

Scientific Documentation

Podophyllum Resin, USP

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



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Specification for Podophyllum Resin, USP (PO105)

Item Number	PO105
Item	Podophyllum Resin, USP
CAS Number	9000-55-9
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (HEXANE INSOLUBLE)	40.0	50.0 %
DISTINCTION FR. RESIN OF INDIAN PODOPHYLLUM		DOES NOT GEL
RESIDUE AFTER IGNITION		1.5 %
ELEMENTAL IMPURITIES		AS REPORTED
IDENTIFICATION (A)	SOLUBLE, PRECIPITATES WITH HCl	
IDENTIFICATION (B)	FILTRATE TURNS BROWN	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

Certificate Of Analysis

Item Number	PO105	Lot Number	4ME0043
Item	Podophyllum Resin, USP	Manufacturer Lot	PPR-2301
CAS Number	9000-55-9	Manufacturer Code	4691

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (HEXANE INSOLUBLE)	40.0	50.0 %	46.8%
DISTINCTION FR. RESIN OF INDIAN PODOPHYLLUM		DOES NOT GEL	DOES NOT GEL
RESIDUE AFTER IGNITION		1.5 %	0.5%
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
IDENTIFICATION (A)	SOLUBLE, PRECIPITATES WITH HCl		SOLUBLE, PRECIPITATES WITH HCL
IDENTIFICATION (B)	FILTRATE TURNS BROWN		FILTRATE TURNS BROWN
EXPIRATION DATE			31-JAN-2027
DATE OF MANUFACTURE			01-JAN-2023
APPEARANCE			LIGHT BROWN TO GREENISH YELLOW POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 ppm
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
17-JUN-23 07:05:52

Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
17-JUN-23 07:06:52

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Inga Pharmaceuticals at Plot No.b-1(pt) Phase II, Zone A, MEPZ Special Economic Zone, NH-45-Tambaram, Chennai, Tamil Nadu 600 045, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.



SAFETY DATA SHEET

Preparation Date: 8/23/2016

Revision date 12/19/2018

Revision Number: G2

1. Identification

Product identifier

Product code: PO105
Product Name: PODOPHYLLUM RESIN, USP

Other means of identification

Synonyms: Podophyllum
Podofillina (Italian)
CAS #: 9000-55-9
RTECS # TP8925000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Tom Tyner (USA - West Coast)

Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 2
Acute toxicity - Dermal	Category 2
Acute toxicity - Inhalation (Dusts/Mists)	Category 2
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Reproductive toxicity	Category 1B
Specific target organ toxicity (single exposure)	Category 3

Label elements

Danger

Hazard statements

Fatal if swallowed

Product code: PO105

Product name: PODOPHYLLUM
RESIN, USP

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Fatal in contact with skin
Fatal if inhaled
Causes skin irritation
Causes serious eye irritation
May damage fertility or the unborn child
May cause respiratory irritation



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

May be harmful in contact with skin

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not get in eyes, on skin, or on clothing
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear respiratory protection
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Gently wash with plenty of soap and water
Immediately call a POISON CENTER or doctor/physician
Remove/Take off immediately all contaminated clothing
Wash contaminated clothing before reuse
If skin irritation occurs: Get medical advice/attention
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Podophyllum Resin	9000-55-9	100

4. FIRST AID MEASURES

First aid measures

General Advice:	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.
Skin Contact:	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required. Call a physician or Poison Control Centre immediately.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms	<p>Contact causes skin irritation</p> <p>Causes eye irritation</p> <p>Irritating to respiratory system</p> <p>May cause abdominal pain, nausea, vomiting, diarrhea</p> <p>May affect the cardiovascular system</p> <p>Hypotension</p> <p>Cardiac arrhythmias</p> <p>Weak, rapid pulse or rapid heart rate (Tachycardia)</p> <p>Dyspnea (Shortness of breath and difficulty breathing)</p> <p>Peripheral neuropathy</p> <p>Paresthesia (numbness and tingling of the extremities)</p> <p>Muscle weakness</p> <p>May cause central nervous system effects</p> <p>Ataxia</p> <p>Excitement</p> <p>May cause metabolic acidosis</p> <p>It may affect the kidneys</p> <p>It may affect the blood</p>
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media**Suitable Extinguishing Media:**

Dry chemical. Carbon dioxide (CO₂). Water spray, mist, or foam.

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical**Hazardous combustion products**

No information available.

Specific hazards

May be combustible at high temperatures.

Special Protective Actions for Firefighters**Specific Methods:**

No information available

Special Protective Equipment for Firefighters:

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures****Personal Precautions:**

Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid breathing dust. Remove all sources of ignition.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas. Prevent product from entering drains.

Methods and material for containment and cleaning up**Methods for containment**

Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up

Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE**Precautions for safe handling****Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities**Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:
Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Podophyllum Resin	9000-55-9	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Podophyllum Resin	9000-55-9	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Podophyllum Resin	9000-55-9	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles
Skin and body protection:	Chemical resistant apron Gloves Long sleeved clothing
Respiratory protection:	Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands and face before breaks and immediately after handling the product

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder.	Color: Light brown. Yellowish-brown.
Odor: No information available.	Taste No information available.	Formula No information available
Molecular/Formula weight (g/mole): No information available	Flammability (solid, gas) no data available	Flashpoint (°C/°F): No information available
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): No information available	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Alcohol Soluble in Chloroform Soluble in Acetone	

10. STABILITY AND REACTIVITY

Reactivity

No information available

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Exposure to light. Incompatible materials.

Incompatible Materials: Oxidizing agents

Hazardous decomposition products: No information available.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation. Skin.

Acute Toxicity

Component Information

Podophyllum Resin	
CAS No	9000-55-9

LD50/oral/rat = No information available

LD50/oral/mouse = 68 mg/kg Oral LD50 Mouse

LD50/dermal/rabbit = No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

Value - Acute Tox = No information available

LD50/oral/mouse =

Value - Acute Tox Oral = 68 mg/kg

LD50/dermal/rabbit

Value - Acute Tox = No information available

LD50/dermal/rat

VALUE - Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: Causes skin irritation. Fatal if absorbed through skin.

Eye Contact: Causes serious eye irritation.

Inhalation Fatal if inhaled. Irritating to respiratory system.

Ingestion Fatal if swallowed. Ingestion may cause nausea, vomiting. May cause hypermotility, diarrhea. May cause abdominal pain. May affect respiration (dyspnea - difficulty breathing and shortness of breath). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (depression or excitement). May affect behavior/central nervous system

(convulsions/seizures). May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (dizziness, drowsiness). May affect the cardiovascular system (tachycardia). May affect cardiovascular system (hypotension, cardiac arrhythmias). May affect the blood. May affect the kidneys. May affect liver. May cause metabolic acidosis. May cause painful or difficult urination. May affect the peripheral nervous system and cause severe peripheral neuropathy with paresthesia (a tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles") generally of the hands and feet (extremities)), muscle weakness.

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity No information available.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Podophyllum Resin	9000-55-9	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity May damage fertility or the unborn child

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility in soil No information available
Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Podophyllum Resin	9000-55-9	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s. (podophyllum resin)
Hazard Class 6.1
Subsidiary Class No information available
Packing group: III
Emergency Response Guide Number 154
Marine Pollutant Severe Marine Pollutant
DOT RQ (lbs): No information available
Special Provisions IB8, IP3, T1, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s., 6.1, III

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No Information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ADR

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Packing group III
Subsidiary Risk: No information available
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

IMDG

UN-No: UN2811

Proper Shipping Name: Toxic solids, organic, n.o.s. (podophyllum resin)
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: III
Marine Pollutant No information available
EMS: F-A
Special Provisions 223, 274
Description UN2811, Toxic solid, organic, n.o.s. (PODOPHYLLUM RESIN), 6.1, III

RID

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group III
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

ICAO (air)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class 6.1
Subsidiary Risk: No information available
Packing Group: III
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III
Special Provisions A3, A5

IATA

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group III
Precautionary Statements - Response 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, III

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia AICS	EINECS-No.
<i>Podophyllum Resin</i>	9000-55-9	Not Listed	Not present	Not present	Not present	Not listed	Present	Present 232-546-2

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Component	CAS No	Carcinogen	Developmental Toxicity	Male	Female
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Product code: PO105

Product name: PODOPHYLLUM
RESIN, USP

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				Reproductive Toxicity	Reproductive Toxicity:
Podophyllum Resin	9000-55-9	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Podophyllum Resin	9000-55-9	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Podophyllum Resin	9000-55-9	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: Not a dangerous product according to HPR classification criteria.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Podophyllum Resin	9000-55-9	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Podophyllum Resin	9000-55-9	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Podophyllum Resin	9000-55-9	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Podophyllum Resin	9000-55-9	

EU - CLP (1272/2008)

R-phrases(s)

not determined (not applicable)

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed

R36/37/38 - Irritating to eyes, respiratory system and skin

S -phrase(s)

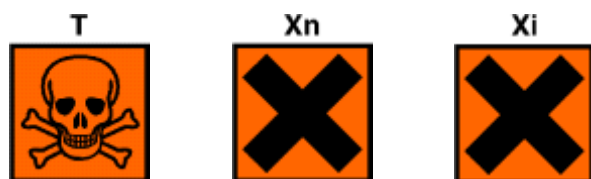
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Podophyllum Resin	9000-55-9		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

T - Toxic
Xn - Harmful
Xi - Irritant



16. OTHER INFORMATION

Preparation Date: 8/23/2016
Revision date 12/19/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
PO105	Podophyllum Resin, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

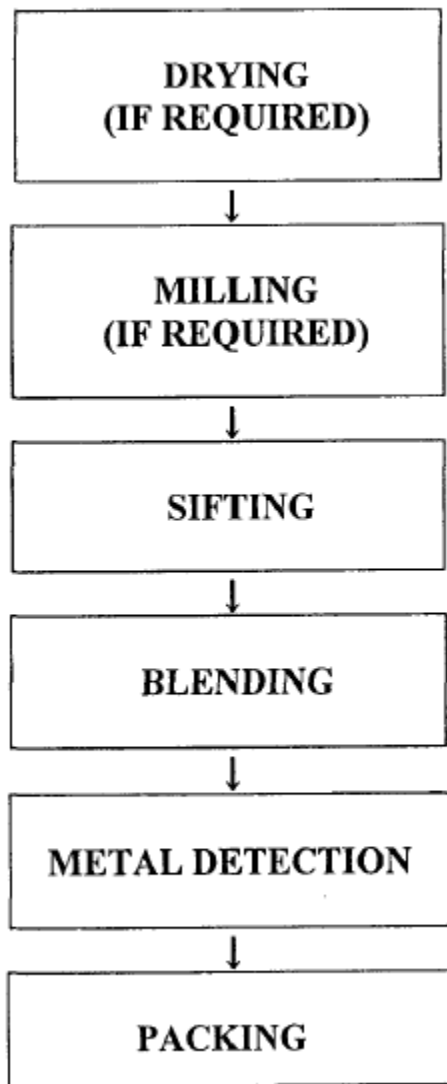
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Podophyllum Resin, USP (Cat# PO105)



CORPORATE HEADQUARTERS

769 Jersey Avenue
New Brunswick, NJ 08901
PHONE 732.214.1300
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

PO105, Podophyllum Resin, USP

Source Statement

The above mentioned catalog item is manufactured by plant derived material (Podophyllum Peltatum root). No animal derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 48 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



RE: Elemental Impurities - Podophyllum Resin, USP (Cat# PO105)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3.0 ppm
Cobalt	Co	2A	< 5.0 ppm
Vanadium	V	2A	< 10.0 ppm
Nickel	Ni	2A	< 20.0 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



This document has been produced electronically and is valid without a signature.

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RE: Residual Solvents - Podophyllum Resin, USP (Cat# PO105)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm

No Class 1, Class 3, or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

<p>Exp. Date: 00-00-0000</p> 	<p>DANGER</p> <p>• Fatal if swallowed, in contact with skin or if inhaled • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation • May damage fertility or the unborn child.</p> <p>• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear respiratory protection, eye protection, face protection, protective gloves, protective clothing • Do not get in eyes, on skin, or on clothing • Do not breathe dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.</p> <p>FIRST AID: Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF ON SKIN: Wash with plenty of water. Take off immediately all contaminated clothing and wash it before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.</p> <p>KEEP FROM CHILDREN</p>	 <p>P0105</p> <p>SIZ SY</p> <p>Podophyllum Resin</p> <p>USP</p> <p>CAS 9000-55-9</p> <p>CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only. Read and understand the label and Safety Data Sheet (SDS) prior to use.</p> <table border="1" style="width: 100%;"> <tr> <td>DOT: UN2811, Toxic solid, organic, n.o.s. (podophyllum resin), 6.1, PG III</td> </tr> <tr> <td>Chemical Emergency: (800)424-9300</td> </tr> <tr> <td>www.SpectrumChemical.com</td> </tr> </table>	DOT: UN2811, Toxic solid, organic, n.o.s. (podophyllum resin), 6.1, PG III	Chemical Emergency: (800)424-9300	www.SpectrumChemical.com	<p>Manufacturer/Supplier Code ?</p> <p>Manufacturer Lot Number ?</p> <p>Assay (Hexane Insoluble) 40.0-50.0%</p> <p>Distinction from Resin of Indian Podophyllum To pass test</p> <p style="text-align: center;">MAXIMUM LIMITS</p> <p>Residue on Ignition 1.5%</p> <p>Elemental Impurities As reported</p> <p>Residual Solvents To pass test</p> <p>LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.</p> <p style="text-align: right;">Repackaged by Spectrum as:</p> <p style="text-align: right;">Lot No. XQ####</p>
DOT: UN2811, Toxic solid, organic, n.o.s. (podophyllum resin), 6.1, PG III						
Chemical Emergency: (800)424-9300						
www.SpectrumChemical.com						

Spectrum Chemical Mfg Corp

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