

# Purdue Products L.P.

## Material Safety Data Sheet

**Betadine® Solution  
(5% povidone iodine)**

**Version: 14-December-07**

### 1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

**Material Identification:** Betadine® Solution (5% povidone iodine)

#### **Chemical Name**

1-ethenyl-2-pyrrolidinone homopolymer compound with iodine

#### **Synonyms**

PVP-I

**Molecular Formula:**  $(C_6H_9I_2NO)_n \cdot I_x$

**Molecular Weight:** not available

**CAS Number:** 25655-41-8

**Product Use:** topical microbicide

#### **Company Identification**

##### **Manufacturer**

Purdue Products L.P.  
One Stamford Forum  
201 Tresser Boulevard  
Stamford, CT 06901-3431  
Telephone: (888) 726-7535

#### **EMERGENCY CONTACT**

Chemtrec (800) 424- 9300. For all international transportation emergencies call Chemtrec collect at (703) 527-3887.

### 2. HAZARDOUS COMPONENTS

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
1-ethenyl-2-pyrrolidinone homopolymer compound with iodine	25655-41-8	5.0-5.5
glycerin	56-81-5	1.5

### 3. Hazards Identification

#### **Emergency Overview**

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Normal handling should not constitute a hazard. The following information is provided for those circumstances where uncontrolled exposure may occur.

Reddish-brown, clear liquid

Characteristic odor

Harmful by inhalation, skin contact, or ingestion

May cause eye irritation and mild skin irritation

Target organs: respiratory system, gastrointestinal tract, skin, eyes, kidneys, thyroid.

## Potential Health Effects

Betadine® Solution is a topical microbicide. Its active ingredient is povidone iodine.

Betadine® Solution is generally non-irritating to skin. However, prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions.

Povidone iodine may cause skin sensitization. Betadine® Solution may cause eye irritation.

Prolonged contact of large skin areas with Betadine® Solution may lead to excessive absorption of iodine and should be avoided.

Overexposure from breathing aerosols and/or iodine vapors may cause irritation to the respiratory tract, bronchitis and absorption through the lungs.

High concentrations of iodine in the blood from inhalation or ingestion may cause thyroid disorder (hyperthyroidism), renal disturbances, acidosis, and electrolyte disturbances such as increased iodine levels and severe hyponatremia.

Conditions that may be aggravated by exposure to povidone iodine: asthma, chronic bronchitis, and thyroid disorders.

## Carcinogenicity Information

None of the components of Betadine® Solution are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

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## 4. First Aid Measures

### First Aid

#### INHALATION

If aerosols or iodine vapor are inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

#### SKIN CONTACT

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Remove contaminated clothing. Flush skin with plenty of water and wash thoroughly with soap and water. If irritation (redness, itching, swelling) develops, seek medical attention. Wash contaminated clothing before reuse.

## EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

## INGESTION

If swallowed, do not induce vomiting. Drink several glasses of milk or water. Never give anything by mouth to an unconscious person. Get medical attention.

## Notes to Physicians

No special first aid. Provide supportive measures.

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## 5. Fire Fighting Measures

### Flammable Properties

Non-flammable.

### Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

### Fire Fighting Instructions

Evacuate personnel to a safe area. Move containers from area if it can be done without risk. Wear protective clothing and positive-pressure, self-contained breathing apparatus with full protective gear.

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## 6. Accidental Release Measures

### Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up to minimize exposure to this material. Evacuate personnel from the area.

### Initial Containment

Prevent material from entering sewers, waterways, or low areas. Dike area for later disposal.

### Spill Clean-up

Wear suitable protective clothing and equipment. Vacuum or mop up liquid and place in a container suitable for chemical waste; avoid generation of aerosols. Place collected material into a suitable container for disposal. Thoroughly wash

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area with detergent and water. Dispose of all solid waste and wash and rinse water in accordance with federal, state, and local regulations.

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## **7. Handling and Storage**

### **Handling (Personnel)**

Avoid procedures that will generate aerosols. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling. Wash contaminated clothing after use. Use with adequate ventilation.

### **Handling (Physical Aspects)**

Close container after each use. Do not generate aerosols.

### **Storage**

Store in an airtight container. Keep container closed. Store at room temperature. Keep from contact with oxidizing materials.

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## **8. Exposure Controls/Personal Protection**

### **Engineering Controls**

Handle material under adequate ventilation. Keep container tightly closed.

### **Personal Protective Equipment**

Wear safety glasses with side shields. Wear full-face protection when judged that the possibility exists for eye and face contact.

Wear an appropriate NIOSH-approved air purifying respirator or positive pressure air-supplied respiratory in situations where a respirator is judged appropriate to prevent inhalation.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate, to prevent skin contact. Consult the site safety professional for additional guidance, as needed.

### **Exposure Guidelines**

#### **Exposure Limits**

**None established for Betadine® Solution.**

**None established for Povidone iodine.**

#### **For Iodine:**

PEL (OSHA): 0.1 ppm

TLV (ACGIH): 0.1 ppm

#### **For Glycerin:**

PEL (OSHA): 15 mg/m<sup>3</sup>, total dust

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5 mg/m<sup>3</sup>, respirable fraction  
TLV (ACGIH): 10 mg/m<sup>3</sup> (mist)

## Exposure Guideline Comments

none

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## 9. Physical and Chemical Properties

### Physical Data

Odor: slight characteristic  
Form: liquid  
Color: reddish brown  
Vapor Pressure: no information available  
Melting Point: no information available  
Solubility: soluble in water and in alcohol  
pH: 1.5-6.5  
Flash Point: >200°F

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## 10. Stability and Reactivity

### Chemical Stability

Low stability hazard expected at normal operating temperatures.

### Reactivity

A mixture of equal parts of a 10% povidone iodine solution and hydrogen peroxide 3% exploded about 100 minutes after mixing.

### Incompatibility with Other Materials

Strong alkalis or reducing agents

### Decomposition

Will not decompose under conditions of usual handling.

### Polymerization

Material will not polymerize.

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## 11. Toxicological Information

### Animal Data

Betadine® Solution has not undergone toxicity testing in animals. The information presented below is for povidone iodine and glycerin.

### Skin/Eyes

#### Povidone iodine

Povidone iodine has been reported to be a mild skin and eye irritant in animals.

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## Glycerin

Glycerin has been reported to produce mild skin and eye irritation in rabbits.

### **Acute**

#### Povidone iodine

Oral LD<sub>50</sub>: rat: >8 g/kg

Oral LD<sub>50</sub>: mouse: 8.1 g/kg

Intravenous LD<sub>50</sub>: rat: 640 mg/kg

Intravenous LD<sub>50</sub>: mouse: 480 mg/kg

Intravenous LD<sub>50</sub>: rabbit 110 mg/kg

#### Glycerin

Oral LD<sub>50</sub>: rat: 12.6 g/kg

Oral LD<sub>50</sub>: mouse: 4.1 g/kg

Intravenous LD<sub>50</sub>: rat: 5.6 mg/kg

Intravenous LD<sub>50</sub>: mouse: 4.2 mg/kg

Dermal LD<sub>50</sub>: rabbit: >10 g/kg

### **Subchronic**

#### **Subchronic Toxicity**

#### Povidone iodine

In a 12-week dietary study in rats, ingestion of povidone iodine at an average povidone iodine dosage of approximately 75 to 750 mg/kg/day produced a dose-dependent increase in serum protein-bound iodine and nonspecific, reversible microscopic changes in the thyroid. No other gross or microscopic povidone iodine-induced changes were observed. At equivalent iodine dosages, dietary potassium iodide produced similar thyroid changes of equal or greater severity.

#### Glycerin

No information available.

### **Chronic**

#### **Chronic Toxicity**

#### Povidone iodine

No information available.

#### Glycerin

No information available.

#### **Carcinogenicity**

#### Povidone iodine

No information available.

#### Glycerin

No information available.

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## **Mutagenicity/Genotoxicity:**

### Povidone iodine

Bacterial mutagenicity: negative

Bone marrow (hamster): negative

Dominant lethal assay (mouse): negative

Mouse lymphoma: negative

Mouse micronucleus: negative

### Glycerin

Bacterial mutagenicity: negative

## **Developmental/Reproductive Toxicity**

### Povidone iodine

No information available.

### Glycerin

No information available.

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## **12. Ecological Information**

### **Ecotoxicological Information**

No information available

### **Chemical Fate Information**

No information available

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## **13. Disposal Considerations**

### **Disposal**

This material is not listed under US RCRA. Disposal of this material must be in accordance with federal, state/provincial, and local regulations.

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## **14. Transportation Information**

### **Shipping Information**

This material is non-hazardous under US DOT.

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## **15. Regulatory/Statutory Information**

**US Federal:** none

**International:** none

**EC Labeling:** none

**FDA:** The Approved Drug Products with Therapeutic Equivalence Evaluations List identifies currently marketed drug products, including povidone-iodine, approved

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on the basis of safety and effectiveness by FDA under Sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act.

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## **16. Other Information**

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared for Purdue Products L.P. by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.