1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

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

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).

<table>
<thead>
<tr>
<th>Hazard Statements</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Causes serious eye irritation</td>
<td>2B</td>
</tr>
</tbody>
</table>

Emergency Overview

<table>
<thead>
<tr>
<th>Signal Word</th>
<th>Hazard Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning</td>
<td>Causes serious eye irritation</td>
</tr>
</tbody>
</table>

Appearance | Physical state | Odor |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reddish-brown</td>
<td>Liquid</td>
<td>Characteristic odor</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone Iodine</td>
<td>25655-41-8</td>
<td>5-10</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

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 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.

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>Ceiling: 2 mg/m³</td>
<td>TWA: 2 mg/m³</td>
<td>IDLH: 10 mg/m³</td>
</tr>
<tr>
<td>1310-73-2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
None required for consumer or medical use. 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

<table>
<thead>
<tr>
<th>Physical property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Reddish-brown</td>
</tr>
<tr>
<td>Odor</td>
<td>Characteristic odor</td>
</tr>
<tr>
<td>Color</td>
<td>Reddish-brown</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
</tbody>
</table>
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 has been reported to be a mild skin and eye irritant in animals.

**Skin contact**

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

**Ingestion**

May be harmful if swallowed.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Povidone Iodine</td>
<td>8 g/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pareth 25-9</td>
<td>2 g/kg (Rat)</td>
<td>1600 mg/kg (Rat)</td>
<td>2500 mg/kg (Rabbit)</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>-</td>
<td>1350 mg/kg (Rabbit)</td>
<td>-</td>
</tr>
<tr>
<td>Polyvinylpyrrolidone</td>
<td>100 g/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Iodine</td>
<td>14 g/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**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 iodine: 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**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Toxicity to microorganisms</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td></td>
<td></td>
<td>LC50 96 h = 45.4 mg/L</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(Oncorhynchus mykiss - static)</td>
<td></td>
</tr>
</tbody>
</table>

- 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**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Hazardous Waste Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>Toxic</td>
</tr>
<tr>
<td>1310-73-2</td>
<td>Corrosive</td>
</tr>
</tbody>
</table>

---

## 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).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CWA - Reportable Quantities</th>
<th>CWA - Toxic Pollutants</th>
<th>CWA - Priority Pollutants</th>
<th>CWA - Hazardous Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1000 lb</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1310-73-2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Hazardous Substances RQs</th>
<th>CERCLA/SARA RQ</th>
<th>Reportable Quantity (RQ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1000 lb</td>
<td>RQ 1000 lb final RQ</td>
<td></td>
</tr>
<tr>
<td>1310-73-2</td>
<td></td>
<td>RQ 454 kg final RQ</td>
<td></td>
</tr>
</tbody>
</table>

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
<table>
<thead>
<tr>
<th>Revision Date</th>
<th>03-Apr-2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision Note</td>
<td>SDS reformated for OSHA (GHS) 2012.</td>
</tr>
</tbody>
</table>

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