



## SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

**PRODUCT IDENTIFIER/TRADE/MATERIAL NAME:** CONDYLOX<sup>®</sup> (PODOFILOX) GEL 0.5%

**CHEMICAL NAME:** For Active Ingredient: 5R, -(5 $\alpha$ , 5 $\beta$ , 8 $\alpha$ , 9 $\alpha$ ]-5,8,8a,9-tetrahydro-9-hydroxy-5-(3,4,5-trimethoxyphenyl) furo[3',4':6,7]naphtho-[2,3,-d]-1,3-dioxol-6(5aH)-one

**OTHER MEANS OF IDENTIFICATION/SYNONYMS:** None

**CHEMICAL FAMILY:** For Active Ingredient: Podophyllotoxin

**FORMULA:** For Active Ingredient: C<sub>22</sub>H<sub>22</sub>O<sub>8</sub>

**RELEVANT USE of the SUBSTANCE:** Anticholinergic Gel Human Pharmaceutical

**USES ADVISED AGAINST:** Non-Pharmaceutical Use

### SUPPLIER OF THE SAFETY DATA SHEET

**RESPONSIBLE PARTY U.S.:**

**ALLERGAN**

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NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This compound has been classified in accordance with the hazard criteria of the countries listed above.

**DATE OF PREPARATION:** October 2, 2017

**DATE OF REVISION:**

### 2. HAZARDS IDENTIFICATION

**EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION:** According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

**EU 67/548/EEC LABELING AND CLASSIFICATION:** According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

#### EMERGENCY OVERVIEW:

**Product Description:** This product is a clear, colorless gel with an alcohol odor supplied in tubes.

**Health Hazards:** The chief health hazard associated with overexposures during normal use and handling is the potential for irritation of contaminated skin. The active ingredient is toxic if swallowed and in contact with skin. Prolonged or chronic skin contact be harmful and cause systemic effects. In therapeutic use, the most common systemic adverse effect reported is headache. The most common adverse effects at the site of application include inflammation, redness, burning, skin erosion, pain, itching and bleeding. Less common adverse effects reported include peeling, scabbing, discoloration, tenderness, dryness, crusting, fissures, soreness, ulceration, swelling/edema, tingling, rash, and blisters. Therapeutic use of may also cause nausea, vomiting, fever, diarrhea, bone marrow depression, and oral ulcers. If vapors or mists created from the gel are inhaled, irritation of the respiratory system can occur. Podofilox may cause harm to the fetus, based on animal data. Animal studies indicate mutagenic potential by causing chromosomal breaks in mouse *in vivo* micronucleus tests. Some components are suspect carcinogens. Refer to Section 11 (Toxicological Information) for more information on potential health effects from therapeutic use.

**Reactivity Hazards:** This product is not reactive.

**Flammability Hazards:** The Gel is a Class 1B flammable liquid that is readily ignited under almost all conditions. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, sodium and nitrogen oxides and acrolein).

**Environmental Hazards:** Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

**Emergency Considerations:** Emergency responders should wear appropriate protection for situation to which they respond.

### 3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
Podofilox	518-28-5	208-250-1	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Reproductive Toxicity Cat. 3, Germ Cell Mutagen Cat. 3, Toxic Risk Phrase Codes: R63, R68, R25, R24 Hazard Symbols: T, Xn <u>GHS and EU 1272/2008</u> Classification: Reproductive Toxicity Cat. 2, Germ Cell Mutagen Cat. 2, Acute Oral Toxicity Cat. 3, Acute Dermal Toxicity Cat. 2 Hazard Codes: H361d, H341, H301, H310 Hazard Symbol/Pictogram: GHS06, GHS08
Butylated Hydroxytoluene	128-37-0	204-881-4	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Harmful Risk Phrase Codes: R22, R51/53 Hazard Symbols: Xn, N <u>GHS and EU 1272/2008</u> Classification: Acute Oral Toxicity Cat. 4, Acute Dermal Toxicity Cat. 5, Aquatic Chronic Toxicity Cat. 2 Hazard Codes: H302, H313, H411 Hazard Symbol/Pictogram: GHS07
Ethanol, USP	64-17-5	200-578-5	Proprietary	<u>EU 67/548</u> Classification: Highly Flammable Risk Phrases: R11 Hazard Symbol: F <u>EU/GHS 1272/2008</u> Classification: Flammable Liquid Cat. 2 Hazard Statement Codes: H225 Hazard Symbol/Pictogram: GHS02 ADDITIONAL SELF-CLASSIFICATION Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbol/Pictogram: Not Applicable
Glycerin	56-81-5	200-289-5	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Not Applicable Risk Phrases: Not Applicable Hazard Symbol: Not Applicable <u>EU/GHS 1272/2008</u> Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbol/Pictogram: Not Applicable
Hydroxypropyl Cellulose	9004-64-2	Not Listed	Proprietary	<u>EU 67/548</u> Classification: Not Applicable <u>EU/GHS 1272/2008</u> Classification: Not Applicable
Lactic Acid	50-21-5	200-018-0	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Irritant Risk Phrases: R38, R41 Hazard Symbol: Xi <u>EU/GHS 1272/2008</u> Classification: Acute Oral Toxicity Cat. 5, Acute Dermal Toxicity Cat. 5, Skin Irritation Cat. 2, Eye Damage/Irritation Cat. 1 Hazard Statement Codes: H303 + H313, H315, H318 Hazard Symbol/Pictogram: GHS05
Sodium Lactate	72-17-3	200-772-0	Proprietary	<u>EU 67/548</u> Classification: Not Applicable <u>EU/GHS 1272/2008</u> Classification: Not Applicable

See Section 16 for full classification information.

### 4. FIRST-AID MEASURES

**PROTECTION OF FIRST AID RESPONDERS:** First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

**DESCRIPTION OF FIRST AID MEASURES:** Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of SDS to physician or other health professional with victim(s).

**Inhalation:** If mists or sprays from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

**Skin Exposure:** If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

**Eye Exposure:** If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

**Ingestion Exposure:** If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately.

## 4. FIRST-AID MEASURES

### DESCRIPTION OF FIRST AID MEASURES (continued):

**Ingestion Exposure (continued):** Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

**IMPORTANT SYMPTOMS AND EFFECTS:** See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** Dermatitis and other skin disorders, or hypersensitivity to ingredients may be aggravated by exposure to this product.

**INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED:** Treat symptoms and eliminate exposure. Treatment of overdosage would consist of discontinuation of the product, washing the application site with soap and water, and appropriate symptomatic and supportive care.

## 5. FIRE-FIGHTING MEASURES

**FLASH POINT:** Not established for product. For Ethanol: 13°C (55°F).

**AUTOIGNITION TEMPERATURE:** Not established for product. For Ethanol: 363°C (685°F).

**FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %):** Not established for product.

LEL	UEL
Ethanol: 3.3%	19.0%

**FIRE EXTINGUISHING MEDIA:** In the event of a fire, use suppression methods for surrounding materials, including water spray (for cooling), dry extinguishing media, carbon dioxide, foam.

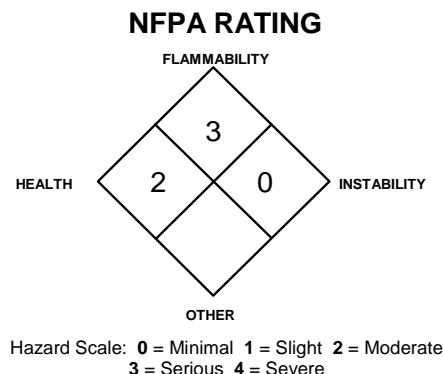
**UNSUITABLE FIRE EXTINGUISHING MEDIA:** None known.

**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL:** This product is a Class 1B flammable liquid that is readily ignited when exposed to a source of ignition or if moderately heated. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, sodium and nitrogen oxides and acrolein).

**Explosion Sensitivity to Mechanical Impact:** Not sensitive.

**Explosion Sensitivity to Static Discharge:** May be sensitive to static discharge.

**SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS:** Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.



## 6. ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS:** In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Spills may be slippery.

### PROTECTIVE EQUIPMENT:

**Small Spills:** For incidental spills (e.g., 1 tube), wear double latex or nitrile disposable gloves and eye protection.

**Large Spills:** For large spills (e.g., 1 liter or more), protective apparel should be used with a respirator when there is any danger of airborne mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus**.

**METHODS FOR CLEANUP AND CONTAINMENT:** Eliminate all sources of ignition before cleanup begins. Use non-sparking tools. The level of vapors must be 10% below of the LELs of Ethanol (LEL = 3.3%), before personnel are allowed into the spill area. In the event of a release of a large quantity of the gel, the appropriate personal protective equipment should be used.

**Small Spills:** Absorb up spilled material with damp sponge, polypads or other suitable material.

**Large Spills:** Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. Absorb spilled product carefully, avoiding the generation of mists or sprays onto polypads or other non-reactive absorption.

**All Spills:** Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

**ENVIRONMENTAL PRECAUTIONS:** Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

## 7. HANDLING and USE

**PRECAUTIONS FOR SAFE HANDLING:** All employees who handle this product should be trained to handle it safely. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product or equipment and containers that contain this product. Do not eat or drink while using this product. Avoid breathing airborne mists or spray generated by this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Remove contaminated clothing immediately. Keep away from heat, sparks, and other sources of ignition. Keep container tightly closed when not in use. Use non-sparking tools. Bond and ground containers during transfers of material. Open containers slowly on a stable surface in areas that have been designated for use of this product. Wipe down areas in which this product is used, so that product does not accumulate. Empty containers may contain residual material; therefore, empty containers should be handled with care.

**PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL:** Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

**CONDITIONS FOR SAFE STORAGE:** Containers of this product must be properly labeled. Store at 20-25°C (68-77°F) and away from moisture, humidity and light. Material should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials (see Section 10, Stability and Reactivity). Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Material should be stored in secondary containers or in a diked area, as appropriate. Store containers away from incompatible chemicals (see Section 10, Stability and Reactivity). Containers should be separated from oxidizing materials by a minimum distance of 20 ft. or by a barrier of non-combustible material at least 5 ft. high having a fire-resistance rating of at least 0.5 hours. Storage areas should be made of fire resistant materials. Post warning and "NO SMOKING" signs in storage and use areas, as appropriate. Have appropriate extinguishing equipment in the storage area (i.e., sprinkler system, portable fire extinguishers). Inspect all incoming containers before storage to ensure containers are properly labeled and not damaged. Refer to NFPA 30, *Flammable and Combustible Liquids Code*, for additional information on storage. Empty containers may contain residual liquid or vapors which are flammable; therefore, empty containers should be handled with care.

**SPECIFIC END USE(S):** This product is a placebo for a human pharmaceutical. Follow all industry standards for use of this product.

**PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT:** When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

### EXPOSURE LIMITS/CONTROL PARAMETERS:

**Ventilation and Engineering Controls:** Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

### Occupational/Workplace Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							OTHER  ppm
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH IDLH	
		TWA ppm	STEL ppm	TWA ppm	STEL ppm	TWA ppm	STEL ppm		
Podofilox	518-28-5	NE	NE	NE	NE	NE	NE	NE	Allergan WEL Range: 0.1 - 10 µg/m <sup>3</sup>
Butylated Hydroxytoluene	128-37-0	2 IVF	NE	10 (vacated 1989 PEL)	NE	NE	NE	NE	DFG MAKs: TWA = 10 (inhalable fraction) PEAK = 4•MAK 15 min, average value, 1- hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C Carcinogen: IARC-3, MAK-4, TLV-A4
Ethanol	64-17-5	NE	1000	1000	NE	1000	NE	3300 (10% of LEL)	DFG MAKs: TWA = 500 PEAK = 2•MAK 15 min, average value, 1- hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C DFG MAK Germ Cell Mutagen: Category 5 Carcinogen: MAK-5, TLV-A3
Glycerin	56-81-5	Mist		15 (total dust), 5 (resp. fract.)	NE	NE	NE	NE	DFG MAKs: TWA = 50 (Inhalable Fraction) PEAK = 2•MAK 15 min, average value, 1- hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C
Lactic Acid	50-21-5	NE	NE	NE	NE	NE	NE	NE	NE
Hydroxypropyl Cellulose Exposure limits are for cellulose	9004-64-2	10	NE	15 (total dust), 5 (resp. fract.)	NE	10 (total dust), 5 (resp. fract.)	NE	NE	NE
Sodium Lactate	72-17-3	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established IVF = Measured as the Inhalable Fraction and Vapor

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

### EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

**International Occupational Exposure Limits:** Currently the following international exposure limits are in place for some components of this product. Limits given may not be the most current and should be checked.

#### BUTYLATED HYDROXYTOLUENE:

Australia: TWA = 10 mg/m<sup>3</sup>, JUL 2008  
Austria: MAK-TMW = 10 mg/m<sup>3</sup>, 2007  
Belgium: TWA = 10 mg/m<sup>3</sup>, MAR 2002  
Denmark: TWA = 10 mg/m<sup>3</sup>, MAY 2011  
Finland: TWA = 10 mg/m<sup>3</sup>, STEL = 20 mg/m<sup>3</sup>, NOV 2011  
France: VME = 10 mg/m<sup>3</sup>, FEB 2006  
Germany: MAK = 20 mg/m<sup>3</sup> (inhalable), 2005  
Iceland: TWA = 10 mg/m<sup>3</sup>, NOV 2011  
Korea: TWA = 10 mg/m<sup>3</sup>, 2006  
Mexico: TWA = 10 mg/m<sup>3</sup>, STEL 20 mg/m<sup>3</sup>, 2004  
The Netherlands: MAC-TGG = 10 mg/m<sup>3</sup>, 2003  
New Zealand: TWA = 10 mg/m<sup>3</sup>, JAN 2002  
Switzerland: MAK-W = 10 mg/m<sup>3</sup>, DEC 2006  
United Kingdom: TWA = 10 mg/m<sup>3</sup>, OCT 2007  
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

#### ETHANOL:

Australia: TWA = 1000 ppm (1880 mg/m<sup>3</sup>), JUL 2008  
AUSTRIA: MAK-TMW = 1000 ppm (1900 mg/m<sup>3</sup>); KZW = 2000 ppm (3800 mg/m<sup>3</sup>), 2007  
Belgium: TWA = 1000 ppm (1907 mg/m<sup>3</sup>), MAR 2002  
Denmark: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), MAY 2011  
Finland: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), STEL = 1300 ppm (2500 mg/m<sup>3</sup>), NOV 2011  
France: VME = 1000 ppm (1900 mg/m<sup>3</sup>), VLE = 5000 ppm (9500), FE B2006  
Germany: MAK = 960 mg/m<sup>3</sup> (500 mL/m<sup>3</sup>), 2005  
Hungary: TWA = 1900 mg/m<sup>3</sup>, STEL = 7600 mg/m<sup>3</sup>, SEP 2000  
Iceland: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), NOV 2011

#### ETHANOL (continued):

Korea: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), 2006  
Mexico: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), 2004  
The Netherlands: MAC-TGG = 1000 mg/m<sup>3</sup>, 2003  
New Zealand: TWA = 1000 ppm (1880 mg/m<sup>3</sup>), JAN 2002  
Norway: TWA = 500 ppm (950 mg/m<sup>3</sup>), JAN 1999  
Peru: TWA = 1000 ppm (1884 mg/m<sup>3</sup>), JUL 2005  
The Philippines: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), JAN 1993  
Poland: MAC(TWA) = 1000 mg/m<sup>3</sup>, MAC(STEL) = 3000 mg/m<sup>3</sup>, JAN 1999  
Russia: TWA = 1000 mg/m<sup>3</sup>, STEL = 2000 mg/m<sup>3</sup>, JUN 2003  
Sweden: TWA = 500 ppm (1000 mg/m<sup>3</sup>); STEL = 1000 ppm (1900 mg/m<sup>3</sup>), JUN 2005  
Switzerland: MAK-W = 500 ppm (960 mg/m<sup>3</sup>), KZG-W = 1000 ppm (1920 mg/m<sup>3</sup>), DEC 2006  
Thailand: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), JAN 1993  
Turkey: TWA = 1000 ppm (1900 mg/m<sup>3</sup>), JAN 1993  
United Kingdom: TWA = 1000 ppm (1920 mg/m<sup>3</sup>), OCT 2007  
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

#### GLYCERIN:

Belgium: TWA = 10 mg/m<sup>3</sup>, MAR 2002  
Finland: TWA = 20 mg/m<sup>3</sup>, SEP 2009  
France: VME = 10 mg/m<sup>3</sup>, FEB 2006  
Korea: TWA = 10 mg/m<sup>3</sup> (mist), 2006  
Mexico: TWA = 10 mg/m<sup>3</sup> (inhalable), 2004  
The Netherlands: MAC-TGG = 10 mg/m<sup>3</sup>, 2003  
New Zealand: TWA = 10 mg/m<sup>3</sup> (mist), JAN 2002  
Switzerland: MAK-W = 50 mg/m<sup>3</sup>, KZG-W = 100 mg/m<sup>3</sup>, DEC 2006  
United Kingdom: TWA = 10 mg/m<sup>3</sup>, 2007  
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

**PERSONAL PROTECTIVE EQUIPMENT:** Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

**Respiratory Protection:** A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations. The following are NIOSH respiratory protection guidelines for the alcohol components and are being provided to assist in selection respiratory equipment, should it be needed.

#### ETHANOL

##### CONCENTRATION RESPIRATORY PROTECTION

Up to 3300 ppm: Any Supplied-Air Respirator (SAR), or any Self-Contained Breathing Apparatus (SCBA) with a full facepiece.

Emergency or Planned Entry into Unknown Concentrations or IDLH Conditions: Any SCBA that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode, or any SAR that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary SCBA operated in pressure-demand or other positive-pressure mode.

Escape: Any appropriate escape-type, SCBA.

**Eye Protection:** During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.

**Hand Protection:** During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

**Body Protection:** Use appropriate protective clothing for the task (e.g., lab coat, etc.)

## 9. PHYSICAL and CHEMICAL PROPERTIES

**FORM:** Gel.

**MOLECULAR WEIGHT:** Mixture.

**ODOR:** Faint odor.

**BOILING POINT:** Not established.

**EVAPORATION RATE (nBuAc = 1):** Not established.

**VAPOR PRESSURE (air = 1):** Not available.

**pH:** Not established.

**COEFFICIENT WATER/OIL DISTRIBUTION:** Not established.

**HOW TO DETECT THIS SUBSTANCE (identification/warning properties):** The gelled appearance of this product may act as a distinguishing characteristic.

**COLOR:** Clear, colorless.

**MOLECULAR FORMULA:** Mixture.

**ODOR THRESHOLD:** Not applicable.

**FREEZING/MELTING POINT** Not established.

**SOLUBILITY IN WATER:** Partially soluble.

**SPECIFIC GRAVITY (water = 1):** Not available.

**VAPOR DENSITY:** Not available.

**VISCOSITY:** Not available.

## 10. STABILITY and REACTIVITY

**CHEMICAL STABILITY:** This product is stable.

**DECOMPOSITION PRODUCTS:** Combustion: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, sodium and nitrogen oxides, acrolein). Hydrolysis: None known.

## 10. STABILITY and REACTIVITY (Continued)

**MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:** This product is generally compatible with other common materials in a medical facility. Due to the components, this product may be incompatible with strong oxidizing agents, hydrogen peroxide, perchloric acid, metal perchlorates, mercuric nitrate, silver nitrate, silver and nitric acid, or silver oxide and aqueous ammonia, alkali metals (e.g. sodium or potassium), bromine pentafluoride or bromides, sodium hydrazide, zirconium tetrachloride, phosphorus (III) oxide, potassium tert-butoxide, acids, acid anhydrides, or acid chlorides (e.g. acetyl chloride), calcium oxide or cesium oxide, platinum black catalyst, bromine and phosphorus or iodine and phosphorus.

**POSSIBILITY OF HAZARDOUS REACTIONS OR POLYMERIZATION:** Will not occur.

**CONDITIONS TO AVOID:** Avoid heat, light, and contact with incompatible chemicals.

## 11. TOXICOLOGICAL INFORMATION

**SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE:** The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

**Inhalation:** If vapors, mists, or sprays of the gel are inhaled, they may cause coughing and temporary bronchial irritation. Symptoms are generally alleviated upon breathing fresh air.

**Contact with Skin or Eyes:** Contact with the skin may cause irritation, which can be alleviated upon rinsing. Prolonged skin contact may cause dermatitis (dry, red, cracked skin) or cause systemic effects as described under 'Other Potential Health Effects'. Contact of this product with the eyes may cause moderate to severe irritation, redness, and tearing.

**Skin Absorption:** As this product is designed to be absorbed via skin, no significant adverse effect is expected under normal situations of use and handling.

**Ingestion:** Ingestion caused by poor hygiene practices may cause adverse symptoms. The active ingredient is toxic by ingestion. Evidence from animal studies involving the main component, Ethanol, and human consumption of alcoholic beverages demonstrates that ingestion of large amounts depresses the central nervous system with symptoms such as lack of coordination, impaired vision, reduced reaction time, slurred speech, impaired judgment, nausea, vomiting and unconsciousness progressing to death from respiratory or circulatory failure. For an average adult, the fatal ingested dose for Ethanol is approximately 1 L (approximately 2 pints) of 40–55% ethanol (the percentage found in whiskey, gin, rum, vodka, or brandy) consumed within a few minutes. Based on animal evidence and its physical properties, Ethanol can be aspirated into the lungs during ingestion or vomiting. Aspiration can cause potentially fatal injury to the lungs.

**Injection:** Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

**OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses:** In therapeutic use, the most common systemic adverse effect reported is headache. The most common adverse effects at the site of application include inflammation, redness, burning, skin erosion, pain, itching and bleeding. Less common adverse effects reported include peeling, scabbing, discoloration, tenderness, dryness, crusting, fissures, soreness, ulceration, swelling/edema, tingling, rash, and blisters. Therapeutic use of may also cause nausea, vomiting, fever, diarrhea, bone marrow depression, and oral ulcers. If vapors or mists created from the gel are inhaled, irritation of the respiratory system can occur. Toxicity reported following systemic administration of podophyllum resin included: nausea, vomiting, fever, diarrhea, peripheral neuropathy, altered mental status, lethargy, coma, tachypnea, respiratory failure, leukocytosis, pancytosis, hematuria, renal failure and seizures. Podofilox may cause harm to the fetus, based on animal data. Animal studies indicate mutagenic potential by causing chromosomal breaks in mouse in vivo micronucleus tests. These effects may also be experienced from occupational exposure.

**HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms.** Exposure to this product may cause the following health effects:

**Acute:** The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Ingestion may be harmful.

**Chronic:** Repeated skin contact may cause dermatitis (dry, red skin) or other effects described under 'Other Potential Health Effects'.

**TARGET ORGANS:** **Acute:** Workplace Exposure: Skin. **Therapeutic Doses:** Skin. **Chronic:** Workplace Exposure: Skin. **Therapeutic Doses:** Skin.

**IRRITANCY OF PRODUCT:** This product may irritate contaminated tissue, especially if contact is prolonged.

**SENSITIZATION OF PRODUCT:** No information available.



### HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
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FLAMMABILITY HAZARD	(RED)	3
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PHYSICAL HAZARD	(YELLOW)	0
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### PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate  
3 = Serious 4 = Severe \* = Chronic hazard

## 11. TOXICOLOGICAL INFORMATION (Continued)

**TOXICITY DATA:** The following are toxicity data for the active ingredient and the Ethanol component. Only human data, LD50 Oral, Rat and Mouse, LD50 Skin, Rabbit and Rat and LC50 Inhalation Rat and mouse data are presented for Ethanol. Additional data are available for Ethanol and for the excipient components of this product, but are not presented in this SDS. Contact Allergan for more information.

### PODOFILOX:

Standard Draize Test (Skin-Mouse) 0.05%/6 weeks-intermittent: Mild  
Standard Draize Test (Skin-Mouse) 0.5%/3 days-intermittent: Mild  
LD<sub>50</sub> (Oral-Mouse) 100 mg/kg  
LD<sub>50</sub> (Skin-Rat) 500 mg/kg  
LD<sub>50</sub> (Skin-Rabbit) 200 mg/kg  
LD<sub>50</sub> (Intraperitoneal-Rat) 15 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting  
LD<sub>50</sub> (Intraperitoneal-Mouse) 30 mg/kg  
LD<sub>50</sub> (Subcutaneous-Rat) 8 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea, respiratory depression  
LD<sub>50</sub> (Intravenous-Rat) 8700 µg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting  
LD<sub>50</sub> (Intravenous-Mouse) 56 mg/kg  
LD<sub>50</sub> (Intravenous-Rabbit) 5 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Skin and Appendages: cutaneous sensitization, experimental (after topical exposure)  
LD<sub>50</sub> (Intravenous-Cat) 1700 µg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting  
LD<sub>50</sub> (Intramuscular-Rat) 3 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting  
LD<sub>50</sub> (Intramuscular-Cat) 4 mg/kg: Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea Skin and Appendages: cutaneous sensitization, experimental (after topical exposure)  
IC<sub>50</sub> (*In vitro*-Hamster-Lung Fibroblast) 0.006 mg/L/72 hours: *In Vitro* Toxicity Studies: cell protein synthesis  
LDLo (Subcutaneous-Mouse) 24,600 µg/kg  
IC<sub>50</sub> (*In vitro*-Rat-Embryonic Cells) 0.004 mg/L/72 hours: *In Vitro* Toxicity Studies: cell metabolic activity: Alamar Blue assay etc  
IC<sub>50</sub> (*In vitro*-Rat Muscular) 0.01 µmol/L/72 hours: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation  
LDLo (Subcutaneous-Dog) 1 mg/kg: Behavioral: convulsions or effect on seizure threshold; Gastrointestinal: nausea or vomiting; Nutritional and Gross Metabolic: weight loss or decreased weight gain  
LDLo (Subcutaneous-Cat) 300 µg/kg: Behavioral: convulsions or effect on seizure threshold; Gastrointestinal: nausea or vomiting; Nutritional and Gross Metabolic: weight loss or decreased weight gain  
LDLo (Subcutaneous-Pigeon) 10 mg/kg: Behavioral: muscle contraction or spasticity; Gastrointestinal: hypermotility, diarrhea  
LDLo (Subcutaneous-Chicken) 6250 µg/kg: Behavioral: muscle contraction or spasticity; Gastrointestinal: hypermotility, diarrhea  
LDLo (Parenteral-Frog) 152 mg/kg: Behavioral: stiffness  
TDLo (Oral-Rat) 11690 µg/kg/7 days-intermittent: Gastrointestinal: other changes; Liver: other changes  
TDLo (Oral-Rat) 500 mg/kg: female 1-5 day(s) after conception: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)  
TDLo (Intraperitoneal-Rat) 10 mg/kg: female 15-16 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus), fetal death

### PODOFILOX (continued):

TDLo (Intraperitoneal-Rat) 10 mg/kg: female 11-12 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)  
TDLo (Subcutaneous-Rat) 500 mg/kg: female 1-5 day(s) after conception: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)  
TDLo (Subcutaneous-Mouse) 250 µg/kg: female 3 day(s) after conception: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)  
DNA Inhibition (Human HeLa Cell) 10 µmol/L  
Mutation Test Systems-Not Otherwise Specified (Human HeLa Cell) 5 µmol/L  
DNA Inhibition-Mammal-Species Unspecified Ascites Tumor) 50 µmol/L  
Micronucleus Test (Mouse Cells-Not Otherwise Specified) 1 mg/L  
Micronucleus Test 250 nmol/L  
Micronucleus Test (Hamster Fibroblast) 0.25 mmol/L  
Mutation Test Systems-Not Otherwise Specified (Non-Mammalian Species Cells-Not Otherwise Specified) 50 nmol/L  
Mutation Test Systems-Not Otherwise Specified (Mouse Cells-Not Otherwise Specified) 10 µmol/L  
Sex Chromosome Loss and Non-Disjunction (Intraperitoneal-Hamster) 160 µg/kg  
**ETHANOL:**  
Open Irritation Test (Skin-Rabbit) 400 mg: Mild  
Standard Draize Test (Skin-Rabbit) 20 mg/24 hours: Moderate  
Standard Draize Test (Eye-Rabbit) 500 mg: Severe  
Standard Draize Test (Eye-Rabbit) 500 mg/24 hours: Mild  
Rinsed with Water (Eye-Rabbit) 100 mg/ seconds: Moderate  
TDLo (Oral-Human) 22,500 mg/kg/4 weeks-intermittent: Endocrine: other changes; Blood: other changes  
TDLo (Oral-Human) 0.5 mg/kg: Behavioral: changes in psychophysiological tests  
TDLo (Oral-Human) 400 mg/kg: Behavioral: alteration of operant conditioning  
TDLo (Oral-Human) 0.7 gm/kg/10 minutes: Behavioral: changes in psychophysiological tests  
TDLo (Oral-Human) 0.5 gm/kg: Behavioral: somnolence (general depressed activity), changes in psychophysiological tests  
TDLo (Oral-Human) 1.4 gm/kg: Behavioral: euphoria, changes in psychophysiological tests; Gastrointestinal: nausea or vomiting  
TDLo (Oral-Infant) 11,712 µL/kg: Behavioral: general anesthetic; Cardiac: arrhythmias (including changes in conduction); Lungs, Thorax, or Respiration; dyspnea  
TDLo (Oral-Child) 14400 mg/kg/30 minutes (intermittent): Behavioral: coma; Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting  
TDLo (Oral-Woman) 1200 mg/kg/3 hours: Endocrine: changes in gonadotropins; Endocrine: other changes; Blood: other changes  
TDLo (Oral-Woman) 256 gm/kg/12 weeks: Behavioral: hallucinations, distorted perceptions; Endocrine: effect on menstrual cycle  
TDLo (Oral-Woman) 0.7 gm/kg: Behavioral: changes in psychophysiological tests  
TDLo (Oral-Woman) 5860 mL/kg: female 3 year(s) pre-mating: 100 day(s) post-birth: Reproductive: Specific Developmental Abnormalities: craniofacial (including nose and tongue); Effects on Newborn: behavioral, delayed effects

### ETHANOL (continued):

TDLo (Oral-Woman) 41 gm/kg: female 41 week(s) after conception: Reproductive: Effects on Newborn: Apgar score (human only), other neonatal measures or effects, drug dependence  
TDLo (Oral-Woman) 250 mg/kg: female 37 week(s) after conception: Reproductive: Effects on Embryo or Fetus: other effects to embryo  
TDLo (Oral-Man) 3371 µL/kg: Behavioral: altered sleep time (including change in righting reflex), excitement, coma  
TDLo (Oral-Man) 700 mg/kg: Behavioral: changes in psychophysiological tests  
TDLo (Oral-Man) 50 mg/kg: Gastrointestinal: alteration in gastric secretion, other changes  
TDLo (Oral-Man) 1430 µg/kg: Behavioral: changes in motor activity (specific assay), ataxia, antipsychotic  
TDLo (Intravenous-Human) 1.6 gm/kg/6 hours: Biochemical: Metabolism (Intermediary): other  
TDLo (Intravenous-Human) 0.89 mL/kg: Vascular: regional or general arteriolar constriction, measurement of regional blood flow  
TDLo (Intravenous-Woman) 8 mg/kg: female 32 week(s) after conception: Reproductive: Effects on Newborn: Apgar score (human only), other neonatal measures or effects  
TDLo (Intravenous-Man) 0.57 gm/kg: Behavioral: changes in psychophysiological tests  
TDLo (Intraarterial-Man) 0.071 mL/kg: Vascular: acute arterial occlusion  
TDLo (Intrauterine-Woman) 200 mg/kg: female 5 day(s) pre-mating: Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)  
TDLo (Multiple Routes-Man) 3660 mg/kg: Endocrine: evidence of thyroid hypofunction  
TCLo (Inhalation-Human) 2500 mg/m<sup>3</sup>/20 minutes: Peripheral Nerve and Sensation: recording from afferent nerve  
LDLo (Oral-Child) 2 gm/kg: Lungs, Thorax, or Respiration: other changes; Liver: fatty liver degeneration; Blood: other changes  
LDLo (Oral-Human) 1400 mg/kg: Behavioral: sleep, headache; Gastrointestinal: nausea or vomiting  
LDLo (Subcutaneous-Infant) 19,440 mg/kg: Behavioral: convulsions or effect on seizure threshold, coma; Nutritional and Gross Metabolic: body temperature decrease  
LC<sub>50</sub> (Inhalation-Rat) 20,000 ppm/10 hours  
LC<sub>50</sub> (Inhalation-Mouse) 39 gm/m<sup>3</sup>/4 hours  
LD<sub>50</sub> (Oral-Rat) 7060 mg/kg: Lungs, Thorax, or Respiration: other changes  
LD<sub>50</sub> (Oral-Rat) 7 gm/kg  
LD<sub>50</sub> (Oral-Mouse) 3450 mg/kg  
LC<sub>50</sub> (Inhalation-Rat) 20,000 ppm/10 hours  
LC<sub>50</sub> (Inhalation-Mouse) 39 gm/m<sup>3</sup>/4 hours  
DNA Inhibition (Human-Lymphocyte) 220 mmol/L  
Micronucleus Test (Oral-Human) 817.6 gm/kg/6 years-intermittent  
Cytogenetic Analysis (Human-Lymphocyte) 2.5 pph/24 hours  
Cytogenetic Analysis (Human-Lymphocyte) 1160 gm/L  
Cytogenetic Analysis (Human-Fibroblast) 12,000 ppm  
Cytogenetic Analysis (Human-Leukocyte) 1 pph/72 hours-continuous  
Cytogenetic Analysis (Oral-Human) 49,014 gm/kg/25 years  
Sister Chromatid Exchange (Human-Lymphocyte) 500 ppm/72 hours-continuous

**CARCINOGENIC POTENTIAL OF COMPONENTS:** The following information is for the active ingredient.

An 80-week carcinogenicity study in the mouse was performed using a 0.5% Podofilox solution applied dermally at 0.04, 0.2 and 1.0 mg/kg/day. There were no differences between the Podofilox treated mice at any dose level and vehicle control in the incidence of neoplasia. Published animal studies, in general, have not shown the drug substance, Podofilox, to be carcinogenic. There are published reports that, in mouse studies, crude Podophyllin resin (containing Podofilox) applied topically to the cervix produced changes resembling carcinoma in situ.<sup>7</sup> 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<sup>8</sup> (the drug was applied twice weekly over a 15-month period).

The excipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

**Butylated Hydroxytoluene:** ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-4 (Substances with carcinogenic potential for which genotoxicity plays no or at most a minor role. No significant contribution to human cancer risk is expected, provided the MAK value is observed.)

## 11. TOXICOLOGICAL INFORMATION (Continued)

### CARCINOGENIC POTENTIAL OF COMPONENTS (continued):

**Ethanol:** ACGIH TLV-A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans); MAK-5 (Substances with Carcinogenic and Genotoxic Effects, the potency of which is considered to be so low that, provided the MAK and BAT values are observed, no significant contribution to human cancer risk is to be expected.)

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

**REPRODUCTIVE TOXICITY INFORMATION:** There are no adequate and well-controlled studies of topical or oral Podofilox use in pregnant women. This product is rated by the FDA as Pregnancy Risk C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.).

**Mutagenicity:** Podofilox was not mutagenic in the Ames plate reverse mutation assay at concentrations up to 5 mg/plate, with and without metabolic activation. No cell transformation related to potential oncogenicity was observed in BALB/3T3 cells after exposure to Podofilox at concentrations up to 0.008 µg/mL, without metabolic activation and 12 µg/mL Podofilox with metabolic activation. Results from the mouse micronucleus *in vivo* assay using Podofilox 0.5% solution at doses up to 25 mg/kg (75 mg/m<sup>2</sup>), indicate that Podofilox should be considered a potential clastogen (a chemical that induces disruption and breakage of chromosomes).

**Embryotoxicity/Teratogenicity:** Podofilox solution was not teratogenic in the rabbit following topical application of up to 0.21 mg/kg (2.85 mg/m<sup>2</sup>, approximately 2 times the maximum human dose) once daily for 13 days. The scientific literature contains references that Podofilox is embryotoxic in rats when administered intraperitoneally at a dose of 5 mg/kg (29.5 mg/m<sup>2</sup>, approximately 19 times the recommended maximum human dose.) Teratogenicity and embryotoxicity have not been studied with intravaginal application. Many anti-mitotic drug products are known to be embryotoxic.

**Reproductive Toxicity:** Daily topical application of 0.5% Podofilox solution at doses up to the equivalent of 0.2 mg/kg (1.18 mg/m<sup>2</sup>, approximately equivalent to the human daily dose) to rats throughout gametogenesis, mating, gestation, parturition and lactation for two generations demonstrated no impairment of fertility. It is not known whether Podofilox is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

**ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs):** Currently, no ACGIH Biological Exposure Indices (BEIs) have been determined for components.

## 12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

**MOBILITY:** This product has not been tested for mobility in soil; it is expected to be somewhat mobile due to its composition. The following information is available for Ethanol.

**ETHANOL:** Using a structure estimation method based on molecular connectivity indices, the Koc can be estimated to be 1. According to a classification scheme, this estimated Koc value suggests that this compound is expected to have very high mobility in soil.

**PERSISTENCE AND BIODEGRADABILITY:** This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known. The following information is available for Ethanol.

**ETHANOL:** If released to the atmosphere, an extrapolated vapor pressure of 59.3 mm Hg at 25°C indicates that this compound will exist solely in the vapor phase. Vapor phase material is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 5 days. If released to soil, this compound is expected to have very high mobility based upon an estimated Koc of 1. Volatilization from moist soil surfaces is expected to be an important fate process based upon a Henry's Law constant of 5X10<sup>-6</sup> atm-cu m/mole. This material may also volatilize from dry soils based upon its vapor pressure. Biodegradation is expected to occur rapidly in the environment based on numerous screening tests using different types of inocula and incubation periods. This compound was degraded with half-lives on the order of a few days using microcosms constructed with a low organic sandy soil and groundwater, indicating it is unlikely to be persistent in the environment. If released into water, this material is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 3 and 39 days, respectively. Hydrolysis and photolysis in sunlight surface waters are not expected since this compound lacks functional groups that are susceptible to hydrolysis or photolysis under environmental conditions.

**BIO-ACCUMULATION POTENTIAL:** The Ethanol BCF of 3 suggests that the bioconcentration potential of this product is low.

**ECOTOXICITY:** This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No specific data is available for this product. The following data are available for some components. Only select data for Ethanol are provided in this SDS. Contact Allergan for additional information.

#### BUTYLATED HYDROXYTOLUENE:

EC<sub>50</sub> (*Daphnia pulex* Water flea) 48 hours = 1.44 mg/L (Intoxication)

EC<sub>50</sub> (*Selenastrum capricornutum* Algae) 72 hours = 6 mg/L

#### ETHANOL:

Toxicity Threshold (Cell Multiplication Inhibition Test) (*Microcystis aeruginosa* algae) 1450 mg/L

Toxicity Threshold (Cell Multiplication Inhibition Test) (*Entosiphon sulcatum* protozoa) 65 mg/L

EC<sub>50</sub> (*Chlorella pyrenoidosa* Green algae; growth inhibition) 48 hours = 9310 mg/L; static

EC<sub>50</sub> (*Pimephales promelas* fathead minnows) 96 hours = 12.9 g/L

#### ETHANOL (continued):

LC<sub>50</sub> (*Palaeomonetes*) 96 hours = > 250 mg/L at 21°C, mature/Static bioassay

LC<sub>50</sub> (*Salmo gairdnerii* Rainbow trout) 96 hours = 13,000 mg/L at 12°C (95% Confidence limit 12000-16000 mg/L), wt 0.8 g /Static bioassay

LC<sub>50</sub> (*Pimephales promelas* fathead minnows) 96 hours = 14.2 g/L (95% confidence limit 13.4-15.1 g/L)

LC<sub>50</sub> (*Artemia franchiscana* Brine shrimp) 96 hours = 7.00 mg/L; static

LC<sub>50</sub> (*Leuciscus idus melanotus* Golden orfe) 48 hours = 8140 mg/L; static

#### ETHANOL (continued):

LC<sub>50</sub> (*Danio rerio* Zebrafish) 24 hours = >100 mg/L; static

LC<sub>50</sub> (*Daphnia magna* Water flea) 48 hours = 11,853-13248 mg/L; static, 20°C

LC<sub>50</sub> (*Artemia salina* Crustacean) 24 hours = >10,000 mg/L; static, 24.5°C

LC<sub>50</sub> (*Oryzias latipes* Medaka) 48 hours = 1350 mg/L; static

#### LACTIC ACID:

LC<sub>50</sub> (*Oncorhynchus* sp Trout) 18 hours = 100 mg/L/Conditions of bioassay not specified in source examined

**OTHER ADVERSE EFFECTS:** This product does not contain any component with known ozone depletion potential.

**RESULTS OF PBT AND vPvB ASSESSMENT:** No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

**ENVIRONMENTAL EXPOSURE CONTROLS:** Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.



### 13. DISPOSAL CONSIDERATIONS

**WASTE TREATMENT/DISPOSAL METHODS:** Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.

**PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING:** Wear proper protective equipment when handling waste materials.

**D001:** for ignitable waste.

**EUROPEAN WASTE CODES:** Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

### 14. TRANSPORTATION INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS:** This product is classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

**UN Identification Number:** UN 1993  
**Proper Shipping Name:** Flammable liquids, n.o.s. (Ethanol)  
**Hazard Class Number and Description:** 3 (Flammable)  
**Packing Group:** II  
**Dot Label(s) Required:** Class 3 (Flammable)  
**Emergency Response Guidebook Number (2013):** 127  
**Marine Pollutant:** No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

**Small Quantity Exception (49 CFR 173.4):** Small quantities of Class 3 material are not subjected to other requirements of the Hazardous Materials Regulations (Subchapter C) when the maximum quantity per inner receptacle is limited to 30 mL (1 oz). Refer to 49 CFR 173.4 for specific information in packaging small quantity materials.

**Limited Quantity Exceptions [49 CFR 173.150(b)]:** Limited quantities for Class 3, Packing Group II materials have inner packagings not over 1.0 L net capacity each, packed in strong outer packaging.

**TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS:** This product is classified as Dangerous Goods, per regulations of Transport Canada. The use of the above U.S. DOT information from the U.S. 49 CFR regulations is allowed for shipments that originate in the U.S. For shipments via ground vehicle or rail that originate in Canada, the information below is applicable.

**UN Identification Number:** UN 1993  
**Proper Shipping Name:** Flammable liquid, n.o.s. (Ethanol)  
**Hazard Class Number and Description:** 3 (Flammable)  
**Packing Group:** II  
**Hazard Label(s) Required:** Class 3 (Flammable)  
**Special Provisions:** 16  
**Explosive Limit & Limited Quantity Index:** 1  
**ERAP Index:** None  
**Passenger Carrying Ship Index:** None  
**PASSENGER CARRYING ROAD Or RAIL VEHICLE INDEX:** 5  
**Marine Pollutant:** Not Applicable

**INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA):** This product is classified as Dangerous Goods, by rules of IATA.

**UN Identification Number:** UN 1993  
**Proper Shipping Name:** Flammable liquid, n.o.s. (Ethanol)  
**Hazard Class Number and Description:** 3 (Flammable)  
**Packing Group:** II  
**Excepted Quantities:** E2  
**Hazard Label(s) Required:** Class 3 (Flammable)  
**PASSENGER and CARGO AIRCRAFT PACKING INSTRUCTION:** 353  
**PASSENGER and CARGO AIRCRAFT MAXIMUM NET QUANTITY PER PKG.:** 5 L  
**PASSENGER and CARGO AIRCRAFT LIMITED QUANTITY PACKING INSTRUCTION:** Y341  
**PASSENGER and CARGO AIRCRAFT LIMITED QUANTITY MAXIMUM NET QUANTITY PER PKG.:** 1 L  
**Cargo Aircraft Only Packing Instruction:** 364  
**Cargo Aircraft Only Maximum Net Quantity per Pkg.:** 60 L  
**Special Provisions:** A3  
**ERG Code:** 3H

**INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION:** This product is classified as Dangerous Goods by the International Maritime Organization.

**UN No.:** 1993  
**Proper Shipping Name:** Flammable liquid, n.o.s. (Ethanol)  
**Hazard Class Number:** 3 (Flammable)  
**Packing Group:** II  
**Special Provisions:** 144  
**Limited Quantities:** 1 L

## 14. TRANSPORTATION INFORMATION (Continued)

### INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION (continued):

Excepted Quantities:	E2
Special Provisions:	274
Packing Instructions:	Instructions: P001, Provisions: None
IBC Information:	Instructions: IBC02, Provisions: None
Tanks:	Instructions: T7, Provisions: TP1, TP8, TP28
EmS:	F-E, S-E
Stowage Category:	Category B

**Marine Pollutant:** No component is a Marine Pollutant under UN criteria or is specifically listed in the MARPOL 73/78 Annex III.

**UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE):** This product is classified by the United Nations Economic Commission for Europe to be dangerous goods. Refer to current regulations for all additional provisions other information not given here.

UN No.:	1993
Name and Description:	Flammable liquid, n.o.s. (Ethanol, Isopropanol)
Class:	3
Classification Code:	F1
Packing Group:	II
Labels:	3
Special Provisions:	274, 601, 640C
Limited Quantities:	1 L
Excepted Quantities:	E2
Packing Instructions:	Packing Instruction: P001, Special Packing Provision: R001
Special Packing Provisions:	None
Mixed Packing Provisions:	MP19
Portable Tanks/Bulk Containers:	Instructions: T7; Special Provisions; TP1, TP8, TP28
Hazard Identification No.:	33

**TRANSPORT IN BULK ACCORDING TO THE IBC CODE:** See the information under the individual jurisdiction listings for IBC information.

**ENVIRONMENTAL HAZARDS:** This product is not environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) no component is listed as a marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

## 15. REGULATORY INFORMATION

### ADDITIONAL UNITED STATES REGULATIONS:

**U.S. SARA Reporting Requirements:** No component of this product is subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

**U.S. SARA Threshold Planning Quantity (TPQ):** There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

**U.S. CERCLA Reportable Quantities (RQ):** Not applicable.

**U.S. TSCA INVENTORY STATUS:** This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

**California Safe Drinking Water and Toxic Enforcement Act (Proposition 65):** No component of this product is on the California Proposition 65 lists. In the form of alcoholic beverages to be consumed, the Ethanol component of this product is on the California Proposition 65 lists as a compound that is known to cause developmental harm. This does not apply to Ethanol that is not consumed as a beverage.

**Other U.S. Federal Regulations:** Not applicable.

### ADDITIONAL CANADIAN REGULATIONS:

**Canadian DSL Inventory Status:** This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is excepted from requirements of the DSL/NDSL Inventory.

**Canadian Environmental Protection Act (CEPA) Priorities Substances Lists:** Not applicable.

**Canadian WHMIS Classification and Symbols:** The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

**Other Canadian Regulations:** Requirements under the Canadian Health Canada, Laboratory Biosafety Guidelines may be applicable.

### ADDITIONAL EUROPEAN UNION REGULATIONS:

**Safety, Health, and Environmental Regulations/Legislation Specific for the Product:** When formulated in a finished medicinal compound for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

**Chemical Safety Assessment:** No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

## 16. OTHER INFORMATION

**ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):** **DANGER!** FLAMMABLE GEL AND VAPOR. MAY CAUSE EYE AND RESPIRATORY TRACT IRRITATION. PROLONGED OR REPEATED CONTACT MAY DRY SKIN AND CAUSE IRRITATION. HARMFUL IF SWALLOWED. CHRONIC SKIN CONTACT MAY BE HARMFUL. MAY CAUSE HARM TO FETUS, BASED ON ANIMAL DATA. ANIMAL DATA INDICATED POTENTIAL MUTAGENIC POTENTIAL. CONTAINS SUSPECT CARCINOGENS.

## 16. OTHER INFORMATION (Continued)

**ANSI LABELING (continued):** Keep away from heat, sparks, and flame. Avoid contact with skin, eyes, and clothing. Avoid breathing vapors. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. **FIRST-AID:** In case of contact, flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, do NOT induce vomiting. If vomiting occurs, have person lean forward. Call physician or poison control center immediately. Never give anything by mouth to an unconscious person. **IN CASE OF FIRE:** Use water fog, dry chemical, CO<sub>2</sub>, or "alcohol" foam. **IN CASE OF SPILL:** Wipe up spilled product. Place residue in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

**GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION:** According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

**EU 67/548/EEC LABELING AND CLASSIFICATION:** According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

### CLASSIFICATION OF COMPONENTS:

#### CLP Regulation (EC) 1272/2008

**Podofilox:** This is a self-classification.

Classification: Reproductive Toxicity Category 2, Germ Cell Mutagen Category 2, Acute Oral Toxicity Category 3, Acute Dermal Toxicity Category 2

Hazard Statements: H361d: Suspected of damaging the unborn child. H341: Suspected of causing genetic effects. H301: Toxic if swallowed. H310: Fatal in contact with skin.

**Butylated Hydroxytoluene:** This is a self-classification.

Classification: Acute Oral Toxicity Category 4, Acute Dermal Toxicity Category 5, Aquatic Chronic Toxicity Category 2

Hazard Statements: H303: Harmful if swallowed. H313: May be harmful in contact with skin. H411: Toxic to aquatic life with long-lasting effects.

**Ethanol:** This is a published classification.

Classification: Flammable Liquid Category 2

Hazard Statements: H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness.

Additional Self-Classification:

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if swallowed.

**Glycerin:** This is a published classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if swallowed.

**Lactic Acid:** This is a self-classification.

Classification: Acute Oral Toxicity Category 5, Acute Dermal Toxicity Category 5, Skin Irritation Category 2, Eye Damage/Irritation Category 1

Hazard Statements: H303 + H313: May be harmful if swallowed or in contact with skin. H315: Causes skin irritation. H318: Causes serious eye damage.

**All Other Components:** An official classification for these substances has not been published nor is applicable.

#### 67/548/EEC:

**Podofilox:** This is a self-classification.

Hazard Classification: Reproductive Toxicity Category 3, Germ Cell Mutagen Category 3, Toxic

Risk Phrases: R63: Possible risk of harm to the unborn child. R68: Possible risk of irreversible effects. R24: Toxic in contact with skin. R25: Toxic if swallowed.

**Butylated Hydroxytoluene:** This is a self-classification.

Hazard Classification: Harmful, Dangerous for the Environment

Risk Phrases: R22: Harmful if swallowed. R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Ethanol:** This is a published classification.

Hazard Classification: Highly Flammable

Risk Phrases: R11: Highly flammable. R36: Irritating to eyes. R67: Vapours may cause drowsiness and dizziness.

**Lactic Acid:** This is a self-classification.

Hazard Classification: Irritant

Risk Phrases: R38: Irritating to skin. R41: Limited evidence of a carcinogenic effect.

**All Other Components:** An official classification for these substances has not been published nor is applicable.

**REFERENCES AND DATA SOURCES:** Contact the supplier for information.

**METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION:** Bridging principles were used to classify this product.

**REVISION DETAILS:** New.

This Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this compound. To the best of Allergan, knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific compound. If this compound is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

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