SAFETY DATA SHEETS

This SDS packet was issued with item:

078093615

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078088855 078363361

Purdue Products L.P.

Material Safety Data Sheet

Betadine® Solution
(10% povidone iodine) **Reviewed: 8-May-13**

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: Betadine® Solution (10% povidone iodine)

Chemical Name

1-ethyenyl-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

Material	CAS Number	%
1-ethenyl-2-pyrrolidinone homopolymer compound with iodine	25655-41-8	10
contains either of the following:		
glycerin	56-81-5	
pareth 25-9	68131-39-5	

3. Hazards Identification

Emergency Overview

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

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.

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.

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. Use dikes to contain spilled material and retain 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

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

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.

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 respirator 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.
None established for Pareth 25-9.

For Iodine:
PEL (OSHA): 0.1 ppm
TLV (ACGIH): 0.1 ppm

For Glycerin:

PEL (OSHA): 15 mg/m^3, total dust
5 mg/m^3, respirable fraction
TLV (ACGIH): 10 mg/m^3 (mist)

Exposure Guideline Comments
none

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
Flash Point (closed cup): >200°F

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.

11. Toxicological Information

Animal Data
Betadine® Solution has not undergone toxicity testing in animals. The information presented below is for povidone iodine, glycerin and pareth 25-9.

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

Glycerin
Glycerin has been reported to produce mild skin and eye irritation in rabbits.
Pareth 25-9
No information available.

Acute

Povidone iodine
Oral LD_{50}: rat: >8 g/kg
Oral LD_{50}: mouse: 8.1 g/kg
Intravenous LD_{50}: rat: 640 mg/kg
Intravenous LD_{50}: mouse: 480 mg/kg
Intravenous LD_{50}: rabbit 110 mg/kg

Glycerin
Oral LD_{50}: rat: 12.6 g/kg
Oral LD_{50}: mouse: 4.1 g/kg
Intravenous LD_{50}: rat: 5.6 mg/kg
Intravenous LD_{50}: mouse: 4.2 mg/kg
Dermal LD_{50}: rabbit: >10 g/kg

Pareth 25-9
No information available. Pareths are ethoxylated long-chain alcohols and are expected to have low acute oral toxicity; e.g., the acute oral LD_{50} for Pareth 25-7 is 2000 mg/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.

Pareth 25-9
No information available.

Chronic

Chronic Toxicity
Povidone iodine
No information available.

Glycerin
No information available.

Pareth 25-9
No information available.

Carcinogenicity
Povidone iodine
No information available.

Glycerin
No information available.

Pareth 25-9
No information available.

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

Pareth 25-9
No information available.

Developmental/Reproductive Toxicity
Povidone iodine
No information available.

Glycerin
No information available.

Pareth 25-9
No information available.

12. Ecological Information

Ecotoxicological Information
No information available

Chemical Fate Information

No information available

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.

14. Transportation Information

Shipping Information

This material is non-hazardous under US DOT.

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

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 do 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.

SAFETY DATA SHEET

Issue Date 14-Dec-2007 **Revision Date** 13-Apr-2015 **Version** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name	Betadine® (povidone-iodine, 10%) Solution - OTC
Synonyms	PVP-I
Recommended Use	This product is a topical microbicide
Uses advised against	Not for oral use.
Distributor Address	Purdue Products L.P. One Stamford Forum 201 Tresser Boulevard Stamford, Connecticut 06901-3431 (888) 726-7535
24 Hour Emergency Phone Number	Chemtrec (800) 424-9300 For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

This product is not considered hazardous by the 2012 OSHA Hazard Communications standard (29 CFR 1910.1200).

Serious eye damage/eye irritation	Category 2B

Emergency Overview

Signal Word Warning

Hazard Statements
Causes serious eye irritation

Appearance Reddish-brown **Physical state** Liquid **Odor** Characteristic odor

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling. Prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions. In pre-operative prepping, avoid "pooling" beneath the patient.

Eyes
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.

Hazards Not Otherwise Classified (HNOC)
Not Applicable.

Other Information
Causes mild skin irritation
0% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight %
Povidone Iodine	25655-41-8	5-10
Sodium hydroxide	1310-73-2	<1

4. FIRST AID MEASURES

First aid measures

Eye contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion	In case of accidential ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media No information available.

Specific hazards arising from the chemical
No information available.

Explosion Data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Protective equipment and precautions 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	Evacuate personnel to safe areas. Use personal protection recommended in Section 8.
Other Information	Not Applicable.

Environmental precautions

Environmental precautions	See section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing.

Conditions for safe storage, including any incompatibilities

Storage conditions Keep container tightly closed in a dry and well-ventilated place.

Incompatible materials Strong alkalis or reducing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m³	TWA: 2 mg/m³	IDLH: 10 mg/m³ Ceiling: 2 mg/m³

Engineering Controls Handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.

Individual Protection Measures (Personal Protective Equipment)

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting or possibility of splashing. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. Contact a health and safety professional for specific information.

Respiratory protection Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used they are to be NIOSH approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

General Hygiene Considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state Liquid
Appearance Reddish-brown
Odor Characteristic odor
Color Reddish-brown
Odor threshold No information available.

Property	Values	Remarks • Method
pH	No information available.	
Melting point / melting range	No information available.	
Boiling point / boiling range	No information available.	
Flash point	> 93.3 °C / > 200 °F	CC (closed cup)
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	No information available.	
Water solubility	No information available.	
Solubility in other solvents	No information available.	
Partition coefficient (n-octanol/water)	No information available.	
Autoignition temperature	No information available.	
Decomposition temperature	No information available.	
Kinematic viscosity	No information available.	
Dynamic viscosity	No information available.	
Explosive properties	No information available.	
Oxidizing properties	No information available.	

Other Information

Softening point	No information available.
Molecular weight	No information available.
VOC content; (%)	No information available.
Density	No information available.
Bulk density	No information available.

10. STABILITY AND REACTIVITY

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

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions No information available.

Hazardous polymerization Hazardous polymerization does not occur.

Conditions to avoid None known based on available information.

Incompatible materials Strong alkalis or reducing agents.

Hazardous decomposition products Will not decompose under conditions of usual handling.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

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

Inhalation

Povidone iodine: 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.

Eye contact

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

Skin contact

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

Ingestion

May be harmful if swallowed.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	-	1350 mg/kg (Rabbit)	-
Povidone Iodine	8 g/kg (Rat)	-	-
Polyvinylpyrrolidone	100 g/kg (Rat)	-	-
Iodine	14 g/kg (Rat)	-	-
Pareth 25-9	2 g/kg (Rat) 1600 mg/kg (Rat)	2500 mg/kg (Rabbit)	-

Information on toxicological effects

Symptoms

No information available.

Skin corrosion/irritation

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.

Sensitization

Povidone iodine: Negative in a human insult patch test as a primary skin irritant. A few cases of dermal sensitivity exist. Chemical-like burn can occur if pooled solution is retained against a patient's skin for several hours while under pressure such as during prolonged hospital procedures (PVP-1 solution, 1% available iodine).

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

Germ cell mutagenicity

Povidone iodine:
Bacterial mutagenicity: negative
Bone marrow (hamster): negative
Dominant lethal assay (mouse): negative
Mouse lymphoma: negative
Mouse micronucleus: negative

Carcinogenicity

Povidone iodone: No information available.

Reproductive toxicity

Caused toxicity in maternal and fetal rabbits without congenital defects. Large scale case-control studies did not increase congenital abnormalities during pregnancy and vaginal treatment.

STOT-single exposure

No information available.

STOT-repeated exposure

No information available.

Chronic Toxicity

Long term testing of Povidone in dogs (12 months) and 2 year in dogs and rats did not cause any effects of note.

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.

Aspiration hazard No information available.

Acute toxicity 0% of the mixture consists of ingredient(s) of unknown toxicity.

The following values are calculated based on chapter 3.1 of the GHS document.

Oral LD50 8036 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium hydroxide		LC50 96 h = 45.4 mg/L (Oncorhynchus mykiss - static)		

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Do not reuse container.

Chemical Name	California Hazardous Waste Status
Sodium hydroxide 1310-73-2	Toxic Corrosive

14. TRANSPORT INFORMATION

DOT Not regulated.

IATA Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA	Not determined.
DSL	Not determined.

Legend:

TSCA - United States Toxic Substances Control Act Section 8 (b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hydroxide 1310-73-2	1000 lb			X

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Sodium hydroxide 1310-73-2	1000 lb		RQ 1000 lb final RQ RQ 454 kg final RQ

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

US State Right-to-Know Regulations

US EPA Label Information

EPA Pesticide Registration Number Not Applicable.

16. OTHER INFORMATION

NFPA	**Health Hazards** 1	**Flammability** 0	**Instability** 0	**Physical and Chemical Properties** -
HMIS	**Health Hazards** 1	**Flammability** 0	**Physical Hazards** 0	**Personal protection** X

General Information No additional information.

Prepared By This SDS was prepared by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.

Issue Date 14-Dec-2007

Revision Date	13-Apr-2015
Revision Note	SDS reformated for OSHA (GHS) 2012.

Disclaimer

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End of Safety Data Sheet