

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Podofilox Solution 0.5%

Synonym: 4U3

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

Telephone number: 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 for topical treatment of genital warts.

Restrictions on use: Use only as directed.

Date of Preparation: March 20, 2015

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Flammable Liquid Category 2	Eye Damage Category 1

Label Elements:
DANGER!



Hazard statement(s)

Highly flammable liquid and vapor
 Causes serious eye damage.

Precautionary statement(s)

Keep away from heat, sparks, open flames and hot surfaces. No smoking.
 Keep container tightly closed.
 Wash hands thoroughly after handling.
 Wear eye protection.

Precautionary statement(s)

IF in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a Poison Center or doctor.
 IF on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
 In case of fire: Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam to extinguish.
 Store in a well-ventilated place. Keep cool.
 Dispose of container and contents in compliance with all national and local regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Podofilox	518-28-5	0.5%
Ethanol	64-17-5	>80%
DL-Lactic Acid	50-21-5	5-10%
Sodium Lactate	72-17-3	<1

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: This product is intended for use on the skin. If irritation develops and persists, discontinue use and get medical attention. Remove and contaminated clothing and launder it before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 15 minutes. Remove contact lenses, if present and easy to do after 5 minutes of flushing, then continue flushing. Get immediate medical attention.

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: Causes severe eye irritation and possible eye damage. Clinical use has caused redness, soreness, tenderness and small sores in the treatment area. Inhalation of ethanol vapors may cause headache, drowsiness and dizziness.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for eye contact. For other unintended exposure, seek medical advice.

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: Highly 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.

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: Prevent eye 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. Do not smoke while using. Do not leave the container in direct sunlight.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging at room temperature. Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Store out of direct sunlight. Store away from oxidizers.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Podofilox	Perrigo OEB 5 (<1 ug/m3)
Ethanol	1000 ppm TWA OSHA PEL 1000 ppm STEL ACGIH TLV
DL-Lactic Acid	None Established
Sodium Lactate	None Established

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 exceeded or 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: This product is intended for use on the skin. Impervious gloves recommended for handling this product other than for use.

Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Colorless liquid

Odor: Alcohol odor

Odor threshold: 100 ppm (Ethanol)	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: 78.3°C
Flash point: 24.4°C (76.1°F)	Evaporation rate: Not determined
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: 3% (ethanol)	UEL: 19% (ethanol)
Vapor pressure: 59.3 mmHg @ 25°C (ethanol)	Vapor density: 1.59 (ethanol)
Relative density: 0.82-0.84	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: 362.8°C (685°F)
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 irritation of the mucous membranes and upper respiratory tract and central nervous system effects such as dizziness, drowsiness and headache. Absorption through the respiratory tract may cause adverse effects as described by other routes of exposure.

Ingestion: Swallowing may cause gastrointestinal irritation and nervous system effects such as drowsiness and dizziness. Absorption of podofilox through the intestinal tract may cause nausea, vomiting, hypotension, irregular heartbeat, kidney effects, peripheral neuropathy and even death.

Skin contact: Clinical use has caused redness, soreness, tenderness and small sores in the treatment area. Podofilox is toxic if absorbed through the skin.

Eye contact: Based on the lactic acid concentration contact causes severe irritation with redness, pain and tearing. Eye damage is possible. Podofilox is absorbed through the eye.

Chronic Effects: None known.

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

Germ Cell Mutagenicity: Podofilox is not mutagenic according to the Ames plate reverse mutation assay (at concentrations up to 5 mg podofilox, with or without metabolic activation) and BALB/3T3 cells (at concentrations up to 0.008 ug/mL without metabolic activation and 12 ug/mL with activation). Chromosome damage occurs at higher doses; 25 mg/kg of podofilox caused disruption and breakage of chromosomes in vivo in the mouse micronucleus assay.

Reproductive Toxicity: Podofilox was embryotoxic in rats that were given daily intraperitoneal doses of 5 mg/kg of body weight. It was not teratogenic in rats that were given daily topical doses of 0.21 mg/kg of body weight. Podofilox did not impair fertility in two generations of rats given daily topical doses of 0.2 mg/kg of body weight during gametogenesis, mating, gestation, parturition, and lactation.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. There are published reports that, in mouse studies, crude podophyllin resin (containing podofilox) applied topically to the cervix produced changes resembling carcinoma in situ. These changes were reversible at five weeks after cessation of treatment. In one reported experiment, epidermal carcinoma of the vagina and cervix was found in 1 out of 18 mice after 120 applications of podophyllin (the drug was applied twice weekly over a 15-month period). Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1).

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 10,000 mg/kg; Acute Dermal Toxicity Estimate (ATE) calculated: 20,000 mg/kg

Podofilox: LD50 oral mouse 100 mg/kg; LD50 dermal rabbit 200 mg/kg

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

DL-Lactic Acid: LD50 oral rat >2000 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
DOT	UN1170	Ethanol Solution	3	III	No
TDG	UN1170	Ethanol Solution	3	III	No
IMDG	UN1170	Ethanol Solution	3	III	No
IATA	UN1170	Ethanol Solution	3	III	No

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, Acute 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.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 3 Flammability = 3 Instability = 0
HMIS Rating: Health = 3 Flammability = 3 Physical Hazard = 0

SDS Revision History: Convert to Hazcom 2012 format and content.

Date of preparation: March 20, 2015

Date of last revision: February 5, 2002

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).