SAFETY DATA SHEETS

This SDS packet was issued with item:

078088855

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

078093615 078363361

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.

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Revision Note	SDS reformated for OSHA (GHS) 2012.

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