

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



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
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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.	Odor	Not available.
Appearance	Solution.	Odor Threshold	Not available.
Color	Reddish-brown.		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>
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
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Sodium Hydroxide 1310-73-2	1000 lb			X
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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