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.

---

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.

US - OSHA SAFETY DATA SHEET

Issue Date 24-Jul-2018 **Revision Date** 24-Jul-2018 **Version** 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Betadine® (povidone-iodine, 10%) Solution

Other means of identification

Synonyms None known.

Recommended use of the chemical and restrictions on use

Recommended Use This product is a topical microbicide.

Uses Advised Against Not for oral use.

Details of the supplier of the safety data sheet

Distributor

Avrio Health L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901-3431
(888) 827-0624.
contactavrio@avriohealth.com

Emergency telephone number

24 Hour Emergency Phone Number Chemtrec (US): 1-800-424-9300. For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Serious Eye Damage/Eye Irritation	Category 2A

Physical Hazards

Not classified.

OSHA Regulatory Status

This product is considered hazardous by the 2012 OSHA Hazard Communication Standard/Globally Harmonized System of Classification and Labelling of Chemicals (GHS); (29 CFR 1910.1200; Revision 3).

Label elements

Emergency Overview

Warning

Hazard Statements

Causes serious eye irritation.

Appearance Solution. **Physical State** Liquid. **Odor** Not available.

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling.

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 attention.

Hazards not otherwise classified (HNOC)
None.

Other information
Not available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Formula Not available.

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 wash exposed area with soap and water. Obtain medical attention if skin reaction occurs.

Inhalation Immediately move exposed subject to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental 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.

Most important symptoms and effects, both acute and delayed

Symptoms Overexposure from breathing iodine aerosols and/or 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 such as asthma, chronic bronchitis, and thyroid disorders may be aggravated by exposure to povidone iodine.

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 Not available.

Specific hazards arising from the chemical
Not available.

Hazardous Combustion Products Not 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 Wear appropriate personal protective equipment (see Section 8). Keep unnecessary personnel away. Ensure adequate ventilation, especially in confined areas.

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 Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry, cool and well-ventilated place.

Incompatible Materials Alkalies. Strong reducing agents.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, contains the following hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium Hydroxide 1310-73-2	Ceiling: 2 mg/m^3	TWA: 2 mg/m^3 (vacated) Ceiling: 2 mg/m^3	IDLH: 10 mg/m^3 Ceiling: 2 mg/m^3

Appropriate engineering controls

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, such as 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. 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. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. 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

Information on basic physical and chemical properties

Physical State	Liquid.		
Appearance	Solution.	**Odor**	Not available.
Color	Reddish-brown.	**Odor Threshold**	Not available.

Property	Values	Remarks
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point/boiling range	Not available.	
Flash point	> 93.3°C / >200 °F	CC (closed cup)
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	

Vapor density	Not available.
Specific Gravity	Not available.
Water solubility	Not available.
Solubility in other solvents	Not available.
Partition coefficient	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.
Kinematic viscosity	Not available.
Dynamic viscosity	Not available.
Explosive Properties	Not available.
Oxidizing Properties	Not available.

Other information

Softening point	Not available.
Molecular weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk density	Not available.

10. STABILITY AND REACTIVITY

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

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
Not available.

Hazardous polymerization
Hazardous polymerization does not occur.

Conditions to avoid
None known.

Incompatible materials
Alkalies. Strong reducing agents.

Hazardous decomposition products
None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Product Information

Acute Toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Povidone Iodine 25655-41-8	> 8 g/kg (Rat)	-	-	-
Sodium Hydroxide 1310-73-2	500 mg/kg (Rabbit)	1350 mg/kg (Rabbit)	-	-

Information on toxicological effects

Symptoms Overexposure from breathing iodine aerosols and/or 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 such as: asthma, chronic bronchitis, and thyroid disorders may be aggravated by exposure to povidone iodine.

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

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.

Serious Eye Damage/Eye Irritation Povidone iodide: In both 5% and 10% concentrations, povidone iodide demonstrates severe toxicity when one drop of either concentration is placed in the anterior chamber of the eye.

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 (1% available iodine solution).

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

Carcinogenicity No data found.

Reproductive Toxicity Povidone iodine 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 data available.

STOT - Repeated Exposure No data available.

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 data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Hydroxide 1310-73-2		45.4 mg/L: 96 h LC50 Static (Oncorhynchus mykiss)		

Persistence and degradability

Not available.

Bioaccumulation
Not available.

Mobility
Not available.

Other adverse effects
Not 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 Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not reuse container.

This product contains the following substances that are listed with the State of California as a hazardous waste.

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

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

CWA (Clean Water Act)
This product contains the following substances which are regulated 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, contains the following substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

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

No component is on the Prop 65 list.

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Sodium Hydroxide 1310-73-2	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

16. OTHER INFORMATION

Prepared By IES Engineers
Issue Date 24-Jul-2018
Revision Date 24-Jul-2018
Revision Note New SDS.

Disclaimer

The information contained in this 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 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 Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

End of Safety Data Sheet