



SAFETY DATA SHEET

(conforming to Regulation (EC) No 1907/2006, as amended)

Sani-Cloth Universal

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product Identifier

Product Name	Sani-Cloth Universal
Product Code	XP00363 XP00365 XP00366 XP00390
Trade Type	Medical Device
Ref No	5326 40178

1.2 Relevant Identified uses of the substance or mixture and uses advised against

Identified uses	Disinfection of Medical Devices
Uses advised against	Personal care

1.3 Details of the supplier of the safety data sheet

Supplier	PDI Ltd Aber Park Flint UK CH6 5EX Tel: +44 (0) 1352 736700 Fax: +44 (0) 1352 736701
Contact person:	sales@pdi-hc.co.uk

1.4 Emergency telephone number

+44 (0) 1352 736700 (0900-1700 UK time)

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 (CLP)

Not Classified

2.1.2 Additional information

If used as directed this product is unlikely to present any hazards

2.2 Label elements

See section 16

2.3 Other hazards

This mixture does not contain any substances that are assessed to be PBT or vPvB.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Description of the mixture: Contains quaternary amine, stabilised when impregnated on wipe.
A mixture is of cationic surfactant at low concentration.

3.2 Hazardous Ingredients:

CAS No.	EC No.	% (W/W)	Name	Classification according to Regulation (EC) No. 1278/2008 (CLP) Raw Ingredients	Classification according to 67/548/EEC
7173-51-5	230-525-2	<0.5	N,N-didecyl-N-dimethylammonium chloride	.H226 Flammable liquid and vapour .H314 Causes severe burns & eye damage .H302 Harmful if swallowed .H400 Very toxic to aquatic life .H410 Very toxic to aquatic life with long lasting effects	.Flammable. .Harmful if swallowed. .Causes burns. .Very toxic to aquatic organisms. .Vapours may cause drowsiness and dizziness.
141-43-5	205-483-3	<0.6	2-Amino ethanol	.H302 Harmful if swallowed .H312 Harmful in contact with skin .H332 Harmful if inhaled .H314 Causes severe skin burns and eye damage. .H335 May cause respiratory irritation. .H412 Harmful to aquatic life with long lasting effects	

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation :

Move exposed person to fresh air. Keep person warm and at rest. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Get medical attention if adverse health effects persist or are severe.

Ingestion :

Wash out mouth with water. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway.

Skin contact :

Wash contaminated skin with soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Eye contact :

Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Inhalation :

Move person to fresh air at once. Rinse nose and mouth with water. Get medical attention if discomfort continues.

Ingestion :

NEVER MAKE AN UNCONCIOUS PERSON VOMIT OR DRINK FLUIDS! Rinse mouth thoroughly. Get medical attention immediately if any discomfort continues.

Skin :

Rinse immediately with plenty of water. Remove contaminated clothing. Contact physician if irritation persists.

Eyes :

Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring along these instructions.

See SECTION 11 for more detailed information on health effects and symptoms.

4.3 Indications of any immediate medical attention and special treatment needed

Skin contact

Prolonged contact may cause redness, irritation.

Eye contact :

Irritating and may cause redness and pain and may lead to some irritation experienced if liquid is in contact to eye.

Notes to physician :

No specific treatment. Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled. Show this Safety Data Sheet to the doctor in attendance.

Protection of first aid personnel

No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

SECTION 5: FIRE FIGHTING MEASURES (for bulk quantities)

5.1 Extinguishing media

Suitable :

This product is not flammable. Use water spray, fog or foam. Use an extinguishing agent suitable for the surrounding fire.

Not suitable : N/A

5.2 Special hazards arising from the substance or mixture

In a fire or if heated, a pressure increase will occur and the container may burst. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Hazardous thermal decomposition products

In combustion emits toxic fumes; may liberate carbon oxides and other toxic gases or vapours.

5.3 Advice for fire fighters

Special precautions for fire-fighters

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Keep run-off water out of sewers and water sources. Prevent for water control & accumulation.

Special protective equipment for fire-fighters

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency Procedures

No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through contaminated/spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see section 8). Beware of slippery floors and surfaces.

6.2 Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Collect and dispose as indicated in section 13.

6.3 Methods and materials for containment and cleaning up

Small spill :

Move packed product from spill area. If satisfactory, return to stock. For any disposal should be via a licensed waste disposal contractor or in accordance with national regulations.

Large spill :

Move containers from spill area. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

For Emergency contact information, see section 1, personal protection, see section 8. See section 11 for additional information on health hazards. For waste disposal, see section 13.

No further advice available

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Put on appropriate personal protective equipment (see section 8). Provide good ventilation. Wash hands and contaminated areas with water and soap before leaving the work site. Do not eat, drink or smoke when using the product. Empty containers retain product residue and can be hazardous. Do not reuse container.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

7.3 Specific end use

Identified use is detailed in Section 1.2

If use of product is going to be long or repeated wear suitable gloves (eg nitrile rubber)

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No information available.

8.2 Exposure controls

Hygiene measures :

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Ensure that there is sufficient ventilation of the area.

Eye and face protection (EN 166) : No special protective equipment is required; for continuous handling eye protection should be worn.

Skin and body protection (EN 14605): No special protective equipment is required.

Hand protection (EN374) : No special protective equipment is required; however for continuous handling gloves protection should be worn including for a long or repeated it is advised to wear suitable gloves (nitrile rubber).

Respiratory protection : None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information.

Environmental exposure controls

General advice : Personal protection; Specific barrier protection items to be used when handling items soiled with blood or body fluids are protective gloves, masks and eye protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	White non-woven substrate dosed with liquid.
Physical state	Liquid
Colour	Colourless
Odour	Characteristic
Odour threshold	Not applicable and/or not determined for the mixture
pH	Extracted liquid 10.9 – 11.2
Initial boiling point and boiling range	Not applicable and/or not determined for the mixture
Flash point	Not applicable and/or not determined for the mixture
Evaporation rate	Not applicable and/or not determined for the mixture
Flammability	Non -Flammable
Vapour pressure	Not applicable and/or not determined for the mixture
Vapour density	Not applicable and/or not determined for the mixture
Relative density	1.00 - 1.01 @ 20·C
Solubility	Highly soluble and miscible in water
Decomposition temperature	Not applicable and/or not determined for the mixture
Viscosity	Newtonian Liquid
Explosive properties	Not applicable and/or not determined for the mixture
Oxidising properties	The substance or mixture is not classified as oxidising.

9.2 Other information
Not applicable.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

The product is stable under normal conditions of storage and use.

10.3 Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid

Avoid exposure to high temperatures.

10.5 Incompatible materials

No specific; or groups of materials are likely to react to produce a hazardous situation.

10.6 Hazardous decomposition products

Decomposition products may include the following materials especially accelerated under fire hazards
. Carbon oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

General Information:

If used as directed this product is unlikely to present any hazard.

a) Acute toxicity

Oral

Based on irritation and cause of stomach pain, vomiting and diarrhoea; based on cause of respiratory hazards in relation to breathing, is possibly not met.

Dermal

Based on the available data on component substances, the classification criteria for acute dermal toxicity can cause hazards such as irritation. Repeated exposures may cause severe irritation, is possibly met.

Inhalation

Based on the available data on component substances, the classification criteria for acute inhalation toxicity to cause damage to organs through prolonged or repeated exposure cause the hazard, is possibly not met.

Other routes

No data.

(b) Skin corrosion/irritation

Based on the available data on component substances, the classification criteria to cause for skin irritation with prolonged contact, may be met.

(c) Serious eye damage/irritation

Based on the available data on component substances, the classification criteria of irritation to cause with direct contact eye, may be met.

(d) Respiratory or skin sensitization

Based on respiratory in take causes to organs through prolonged or repeated exposure exposure cause hazard, is possibly not met.

(e) Germ cell mutagenicity

Based on the available data on component substances, the classification criteria for germ cell mutagenicity, is not met.

(f) Carcinogenicity

Based on the available data on component substances, the classification criteria for carcinogenicity, is not met.

(g) Reproductive toxicity

Based on the available data on component substances, the classification criteria for reproductive toxicity, is not met.

(h) STOT-single exposure

Based on the available data on component substances, the classification criteria for specific target organ toxicity as a result of single exposure, is not met.

(i) STOT-repeated exposure

Based on the available data on component substances, the classification criteria for specific target organ toxicity as a result of repeated exposure, is not met.

(j) Aspiration hazard

Based on the available data on component substances, the classification criteria for aspiration hazard, is not met.

Other information

No applicable toxicity data. No known significant effects or critical hazards.

SECTION 12: ECOLOGICAL INFORMATION

12.0 Toxicity

12.1 Bio-concentration in aqueous organisms is low.

Reasoning : Not Hazardous to environment

Ecologically : Fish etc

The amount of mixture obtained from wipes would be negligible to cause any hazards unless it is disposed in large quantities into rivers, waters and environment. **See Section 13.**

12.2 Persistence and degradability

Results of PBT and vPvB assessment: The product does not contain any PBT or vPvB substances.

12.3 Bio accumulative potential

There is data on the degradability of ingredients in this product. The surfactant(s) contained in this preparation comply with Regulation Detergent 648/2004; the readily biodegradability resulting to >70%.

12.4 Mobility in soil

Information not available

12.5 Results of PBT and vPvB assessment

The product does not contain any PBT or vPvB substances at reportable levels

12.6 Other adverse effects

None known

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

General Information:

Do not discharge into drains, water courses or onto the ground.

Methods of disposal :

The generation of waste should be avoided or minimized wherever possible. Empty packs or liners may retain some product residues. This material and its pack must be disposed of in a safe way. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Product : Dispose of in accordance with local, state, and federal regulations.

Contaminated packaging : Dispose of in accordance with local, state, and federal regulations.

Hazardous waste : The classification of the product may meet the criteria for non- hazardous waste.

SECTION 14 : TRANSPORT INFORMATION

Land transport (ADR/ADN/RID) & Air transport (IATA)

- 14.1 **UN number** :Not dangerous goods
- 14.2 **UN proper shipping name** :Not dangerous goods
- 14.3 **Transport hazard class(es)** :Not dangerous goods
- 14.4 **Packing group** :Not dangerous goods
- 14.5 **Environmental hazards** :Not dangerous goods
- 14.6 **Special precautions for user** :Not dangerous goods

Sea transport (IMDG/IMO)

- 14.1 **UN number** :Not dangerous goods
- 14.2 **UN proper shipping name** :Not dangerous goods
- 14.3 **Transport hazard class(es)** :Not dangerous goods
- 14.4 **Packing group** :Not dangerous goods
- 14.5 **Environmental hazards** :Not dangerous goods
- 14.6 **UN proper shipping name** :Not dangerous goods

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulations

Environmental

Environmental Protection Act 1990 (and amendments)
Hazardous Waste Regulations 2005 (and amendments)

EU Regulations / Directives

Biocidal Product Regulation (BPR, Regulation (EU) 528/2012)
EC Directive 93/42/EEC (and amendments) concerning medical devices.
Regulation (EC) No 1907/2006 (and amendments) Registration, Evaluation, Authorisation and Restriction of Chemicals – REACH.
Regulation (EC) No 1272/2008 (and amendments) Classification, Labelling and Packaging Regulations (applies to ingredients only) – CLP.
Road Transport Regulations ADR.
COSHH – Control of Substances Hazardous to Health Regulations 2002 (as amended).

15.2 Chemical safety assessment

A chemical safety assessment has been carried out on the main ingredient of the product (propan-2-ol). Most of the information given in this document relates to the liquid component isopropanol (isopropyl alcohol), of which there is very little surplus in the product.

SECTION 16: OTHER INFORMATION

Labelling according to Regulation (EC) No. 1272/2008 (CLP)

Pictograms	Not Required	
Signal Word	Not Required	
Hazard Statements	Not Required	
Precautionary Statements (RECOMMENDED)	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P285	In case of inadequate ventilation wear respiratory protection.
	P302+P305+P306 P352	If on Contact: Wash with plenty of soap and water.
	P333 +P337+P315	If skin/eye irritation or rash occurs: Get immediate medical advice/attention.
	P304+P312	If inhaled: Call a POISON CENTRE or doctor if you feel unwell.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P363	Wash contaminated clothing before reuse.
	P501	Dispose of contents/container in accordance with local/regional/national regulation.

Other abbreviations

PBT : Persistent, bioaccumulative and toxic.

vPvB : Very persistent and very bioaccumulative.

Safety Data Sheet compiled according to Regulation (EC) No. 1907/2006, as amended

Notice to readers

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.