



SAFETY DATA SHEET
(conforms to Regulation EC No 1907/2006)

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

1.1 Product Identifier

Product Name Sani Cloth 70 Sterile
Product type Medical device
Product No. XPD24100

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

Identified uses Disinfection wipes for medical devices
Uses advised against Use around the eye area.

1.3 Details of the supplier of the safety data sheet

Supplier PDI International
 Aber Park
 Flint
 Flintshire
 CH6 5EX
 United Kingdom

 Tel: +44 (0) 1352 736700
 Fax: +44 (0) 1352 736701

Contact person: reg@nice-pak.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

Classification (EC (No) 1272/2008 Physical Flam. Liq – H225
 Health Eye Irrit. 2 – H319; STOT Single 3 – H336

2.2 Label elements

EC (No) 1272/2008



Irritant



Highly Flammable

Signal Word	Danger
Hazard Statements	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness
Precautionary Statements	P210 Keep away from heat/sparks/open flames/hot surfaces – No Smoking P305 IF IN EYES; Rinse cautiously for several minutes. Remove contact lenses, If present and easy to do. Continue rinsing P313 Get medical advice

2.3 Other hazards

This product does not contain any SVHCs above reportable levels

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Ingredient	Cas No	EC No	%
Propan-2-ol	67-63-0	200-661-7	60-80
Classification (EC1272/2008)	Flam. Liq.2 – H225 Eye Irrit. 2 – H319; STOT Single 3- H336		

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General

As product consists of individual wipes impregnated with relatively small amounts of liquid and contained in foil sachets, any harmful exposure should be fairly limited.

Ingestion

Fairly unlikely to be routes of exposure but if it should occur, rinse out mouth with water. Do not induce vomiting. Obtain medical advice

Skin contact

If skin contact is prolonged, redness or irritation may be experienced. Wash affected areas with soap and water. If effects persist seek medical advice.

Eye contact

Wash out eye cautiously with copious amounts of water, holding the eye lid open. If any irritation persists, seek medical advice.

4.2 Most Important symptoms and effects, both acute and delayed

General information

As the liquid is held in a non woven substrate and the wipes are packed singly in foil sachets, any harmful effects should be minimal. Nonetheless if any effects persist, medical advice should be obtained

Inhalation

Due to small amounts of dosed liquid involved inadvertent effects should be minimal. If deliberately inhaled, headache and nausea may result.

Skin contact

Prolonged or repeated skin contact may result in redness or irritation

Eye contact

May cause irritation to eyes

4.3 Indication of any immediate medical attention and special treatment need

No recommendation given. If any effects persist obtain medical advice.

SECTION 5: FIRE FIGHTING MEASURES (for bulk quantities)

5.1 Extinguishing media

Use water spray, Alcohol resistant foam, Carbon dioxide

Unsuitable media: non alcohol resistant foam

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Combustion may liberate carbon oxides

5.3 Advice for fire fighters

Packets close to fire should be removed if it can be done without risk.

Prevent any run off water from extinguishing media entering the sewers or water courses.

Wear self contained breathing apparatus and full protective clothing.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Pads are singly packed in foil sachets with no free liquid available therefore it is very unlikely that any emergency procedures should be necessary.

In the unlikely event of handling bulk unwrapped pads, protective gloves and eye protection should be worn.

6.2 Environmental precautions

Refer to 6.1

6.3 Methods and materials for containment and cleaning up.

Wrapped product should be picked up and, if possible, returned to stock.
If product is unwrapped and/or unusable it should be swept up and placed in a suitable container eg polyethylene drum, for disposal as hazardous waste.

6.4 Reference to other sections

Wear protective clothing as described in Section 8 of this safety data sheet. Collect and dispose of any spillage as described in Section 11.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid direct contact with bulk unwrapped pads.
As pads are wrapped singly in foil sachets necessary precautions are minimal.
Wash hands after use.

7.2 Conditions for safe storage, including any incompatibilities

Ideally pads should be stored in a cool, dry area avoiding extremes of temperature. Store away from naked flames.
Keep away from food, drink and animal feed stuff.

7.3 Specific end use

Identified use is detailed in Section 1.2

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Ingredient

Propan-2-ol WEL: TWA (8hrs) 400ppm (999mg/m³) STEL (15 mins) 500ppm (1250mg/m³)

WEL = Workplace Exposure Limit

8.2 Exposure controls

Product consists of singly wrapped, liquid dosed pads. There is no available free liquid.
Pads are single use.

Hand protection

If use is continuous or prolonged, butyl or nitrile gloves should be worn.

Eye protection

Not necessary in normal use

Respiratory equipment

Not necessary in normal use

Hygiene measures

Wash hands after use

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	White non-woven substrate dosed with liquid
Colour	White
Odour	Alcohol

Properties of the liquid:

Water solubility	soluble
Relative Density	0.872-0.883

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reacts with strong oxidising agents and acids

10.2 Chemical stability

Stable under normal conditions of use

10.3 Possibility of hazardous reactions

Strong oxidising agents

10.4 Conditions to avoid

Avoid naked flames

10.5 Incompatible materials

Strong oxidisers, strong acids, alkali metals

10.6 Hazardous decomposition products

Combustion may liberate carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

No toxicological testing has been carried out on the product itself or on the dosed liquid. The following information is based on that of the main ingredient of the liquid i.e. propan-2-ol.

11.1 Information on toxicological effects

Acute toxicity (Oral LD50)	>2000mg/kg Rat
Acute Toxicity (Dermal LD50)	>2000mg/kg Rabbit
Acute Toxicity (Inhalation LC50)	>20mg/l (vapours) Rat 4 hours
	Not irritating
Serious eye damage/Irritation	Irritating
	Not sensitising
	Not a carcinogen

General

Pads are single use. Level of liquid on each pad is low therefore any likelihood of a toxicological effect would be minimal if instructions for use are followed.

Skin Contact

In the unlikely event of continuous or prolonged use, irritation and redness of the skin may result

Eye Contact

If liquid from the pad comes in direct contact with the eye, some irritation may be experienced.

Main routes of exposure

Continuous skin contact. Direct contact of the dosed liquid with the eyes.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:

No direct testing has been carried out on the finished product but based on the ingredients, no harmful effects on the environment would be expected.

The following information is based on that obtained on testing of the main ingredient (Propan-2-ol)

12.1 Toxicity

Acute Toxicity – Fish	LC50 48 hours > 100mg/l <i>Leuciscus idus</i> (Golden orfe)
Acute toxicity – Aquatic Invertebrates	EC50 48 hours > 100mg/l <i>Daphnia magna</i>
Acute toxicity – Aquatic plants	EC50 72 hours > 100mg/l <i>Scenedesmus subspicatus</i>

12.2 Persistence and degradability

12.3 Bioaccumulative potential

Does not bioaccumulate significantly

12.4 Mobility in soil

The liquid is water soluble; however the amounts of liquid involved will not present any problems.

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

Dispose of discarded pads and packs according to local authority requirements

SECTION 14: TRANSPORT INFORMATION

Packed product is not classified for European road transport under ADR 2009 or ADR 2011 with reference to SP216

SECTION 15 REGULATORY INFORMATION

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

Environmental

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

EU Regulations/Directives

Regulation (EC) No 1907/2006 (and amendments) Registration, Evaluation, Authorisation and Restriction of Chemicals
EC Directive 93/42/EEC (and amendments) concerning medical devices.
Regulation (EC) No 1272/2008 (and amendments) Classification, Labelling and Packaging Regulations
(applies to ingredients only)
Road Transport Regulations ADR 2009 and ADR 2011.

15.2 Chemical Safety Assessment

A chemical safety assessment has been carried out on the main ingredient of the product (propan-2-ol)

SECTION 16: OTHER INFORMATION

Revision Date 29th July 2015
Revision Issue No 3

Hazard Statements/Risk Phrases from ingredients in SECTION 3

Hazard Statements	H225	Highly flammable liquid and vapour
	H319	Causes serious eye irritation
	H336	May cause drowsiness or dizziness