

## 1. Product and Company Identification

<b>Product identifier</b>	<b>Prevantics® Device Swab</b>	<b>SDS0174</b>
<b>Other means of identification</b>	Not available	
<b>Recommended use</b>	Disinfects needleless access sites prior to use.	
<b>Recommended restrictions</b>	May be used in the home or healthcare facility	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	Professional Disposables International, Inc.	
<b>Address</b>	Two Nice-Pak Park Orangeburg, NY 10962-1376	
<b>Telephone</b>	Phone (USA)	1-845-365-1700 (M-F 9am - 5pm)
<b>E-mail</b>	www.pdihc.com	
<b>Emergency phone number</b>	1-800-999-6423	

## 2. Hazards Identification

<b>Physical hazards</b>	Flammable solids	Category 1
<b>Health hazards</b>	Serious eye damage/eye irritation	Category 1
<b>Environmental hazards</b>	Not determined.	
<b>OSHA defined hazards</b>	None additional.	

### Label elements



<b>Signal word</b>	Warning
<b>Hazard statement</b>	Flammable solid. Causes serious eye damage.
<b>Precautionary statement</b>	
<b>Prevention</b>	Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only in a well-ventilated area. Wear gloves/eye protection.
<b>Response</b>	If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. In case of fire: Use appropriate media to extinguish.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Not applicable.

## 3. Composition/Information on Ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Isopropanol		67-63-0	70 (v/v)
Chlorhexidine gluconate		18472-51-0	3.15 (w/v)

**Composition comments** Active ingredient(s) are listed above.

---

#### 4. First Aid Measures

---

<b>Inhalation</b>	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	In case of skin irritation, discontinue use of product. Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
<b>Ingestion</b>	If swallowed, get medical help or contact a Poison Control Center immediately. Immediately rinse mouth out with water. Do not induce vomiting. If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Never give anything by mouth if victim is unconscious, or is convulsing.
<b>Most important symptoms/effects, acute and delayed</b>	Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. These products may cause irritation or chemical burns.

---

#### 5. Fire Fighting Measures

---

<b>Suitable extinguishing media</b>	Alcohol resistant foam. Carbon dioxide (CO <sub>2</sub> ). Dry chemical.
<b>Unsuitable extinguishing media</b>	Not available.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Structural firefighters protective clothing will only provide limited protection.
<b>Fire-fighting equipment/instructions</b>	In case of fire and/or explosion do not breathe fumes. In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk. Cool containers exposed to flames with water until well after the fire is out. In the event of fire and/or explosion do not breathe fumes.
<b>General fire hazards</b>	Flammable solid.

---

#### 6. Accidental Release Measures

---

<b>Personal precautions, protective equipment and emergency procedures</b>	Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). For waste disposal, see Section 13 of the SDS.  Never return spills in original containers for re-use. Collect and dispose of spillage as indicated in section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into water courses.

---

#### 7. Handling and Storage

---

<b>Precautions for safe handling</b>	<p>WARNING</p> <p>Flammable, keep away from fire or flame.</p> <p>For external use only.</p> <p>Do not use with electrocautery procedures.</p> <p>Use according to package label instructions.</p> <p>Discard after single use.</p> <p>Wear appropriate personal protective equipment.</p> <p>Do not handle, store or open near an open flame, sources of heat or sources of ignition.</p> <p>Observe good industrial hygiene practices.</p> <p>Use care in handling/storage.</p>
<b>Conditions for safe storage, including any incompatibilities</b>	<p>Store between 68°F and 77°F ( 20°C - 25°C).</p> <p>Do not store at temperatures above 40°C (104°F).</p> <p>Keep from freezing.</p> <p>Keep away from heat, sparks and open flame.</p> <p>Store away from incompatible materials (see Section 10 of the SDS).</p> <p>Keep out of reach of children.</p>

---

## 8. Exposure Controls/Personal Protection

### Occupational exposure limits

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Isopropanol (CAS 67-63-0)	PEL	980 mg/m3
		400 ppm

#### US. ACGIH Threshold Limit Values

Components	Type	Value
Isopropanol (CAS 67-63-0)	STEL	400 ppm
	TWA	200 ppm

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Isopropanol (CAS 67-63-0)	STEL	1225 mg/m3
		500 ppm
	TWA	980 mg/m3 400 ppm

### Biological limit values

#### ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
Isopropanol (CAS 67-63-0)	40 mg/l	Acetone	Urine	*

\* - For sampling details, please see the source document.

### Exposure guidelines

See above

### Appropriate engineering controls

Ensure adequate ventilation. Provide eyewash station.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear gear as deemed necessary. Follow label directions.

#### Skin protection

##### Hand protection

Wear as deemed necessary, follow label directions.

##### Other

Follow label directions carefully.

#### Respiratory protection

Wear positive pressure self-contained breathing apparatus (SCBA).

#### Thermal hazards

Not available.

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product. When using do not smoke. When using do not eat or drink.

## 9. Physical and Chemical Properties

Appearance	Liquid Saturated Swab
Physical state	Solid.
Form	Solid containing liquid.
Color	Clear colorless
Odor	Mild alcohol.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Pour point	Not available.
Specific gravity	Not available.
Partition coefficient (n-octanol/water)	Not available.
Flash point	78.0 °F (25.6 °C) Tag Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Flammable solid.

**Upper/lower flammability or explosive limits**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

---

**10. Stability and Reactivity**

---

<b>Reactivity</b>	This product may react with strong oxidizing agents.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Conditions to avoid</b>	Heat, flames and sparks. Avoid temperatures exceeding the flash point. Do not mix with other chemicals. Do not use hypochlorite bleach on fabrics exposed to Chlorhexidine Gluconate.
<b>Incompatible materials</b>	Strong oxidizing agents. Anionic surfactants. Soaps. Hypochlorite bleach
<b>Hazardous decomposition products</b>	May include and are not limited to: Oxides of carbon. Oxides of nitrogen. Hydrogen chloride. Ammonia.

---

**11. Toxicological Information**

---

**Information on likely routes of exposure**

<b>Ingestion</b>	Not applicable under normal conditions of use.
<b>Inhalation</b>	Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Health injuries are not known or expected under normal use.
<b>Skin contact</b>	Not expected to be a primary skin irritant.
<b>Eye contact</b>	Causes irritation.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

**Information on toxicological effects**

<b>Acute toxicity</b>	Narcotic effects.
-----------------------	-------------------

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
-------------------	----------------	---------------------

Chlorhexidine gluconate (CAS 18472-51-0)

<b>Acute</b>		
LC50	Not available	
<i>Oral</i>		
LD50	Mouse	1260 mg/kg
	Rat	2000 mg/kg
Isopropanol (CAS 67-63-0)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	12800 mg/kg
<i>Inhalation</i>		
LC50	Rat	16970 mg/l/4h
<i>Oral</i>		
LD50	Dog	4797 mg/kg
	Mouse	3600 mg/kg
	Rabbit	5030 mg/kg

Components	Species	Test Results
	Rat	4396 mg/kg
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.	
Exposure minutes	Not available.	
Erythema value	Not available.	
Oedema value	Not available.	
<b>Serious eye damage/eye irritation</b>	Causes irritation.	
Corneal opacity value	Not available.	
Iris lesion value	Not available.	
Conjunctival reddening value	Not available.	
Conjunctival oedema value	Not available.	
Recover days	Not available.	
<b>Respiratory or skin sensitization</b>		
Respiratory sensitization	Not available.	
Skin sensitization	This product is not expected to cause skin sensitization.	
<b>Germ cell mutagenicity</b>	The finished product is not expected to have chronic health effects.	
<b>Carcinogenicity</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
<b>US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>		
Not listed.		
<b>Reproductive toxicity</b>	The finished product is not expected to have chronic health effects.	
<b>Specific target organ toxicity - single exposure</b>	Narcotic effects.	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Not classified.	
<b>Chronic effects</b>	Prolonged inhalation may be harmful.	
<b>Further information</b>	Not available.	

## 12. Ecological Information

<b>Ecotoxicity</b>	See below		
<b>Components</b>		<b>Species</b>	<b>Test Results</b>
Isopropanol (CAS 67-63-0)			
Algae	IC50	Algae	1000 mg/L, 72 Hours
Crustacea	EC50	Daphnia	13299 mg/L, 48 Hours
<b>Aquatic</b>			
Fish	LC50	Bluegill (Lepomis macrochirus)	> 1400 mg/l, 96 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.		
<b>Bioaccumulative potential</b>	No data available.		
<b>Partition coefficient n-octanol / water (log Kow)</b>			
Isopropanol		0.05	
<b>Mobility in soil</b>	No data available.		
<b>Mobility in general</b>	Not available.		
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.		

## 13. Disposal Considerations

<b>Disposal instructions</b>	Follow container label directions carefully. Do not reuse swab. Dispose of used swab in trash. Do not flush in toilet. Do not reuse empty container. Wrap container and put in trash collection. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	Dispose in accordance with all applicable regulations.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

---

**14. Transport Information**

---

**U.S. Department of Transportation (DOT)**

Not regulated as dangerous goods.  
Special Provision 47

---

**15. Regulatory Information**

---

**US federal regulations**

This product is regulated by the US FDA as a medical device.

510K Registration: K132380

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Isopropanol (CAS 67-63-0)

Listed.

**US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****Hazard categories**

Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - Yes  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

No

**SARA 311/312 Hazardous chemical**

No

**SARA 313 (TRI reporting)**

Chemical name	CAS number	% by wt.
Isopropanol	67-63-0	70 (v/v)

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**Food and Drug Administration (FDA)**

Not regulated.

**US state regulations**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**US - California Hazardous Substances (Director's): Listed substance**

Isopropanol (CAS 67-63-0)

Listed.

**US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance**

Not listed.

**US - Illinois Chemical Safety Act: Listed substance**

Isopropanol (CAS 67-63-0)

Listed.

**US - Louisiana Spill Reporting: Listed substance**

Isopropanol (CAS 67-63-0)

Listed.

**US - Minnesota Haz Subs: Listed substance**

Isopropanol (CAS 67-63-0)

Listed.

**US - New Jersey RTK - Substances: Listed substance**

Isopropanol (CAS 67-63-0)

Listed.

**US. Massachusetts RTK - Substance List**

Isopropanol (CAS 67-63-0)

Listed.

**US. Pennsylvania RTK - Hazardous Substances**

Isopropanol (CAS 67-63-0)

Listed.

**US. Rhode Island RTK**

Isopropanol (CAS 67-63-0)

Listed.

**Country(s) or region**

United States &amp; Puerto Rico

**Inventory name**

Toxic Substances Control Act (TSCA) Inventory

**On inventory (yes/no)\***

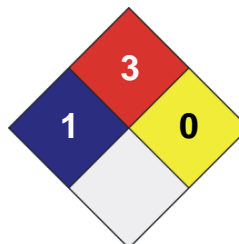
Yes

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

**16. Other Information**

LEGEND	
Severe	4
Serious	3
Moderate	2
Slight	1
Minimal	0

HEALTH	/ 1
FLAMMABILITY	3
PHYSICAL HAZARD	0
PERSONAL PROTECTION	X

**Disclaimer**

The information in the sheet was written based on the best knowledge and experience currently available. Information contained herein was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond control of the supplier, it is assumed that users of this material have been fully trained according to the requirements of all applicable legislation and regulatory instruments. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this document.

**Issue date**

16-October-2014

**Further information**

For any questions surrounding this SDS, please contact the supplier/manufacturer listed on the first page of the document.

**Other information**

DO NOT USE IF PACKAGE IS OPENED.

This Safety Data Sheet was prepared to comply with the current OSHA Hazard Communication Standard (HCS) adoption of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

**Prepared by**

Dell Tech Laboratories, Ltd. Phone: (519) 858-5021