The Purdue Frederick Company

Material Safety Data Sheet

Betadine® Solution
(10% povidone iodine) **Version: 06-Oct-03**

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 microbiocide

Company Identification

Manufacturer
The Purdue Frederick Company
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	10.0-10.7
glycerin	56-81-5	1.0

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 microbiocide. 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. 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

area with detergent and water. Dispose of all solid waste and wash and rinse 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 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^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
pH: 1.5-6.5

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 and glycerin.

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.

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

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.

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.

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 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 The Purdue Frederick Company by the Occupational and Environmental Assessment Section of Purdue Pharma, L.P. and Ariel Research Corporation.