

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Podocon-25® (25% Podophyllin in Benzoin Tincture)

Synonym: 1J1

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.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Flammable Liquid Category 2	Acute Toxicity Category 4 (oral, inhalation) Acute Toxicity Category 3 (dermal) Skin Corrosion Category 1B Eye Damage Category 1 Skin Sensitization Category 1 Reproductive Toxicity Category 1B

Label Elements:
DANGER!



Hazard statement(s)

Highly flammable liquid and vapor
 Harmful if swallowed or inhaled.
 Toxic in contact with skin.
 Causes severe skin burns and eye damage.
 May cause an allergic skin reaction.
 May damage fertility or the unborn child.

Precautionary statement(s)

Keep away from heat, sparks, open flames and hot surfaces. No smoking.
 Keep container tightly closed.
 Obtain special instructions before use.

Precautionary statement(s)

Contaminated work clothing should not be allowed out of the workplace
 Wear protective clothing, protective gloves, eye protection and face protection.
 IF swallowed: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor.
 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. Immediately call a POISON Center or doctor. Wash contaminated clothing before reuse.

Do not handle until all safety precautions have been read and understood.

Wash exposed skin thoroughly after handling.

Do not get in eyes, on skin or on clothing.

Do not breathe vapors, mists or sprays.

Use only outdoors or in a well ventilated area.

Do not eat, drink or smoke while using this product.

IF inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor.

IF exposed or concerned: Get medical advice

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. Store locked up.

Dispose of container and contents in compliance with all national and local regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Podophyllin Resin	9000-55-9	25%
Tincture Benzoi Sumatra	9000-05-9	10-20%
Ethanol	64-17-5	50-70%

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If breathing is difficult, have qualified person administer oxygen. If breathing stops, give artificial respiration – avoid mouth to mouth.

Skin contact: Immediately remove contaminated clothing and wash thoroughly with soap and water for at least 20 minutes. Get immediate medical attention. Launder. Contaminated clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 20 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. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

Most important symptoms/effects, acute and delayed: Toxic if absorbed through the skin. Harmful if swallowed or inhaled. Symptoms include paresthesia, polyneuritis, paralytic ileus, pyrexia, leukopenia, thrombocytopenia, renal failure, liver toxicity, coma and death. Corrosive to eyes and skin. Causes severe eye irritation and possible eye damage. May cause skin burns. Tincture of benzoin may cause skin sensitization with an allergic skin reaction. Inhalation of ethanol vapors may cause headache, drowsiness and dizziness. Reproductive toxin.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for contact, inhalation or ingestion.

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 toxic material. 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. 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 and skin contact. Do not breathe vapors, mists or sprays. Use only with adequate ventilation. Wash thoroughly after handling. Immediately remove contaminated clothing and launder 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 in a secure area. Protect containers from physical damage. Keep away from excessive heat and open flames. Store out of direct sunlight. Store away from oxidizers.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Podophyllin Resin	Perrigo OEB5 (<1 ug/m3) skin
Tincture Benzoi Sumatra	None Established
Ethanol	1000 ppm TWA OSHA PEL 1000 ppm STEL ACGIH TLV

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: If inhalation exposure can occur (if spray or mist is formed), 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: Impervious gloves required.

Eye protection: Chemical safety goggles and face shield recommended.

Other: Impervious clothing as needed to prevent skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Dark brown liquid

Odor: Characteristic odor

Odor threshold: Not determined	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: 18°C (64.5°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: Not determined	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not determined
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: Harmful if inhaled. 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 under ingestion.

Ingestion: Harmful if swallowed. Symptoms include headache, rapid heartbeat, hypotension, paresthesia, polyneuritis, paralytic ileus, pyrexia, leukopenia, thrombocytopenia, renal failure, liver toxicity and coma.

Skin contact: May cause skin burns. Podophyllin can cause severe systemic toxicity, which may result from topical application. The toxic effects are usually reversible but in some instances, they have been fatal. Symptoms of exposure are as described under ingestion. Tincture of benzoin may cause skin sensitization with an allergic skin reaction.

Eye contact: Corrosive to eyes. Causes severe eye irritation and possible eye damage.

Chronic Effects: May cause peripheral neuropathy with can persist for several months.

Sensitization: Tincture of benzoin may cause skin sensitization with an allergic skin reaction.

Germ Cell Mutagenicity: Podophyllin is mutagenic in Lalmonella typhimurium strain of bacteria but negative in the AMES assay and the mouse lymphoma assay. Results from an in-vitro Chinese hamster ovary cell test were inconclusive.

Reproductive Toxicity: There have been reports of complications associated with the topical use of podophyllin on condylomata of pregnant patients including birth defects, fetal death and stillbirth. Podophyllotoxin did not impair fertility in a 2-generation topical study with rats at a dose of 0.2 mg/kg/day. No fertility impairment was observed in an oral study with rats at a dose of 2.5 mg/kg/day.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1). No carcinogenicity was observed in studies with rats and mice treated orally with 0.3 mg/kg/day for 104 and 80 weeks respectively.

Acute Toxicity Values: Product Acute Oral Toxicity (test result): 550 mg/kg rat; Acute Dermal Toxicity Estimate (ATE) calculated: 800 mg/kg

Podophyllin: LD50 oral mouse 68 mg/kg LD50 dermal rabbit 200 mg/kg, LD50 dermal rat 500 mg/kg
Ethanol: LD50 oral rat 7060 mg/kg; LC50 inhalation rat 20000 ppm/10 hr.

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	UN3286	Flammable liquid, toxic, corrosive, n.o.s. (podophyllin, ethanol)	3, (6.1, 8)	II	No
TDG	UN3286	Flammable liquid, toxic, corrosive, n.o.s. (podophyllin, ethanol)	3, (6.1, 8)	II	No
IMDG	UN3286	Flammable liquid, toxic, corrosive, n.o.s. (podophyllin, ethanol)	3, (6.1, 8)	II	No
IATA	UN3286	Flammable liquid, toxic, corrosive, n.o.s. (podophyllin, ethanol)	3, (6.1, 8)	II	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, Chronic 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.

16. OTHER INFORMATION

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

SDS Revision History: New Toxicity data – changes to Sections 2, 4, 11.

Date of preparation: October 23, 2015

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).