the topical treatment of seborrheic dermatitis of the scalp in adults.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals International, Inc.
2150 St. Elzear West
Laval H7L 4A8
Canada
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS Revision 3

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS): Third Revised Edition

Classification of the substance or mixture

UN GHS • Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

Hazard statements • May cause eye irritation

Precautionary statements

Prevention • Use personal protective equipment as required.
Wash thoroughly after handling.

Response • 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.

- Storage/Disposal** • Keep tightly closed and store in upright position.
Store at room temperature 15-30C (59-86F).

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	Identifiers	%
Alkyl Ether Sulfate (Sodium Laureth Sulfate)	CAS:68585-34-2	N/A
Ciclopirox	CAS:29342-05-0 EINECS:249-577-2	1%
Disodium Laureth Sulfosuccinate	CAS:68815-56-5	N/A
Laureth-2	CAS:68439-50-9	N/A
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	N/A
Water	CAS:7732-18-5 EINECS:231-791-2	N/A

N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- 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.

Ingestion

- No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion Products • No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8.

Emergency Procedures • No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

Section 7 - Handling and Storage

Precautions for safe handling

Handling • No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage • Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. Use before expiration date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines • Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls • Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable

level.

Personal Protective Equipment**Respiratory**

- No respiratory protection required during normal handling.

Eye/Face

- Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- Gloves are not required under normal handling conditions.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties**Information on Physical and Chemical Properties**

Material Description			
Physical Form	Liquid	Appearance/Description	colorless, translucent shampoo.
Color	Colorless Translucent .	Odor	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	4.5 to 6.5
Specific Gravity/Relative Density	Not relevant	Water Solubility	Not relevant
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity**Reactivity**

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- No data available

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

- Other Material Information**
- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

GHS Properties	Classification
Acute toxicity	UN GHS 3 • Classification criteria not met
Skin corrosion/Irritation	UN GHS 3 • Classification criteria not met
Serious eye damage/Irritation	UN GHS 3 • Eye Mild Irritation 2B
Skin sensitization	UN GHS 3 • Classification criteria not met
Respiratory sensitization	UN GHS 3 • Classification criteria not met
Aspiration Hazard	UN GHS 3 • Classification criteria not met
Carcinogenicity	UN GHS 3 • Classification criteria not met
Germ Cell Mutagenicity	UN GHS 3 • Classification criteria not met
Toxicity for Reproduction	UN GHS 3 • Classification criteria not met
STOT-SE	UN GHS 3 • Classification criteria not met
STOT-RE	UN GHS 3 • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Skin

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Eye

- Acute (Immediate)**
 - Causes mild eye irritation with direct contact to eye.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Other

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Ciclopirox	29342-05-0	No	Yes	No
Laureth-2	68439-50-9	Yes	No	Yes
Disodium Laureth Sulfosuccinate	68815-56-5	Yes	No	Yes
Alkyl Ether Sulfate (Sodium Laureth Sulfate)	68585-34-2	Yes	No	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes

Canada

Labor**Canada - WHMIS 1988 - Classifications of Substances**

• Laureth-2	68439-50-9	Not Listed
• Alkyl Ether Sulfate (Sodium Laureth Sulfate)	68585-34-2	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Ciclopirox	29342-05-0	Not Listed
• Disodium Laureth Sulfosuccinate	68815-56-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Laureth-2	68439-50-9	Not Listed
• Alkyl Ether Sulfate (Sodium Laureth Sulfate)	68585-34-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ciclopirox	29342-05-0	Not Listed
• Disodium Laureth Sulfosuccinate	68815-56-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Laureth-2	68439-50-9	Not Listed
• Alkyl Ether Sulfate (Sodium Laureth Sulfate)	68585-34-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ciclopirox	29342-05-0	Not Listed
• Disodium Laureth Sulfosuccinate	68815-56-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Laureth-2	68439-50-9	Not Listed
• Alkyl Ether Sulfate (Sodium Laureth Sulfate)	68585-34-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ciclopirox	29342-05-0	Not Listed
• Disodium Laureth Sulfosuccinate	68815-56-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Laureth-2	68439-50-9	Not Listed
• Alkyl Ether Sulfate (Sodium Laureth Sulfate)	68585-34-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ciclopirox	29342-05-0	Not Listed
• Disodium Laureth Sulfosuccinate	68815-56-5	Not Listed

Section 16 - Other Information

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