

1. Product and Company Identification

Product identifier	Prevantics® Swab, Swabstick and Maxi Swabstick	SDS No.0001
Other means of identification	Not available	
Recommended use	For the preparation of the patient's skin prior to an injection/surgery.	
Recommended restrictions	For Professional and Hospital Use	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
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	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

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

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. Use with care in premature infants or infants under 2 months of age, 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. Do not use under occlusive patches. Use according to package label instructions. Do not use on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol. Do not use for lumbar puncture or in contact with the meninges. Do not use on open wounds or as a general skin cleanser. Discard after single use. Wear appropriate personal protective equipment. Do not get this material in contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. 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.
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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.
For hospital and professional use only.

Keep away from heat, sparks and open flame.
Store in a cool, dry place out of direct sunlight.
Store in a well-ventilated place.
Store in original tightly closed container.
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**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**Eyeface 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 and Swabstick
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.
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Information on toxicological effects

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

Components	Species	Test Results
Isopropanol (CAS 67-63-0)		
Acute		
<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
	Rat	4396 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
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		
Respiratory sensitization	Not available.	
Skin sensitization	This product is not expected to cause skin sensitization.	
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)	Not listed.	
Reproductive toxicity	The finished product is not expected to have chronic health effects.	
Specific target organ toxicity - single exposure	Narcotic effects.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not classified.	
Chronic effects	Prolonged inhalation may be harmful.	
Further information	Not available.	

12. Ecological Information

Ecotoxicity	See below		
Components		Species	Test Results
Isopropanol (CAS 67-63-0)			
Algae	IC50	Algae	1000 mg/L, 72 Hours
Crustacea	EC50	Daphnia	13299 mg/L, 48 Hours
Aquatic			
Fish	LC50	Bluegill (Lepomis macrochirus)	> 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.
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13. Disposal Considerations

Disposal instructions	Follow container label directions carefully. Do not reuse swab/swabstick. Dispose of used swab/swabstick 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 drug product.

FDA Registration No: 021524

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 & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

On inventory (yes/no)*

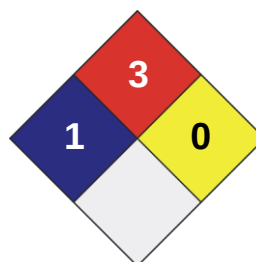
Yes

*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

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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.

Registration Numbers:

B10800- NDC 10819-1080-1

B11400- NDC 10819-1080-2

S40750- NDC 10819-4075-1

S32450- NDC 10819-4075-2

S42850- NDC 10819-4075-5

S41950- NDC 10819-4075-4

S27350- NDC 10819-4075-3

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

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