SAFETY DATA SHEET

1. Product and Company Identification

Product identifier: Prevantics® Device Swab SDS0174
Other means of identification: Not available
Recommended use: Disinfects needleless access sites prior to use.
Recommended restrictions: May be used in the home or healthcare facility
Manufacturer/Importer/Supplier/Distributor information:

Company name: Professional Disposables International, Inc.
Address: Two Nice-Pak Park
Orangeburg, NY 10962-1376
Telephone: Phone (USA) 1-845-365-1700 (M-F 9am - 5pm)
E-mail: www.pdihc.com
Emergency phone number: 1-800-999-6423

2. Hazards Identification

Physical hazards: Flammable solids Category 1
Health hazards: Serious eye damage/eye irritation Category 1
Environmental hazards: Not determined.
OSHA defined hazards: None additional.
Label elements:

Signal word: Warning
Hazard statement: Flammable solid. Causes serious eye damage.
Precautionary statement:

Prevention: Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Use only in a well-ventilated area. Wear gloves/eye protection.
Response: 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.
Storage: Store in a well-ventilated place. Keep container tightly closed.
Disposal: Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC): None known.
Supplemental information: Not applicable.

3. Composition/Information on Ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropanol</td>
<td></td>
<td>67-63-0</td>
<td>70 (v/v)</td>
</tr>
<tr>
<td>Chlorhexidine gluconate</td>
<td></td>
<td>18472-51-0</td>
<td>3.15 (w/v)</td>
</tr>
</tbody>
</table>

Composition comments: Active ingredient(s) are listed above.
4. First Aid Measures

Inhalation
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.

Skin contact
In case of skin irritation, discontinue use of product. Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact
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.

Ingestion
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.

Most important symptoms/effects, acute and delayed
Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically.

General information
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

Suitable extinguishing media
Alcohol resistant foam. Carbon dioxide (CO2). Dry chemical.

Unsuitable extinguishing media
Not available.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters
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.

Fire-fighting equipment/instructions
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.

Specific methods
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.

General fire hazards
Flammable solid.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures
Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
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.

Environmental precautions
Avoid discharge into water courses.

7. Handling and Storage

Precautions for safe handling
WARNING
Flammable, keep away from fire or flame.
For external use only.
Do not use with electrocautery procedures.
Use according to package label instructions.
Discard after single use.

Wear appropriate personal protective equipment.
Do not handle, store or open near an open flame, sources of heat or sources of ignition.
Observe good industrial hygiene practices.
Use care in handling/storage.

Conditions for safe storage, including any incompatibilities
Store between 68°F and 77°F (20°C - 25°C).
Do not store at temperatures above 40°C (104°F).
Keep from freezing.

Keep away from heat, sparks and open flame.
Store away from incompatible materials (see Section 10 of the SDS).
Keep out of reach of children.
8. Exposure Controls/Personal Protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropanol (CAS 67-63-0)</td>
<td>PEL</td>
<td>980 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>400 ppm</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropanol (CAS 67-63-0)</td>
<td>STEL</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
</tr>
</tbody>
</table>

US. NIOSH: Pocket Guide to Chemical Hazards

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropanol (CAS 67-63-0)</td>
<td>STEL</td>
<td>1225 mg/m3</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>980 mg/m3</td>
</tr>
</tbody>
</table>

Biological limit values

<table>
<thead>
<tr>
<th>ACGIH Biological Exposure Indices</th>
<th>Value</th>
<th>Determinant</th>
<th>Specimen</th>
<th>Sampling Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropanol (CAS 67-63-0)</td>
<td>40 mg/l</td>
<td>Acetone</td>
<td>Urine</td>
<td>*</td>
</tr>
</tbody>
</table>

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

Exposure guidelines

- Ensure adequate ventilation. Provide eyewash station.

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

| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |

Vapor pressure | Not available.
Vapor density | Not available.
Relative density | Not available.
Solubility(ies) | Not available.
Auto-ignition temperature | Not available.
Decomposition temperature | Not available.
Viscosity | Not available.

10. Stability and Reactivity

Reactivity
This product may react with strong oxidizing agents.

Possibility of hazardous reactions
Hazardous polymerization does not occur.

Chemical stability
Material is stable under normal conditions.

Conditions to avoid
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.

Incompatible materials
Strong oxidizing agents. Anionic surfactants. Soaps. Hypochlorite bleach

Hazardous decomposition products
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

| Ingestion | Not applicable under normal conditions of use. |
| Inhalation | Vapors have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Health injuries are not known or expected under normal use. |
| Skin contact | Not expected to be a primary skin irritant. |
| Eye contact | Causes irritation. |

Symptoms related to the physical, chemical and toxicological characteristics
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

Acute toxicity
Narcotic effects.

| Components | Species | Test Results |
| Chlorhexidine gluconate (CAS 18472-51-0) | | |
| Acute | LC50 | Not available |
| Oral | LD50 | Mouse | 1260 mg/kg |
| | | Rat | 2000 mg/kg |

Isopropanol (CAS 67-63-0)

| Acute | Dermal |
| Lipid | Rabbit | 12800 mg/kg |
| Oral | LD50 | Dog | 4797 mg/kg |
| | LC50 | Rat | 16970 mg/l/4h |
| Oral | LD50 | Mouse | 3600 mg/kg |
| | | Rabbit | 5030 mg/kg |
Components | Species | Test Results |
--- | --- | --- |
Skin corrosion/irritation | Rat | 4396 mg/kg |
Exposure minutes | Not available. |
Erythema value | Not available. |
Oedema value | Not available. |
Serious eye damage/eye irritation | 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. |
Respiratory or skin sensitization | Not available. |
Respiratory sensitization | This product is not expected to cause skin sensitization. |
Skin sensitization | The finished product is not expected to have chronic health effects. |
Germ cell mutagenicity | The finished product is not expected to have chronic health effects. |
Carcinogenicity | This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. |

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

12. Ecological Information

Ecotoxicity | See below
--- | ---
Components | Species | Test Results |
Isopropanol (CAS 67-63-0) | Algae | IC50 | 1000 mg/L, 72 Hours |
 | Crustacea | EC50 | 13299 mg/L, 48 Hours |
 | Aquatic Fish | LC50 | > 1400 mg/l, 96 hours |
Persistence and degradability | No data is available on the degradability of this product. |
Bioaccumulative potential | No data available. |
Partition coefficient n-octanol / water (log Kow) | Isopropanol | 0.05 |
Mobility in soil | No data available. |
Mobility in general | Not available. |
Other adverse effects | 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

Disposal instructions | 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. |
Local disposal regulations | Dispose in accordance with all applicable regulations. |
Hazardous waste code | Dispose in accordance with all applicable regulations. |
Waste from residues / unused products | 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)

<table>
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<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>% by wt.</th>
</tr>
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<tbody>
<tr>
<td>Isopropanol</td>
<td>67-63-0</td>
<td>70 (v/v)</td>
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</table>

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.
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  | Inventory name                           | On inventory (yes/no) |
---------------------|------------------------------------------|-----------------------|
United States & Puerto Rico  | Toxic Substances Control Act (TSCA) Inventory | Yes                   |

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

### 16. Other Information

**LEGEND**

| HEALTH       | 1 |
| FLAMMABILITY | 3 |
| PHYSICAL HAZARD | 0 |
| PERSONAL PROTECTION | X |

**Disclaimers**

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.

DO NOT USE IF PACKAGE IS OPENED.

**Other information**

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