



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **Podofilox Topical Solution, 0.5%**

Product Code • NDC 68682-926-35

Product Description • Prescription pharmaceutical product.

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

Recommended use • Podofilox 0.5% solution is indicated for the topical treatment of external genital warts (Condyloma acuminatum).

Restrictions on use • For topical use only. 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 • Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals N. America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
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

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

Classification of the substance or mixture

UN GHS

- Skin Mild Irritation 3
- Eye Mild Irritation 2B
- Reproductive Toxicity 1A
- Specific Target Organ Toxicity Single Exposure 3: Respiratory Tract Irritation
- Specific Target Organ Toxicity Repeated Exposure 2
- Carcinogenicity 1A
- Flammable Liquids 2

Label elements

UN GHS

DANGER



- Hazard statements**
- Highly flammable liquid and vapour
 - Causes mild skin irritation
 - Causes eye irritation
 - May cause cancer.
 - May damage fertility or the unborn child.
 - May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

- Prevention**
- Do not handle until all safety precautions have been read and understood.
 - Keep away from heat, sparks, open flames and/or hot surfaces. - No smoking.
 - Keep container tightly closed.
 - Ground and/or bond container and receiving equipment.
 - Wash thoroughly after handling.
 - Use personal protective equipment as required.

- Response**
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - IF exposed or concerned: Get medical advice/attention.

- Storage/Disposal**
- Store in a well-ventilated place. Keep cool.
 - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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	%	Classifications According to Regulation/Directive
Ethanol	CAS:64-17-5 EINECS:200-578-6	> 90%	UN GHS: Skin Irrit. 2; Eye Irrit. 2; Acute Tox. Inhal. 3; STOT RE 1; STOT SE 3: Narc.; Flam. Liq. 2; Muta. 2; Carc. 1A; Repr. 1A; Lact.; Aquatic Acute 2; Aquatic Chronic 3
Lactic acid	CAS:50-21-5 EINECS:200-018-0	7.22%	UN GHS: Skin Corr. 1A; Eye Dam. 1
Sodium lactate	CAS:72-17-3 EINECS:200-772-0	0.91%	UN GHS: NDA
Podophyllotoxin	CAS:518-28-5 EINECS:208-250-4	0.61%	UN GHS: NDA

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

Section 4: First-Aid Measures

Description of first aid measures

- | | |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Inhalation | <ul style="list-style-type: none"> Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist. |
| Skin | <ul style="list-style-type: none"> Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse. |
| Eye | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> If swallowed, wash out mouth with water provided person is conscious. Seek medical attention. |

Most important symptoms and effects, both acute and delayed

- Symptoms of overexposure after systemic administration: vomiting, fever, diarrhea, peripheral neuropathy, altered mental status, lethargy, coma, tachypnea, respiratory failure, leukocytosis, pancytosis, hematuria, renal failure, and seizures.

Indication of any immediate medical attention and special treatment needed

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

- | | |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Suitable Extinguishing Media | <ul style="list-style-type: none"> SMALL FIRES: Dry chemical, CO₂, water spray or regular foam. LARGE FIRE: Water spray, fog or regular foam. |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

- | | |
|---------------------------------------|---------------------------------------------------------------------|
| Unsuitable Extinguishing Media | <ul style="list-style-type: none"> No data available |
|---------------------------------------|---------------------------------------------------------------------|

- | | |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Firefighting Procedures | <ul style="list-style-type: none"> As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes. |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Special hazards arising from the substance or mixture

- | | |
|-------------------------------------------|------------------------------------------------------------------------------|
| Unusual Fire and Explosion Hazards | <ul style="list-style-type: none"> Contains flammable liquid. |
|-------------------------------------------|------------------------------------------------------------------------------|

- | | |
|--------------------------------------|---------------------------------------------------------------------|
| Hazardous Combustion Products | <ul style="list-style-type: none"> No data available |
|--------------------------------------|---------------------------------------------------------------------|

Advice for firefighters

- Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- | | |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal Precautions | <ul style="list-style-type: none"> Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Evacuate immediate area. Ventilate enclosed areas. |
| Emergency Procedures | <ul style="list-style-type: none"> ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep unauthorized personnel away. 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.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete. Refer to Section 13 for appropriate disposal procedures.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Keep away from fire - No Smoking. Keep away from heat and sparks.

Conditions for safe storage, including any incompatibilities

Storage

- Solution is flammable, keep away from heat or flame. Keep tightly closed. Store at room temperature 20-25°C (68-77°F), to maintain product integrity. Use before 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 Limits/Guidelines

	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Ethanol (64-17-5)	TWAs	Not established	1000 ppm TWAEV; 1880 mg/m ³ TWAEV	1000 ppm TWA; 1900 mg/m ³ TWA	1000 ppm TWA; 1900 mg/m ³ TWA
	STELs	1000 ppm STEL	Not established	Not established	Not established

Exposure Control Notations

ACGIH

- Ethanol (64-17-5): **Carcinogens:** (A3 - Confirmed Animal Carcinogen with Unknown Relevance to Humans)

Exposure Limits Supplemental

ACGIH

- Ethanol (64-17-5): **TLV Basis - Critical Effects:** (upper respiratory tract irritation)

Exposure controls

Engineering

Measures/Controls

- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Pictograms



Respiratory

- Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH

(US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

- Eye/Face**
 - Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a spill, appropriate eye protection should be worn.
- Hands**
 - Wear protective gloves .
- Skin/Body**
 - No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.
- General Industrial Hygiene Considerations**
 - Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke during work. Avoid contact with skin, eyes or clothing. Wash thoroughly after handling.
- Environmental Exposure Controls**
 - No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Clear Liquid.
Color	Colorless	Odor	Mild alcohol odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	No data available	Water Solubility	Miscible
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	<= 20 °C(<= 68 °F)	UEL	No data available
LEL	No data available	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	Not relevant		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and humidities.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Heat, direct sunlight.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information • Toxicological information refers to raw materials only. Concentrations and toxicological effects may be substantially reduced in the product.

Components	
Ethanol (> 90%)	64-17-5 Acute Toxicity: Ingestion/Oral-Rat LD50 • 7 g/kg; Irritation: Eye-Rabbit • 500 mg • Severe irritation; Skin-Rabbit • 20 mg 24 Hour(s) • Moderate irritation; Multi-dose Toxicity: Ingestion/Oral-Rat TDLo • 188 g/kg 25 Day(s)-Intermittent; Liver:Fatty liver degeneration; <i>Biochemical:Enzyme inhibition, induction, or change in blood or tissue levels:Multiple enzyme effects;</i> <i>Biochemical:Metabolism (intermediary):Lipids, including transport;</i> Mutagen: Cytogenetic analysis • Ingestion/Oral-Human • 49014 g/kg 25 Year(s); Dominant lethal test • Ingestion/Oral-Mouse • 3720 mg/kg 3 Day(s); Sperm Morphology • Ingestion/Oral-Mouse • 1500 mg/kg 50 Day(s); Reproductive: Ingestion/Oral-Rat TDLo • 12 g/kg (9-12D preg); <i>Reproductive Effects:Effects on Embryo or Fetus:Fetotoxicity (except death, e.g., stunted fetus);</i> Ingestion/Oral-Woman TDLo • 5860 mL/kg (3Y pre-100D post); <i>Reproductive Effects:Specific Developmental Abnormalities:Craniofacial (including nose and tongue);</i> <i>Reproductive Effects:Effects on Newborn:Behavioral; Reproductive Effects:Effects on Newborn:Delayed effects;</i> Tumorigen / Carcinogen: Ingestion/Oral-Mouse • 400 g/kg 57 Week(s)-Intermittent; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria;</i> Gastrointestinal:Tumors; Ingestion/Oral-Mouse TDLo • 320 mg/kg 50 Week(s)-Intermittent; <i>Tumorigenic:Equivocal tumorigenic agent by RTECS criteria;</i> Liver:Tumors; Blood:Lymphoma, including Hodgkin's disease
Podophyllotoxin (0.61%)	518-28-5 Acute Toxicity: Ingestion/Oral-Mouse LD50 • 100 mg/kg; Skin-Rat LD50 • 500 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3
Serious eye damage/Irritation	UN GHS • Eye Mild Irritation 2B
Skin sensitization	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Carcinogenicity 1A
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 1A
STOT-SE	UN GHS • Specific Target Organ Toxicity Single Exposure 3: Respiratory Tract Irritation
STOT-RE	UN GHS • Specific Target Organ Toxicity Repeated Exposure 2

Target Organs

- Liver

Potential Health Effects

Inhalation

- Acute (Immediate)** • May cause irritation.
- Chronic (Delayed)** • No data available.

Skin

- Acute (Immediate)** • Causes mild skin irritation.
- Chronic (Delayed)** • Causes mild skin irritation.

Eye

- Acute (Immediate)** • Causes mild eye irritation.
- Chronic (Delayed)** • No data available.

Ingestion

- Acute (Immediate)** • May be harmful if swallowed.
- Chronic (Delayed)** • No data available.

Carcinogenic Effects

- Component information: Ethyl alcohol (CAS# 64-17-5) - IARC Group 1 Carcinogenic, NTP - Evidence of Carcinogenicity.

Carcinogenic Effects			
	CAS	IARC	NTP
Ethanol	64-17-5	Group 1-Carcinogenic	Evidence of Carcinogenicity

Reproductive Effects

- Ethyl alcohol when ingested has developmental toxicity.

Section 12 - Ecological Information**Toxicity**

Components		
Ethanol (> 90%)	64-17-5	Aquatic Toxicity-Fish: 96 Hour(s) LC50 <i>Fathead Minnow (Pimephales promelas)</i> 100 mg/L 84 Day(s) NOEC <i>Eastern mosquito fish</i> 0.375 mg/L Aquatic Toxicity-Crustacea: 48 Hour(s) NOEC <i>Water Flea (Ceriodaphnia dubia)</i> 2 mg/L 48 Hour(s) EC50 <i>Water Flea (Ceriodaphnia dubia)</i> 2 mg/L Aquatic Toxicity-Algae and Other Aquatic Plant(s): 24 Hour(s) EC50 <i>298 Dunaliella tertiolecta (Green Algae)</i> 5000 mg/L 96 Hour(s) NOEC <i>Algae</i> 14 mg/L

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	UN 1170	Ethyl alcohol solution	3	II	
	ID8000	Limited quantity	3	II	
TDG	UN 1170	Ethyl alcohol solution	3	II	
IMO/IMDG	UN 1170	Ethyl alcohol solution	3	II	
IATA/ICAO	UN 1170	Ethyl alcohol solution	3	II	
	ID8000	Limited quantity	3	II	

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

Other information

DOT • See DOT Part 173.150(g): Exception. For inner packagings containing liquids the volume does not exceed 8 fluid ounces in capacity. The net liquid contents of all inner packagings in any single outer packaging may not exceed 192 fluid ounces. The gross weight of any single outer package shipped may not exceed 65 pounds.

Section 15 - Regulatory Information

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

SARA Hazard Classifications • Acute

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Ethanol	64-17-5	Yes	Yes	Yes
Podophyllotoxin	518-28-5	No	Yes	No
Lactic acid	50-21-5	Yes	Yes	Yes
Sodium lactate	72-17-3	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Ethanol	64-17-5	B2, D2B
• Lactic acid	50-21-5	Not Listed
• Sodium lactate	72-17-3	Uncontrolled product according to WHMIS classification criteria (including 60%)
• Podophyllotoxin	518-28-5	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Ethanol	64-17-5	0.1 %
• Lactic acid	50-21-5	1 %
• Sodium lactate	72-17-3	Not Listed
• Podophyllotoxin	518-28-5	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Ethanol	64-17-5	F; R11
• Lactic acid	50-21-5	Not Listed
• Sodium lactate	72-17-3	Not Listed
• Podophyllotoxin	518-28-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Ethanol	64-17-5	F R:11 S:(2)-7-16
• Lactic acid	50-21-5	Not Listed
• Sodium lactate	72-17-3	Not Listed
• Podophyllotoxin	518-28-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Ethanol	64-17-5	S:(2)-7-16
• Lactic acid	50-21-5	Not Listed
• Sodium lactate	72-17-3	Not Listed
• Podophyllotoxin	518-28-5	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Ethanol	64-17-5	carcinogen, 4/29/2011 (in alcoholic beverages)
• Lactic acid	50-21-5	Not Listed
• Sodium lactate	72-17-3	Not Listed
• Podophyllotoxin	518-28-5	Not Listed

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

• Ethanol	64-17-5	developmental toxicity, 10/1/1987 (in alcoholic beverages)
• Lactic acid	50-21-5	Not Listed
• Sodium lactate	72-17-3	Not Listed
• Podophyllotoxin	518-28-5	Not Listed

Section 16 - Other Information

Revision Date

- 10/March/2016

Last Revision Date

- 10/February/2016

Preparation Date

- 10/February/2016

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