



SAFETY DATA SHEET

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

Sani-Cloth CHG 2%

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

1.1 Product Identifier

Product Name Sani-Cloth CHG 2%

Product No. XP00220
XP00294
XP00314

Product type Medical device

Ref: 4794

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

Identified uses Disinfectant for Medical Devices

Uses advised against Use around the eye area.

1.3 Details of the supplier of the safety data sheet

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

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 Classification of the substance or mixture

Repeated Exposure may cause skin dryness or cracking	- HUH066
Flammable Liquid 2	- H225
Serious Eye Irrit. 2	- H319
May cause drowsiness or dizziness	- H336, STOT Single 3
Aquatic Acute Category 1	- H400
Aquatic Chronic Category 1	- H410

2.2 Label elements

SYMBOLS			
Signal Word	DANGER		
Hazard Statements			
H225	Highly flammable liquid and vapour		
H319	Causes serious eye irritation		
H336	May cause drowsiness or dizziness		
H410	Very toxic to aquatic life with long lasting effects.		
HUH066	Repeated exposure may cause skin dryness or cracking		
Precautionary Statements			
P273	Avoid release to the environment		
P280	Wear protective gloves/protective clothing		
P210	Keep away from heat/sparks/open flames/hot surfaces – No Smoking		
P235	Keep Cool.		
P302+P350	IF ON SKIN: Wash with plenty of soap and water.		
P305+P351+P338+P337+P313	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses; if present and easy to do so. Continue rinsing. If eye irritation persists: Get medical advice/attention.		
P391	Collect Spillage		
P501	Dispose of contents/container in accordance with local/regional/national regulation.		

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

3.2 Mixtures

Description of the mixture: Contains dual quaternary amines, stabilised when impregnated on wipe.

A mixture of Propanol-2-ol and Chlorhexidine Digluconate.

Hazardous ingredients:

Propan-2-ol CAS number: 67-63-0 EC number: 200-661-7 REACH registration number:	70%
Classification Flammable Liquid 2 – H225 Eye Irrit 2 – H319 May cause drowsiness or dizziness - H336, STOT Single 3 Repeated exposure may cause skin dryness or cracking – HUH066	
Chlorhexidine Digluconate CAS number: 18472-51-0 EC number: 242-354-0 REACH registration number:	<2.5%
Classification Eye Irrit 2 – H319 Aquatic Acute 1 – H400 (M=10) Aquatic Chronic 1 – H410 (M=10)	

The Full text for all R-Phrases and Hazards Statements are stated in Section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General :

As product consists of sachets of applicator material impregnated with very small amounts of liquid and contained in boxes, any harmful exposure should be limited.

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 :

If skin contact is prolonged, redness or irritation may be experienced. Wash affected areas with soap and water. If effects persist seek medical advice. In the event of any complaints or symptoms, avoid further exposure.

Eye contact :

Wash out eye cautiously with copious amounts of water, holding the eye lid open, continue for 15 minutes. Remove contact lenses if present and easy to do so – continue rinsing.
If any irritation persists, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Inhalation :

Unlikely to occur unless accidentally during use wipe may cause signs of inhalation. Get medical attention if discomfort continues.

Ingestion :

Unlikely to be a route of exposure but should it occur rinse out mouth with water. Do not induce vomiting. Obtain medical advice.

Skin :

Advised to wear gloves during repeated use. If irritation occurs rinse immediately with plenty of water. Remove contaminated clothing. Contact physician if irritation persists.

Eyes :

Wash out eye cautiously with copious amounts of water, holding the eye lid open, continue for 15 minutes. Remove contact lenses if present and easy to do so – continue rinsing. If any irritation persists, seek medical advice.

Notes to physician :

No specific treatment. Treat symptomatically. Contact poison treatment specialist immediately if unconsciousness appears with a user due to 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.

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

Suitable : This product is flammable. Use water spray, fog or foam, dry chemical, CO₂. Use an extinguishing agent suitable for the surrounding fire.

Not suitable : Do not use a solid water stream as it may scatter and spread fire.

5.2 Special hazards arising from the substance or mixture

Product is highly flammable. Irritating to eyes. If there is a spillage or a risk of product splashing wear protective gloves/protective clothing/eye protection. Collect any spillage in a suitable container for disposal. 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

Containers close to fire should be removed if it can be done so without risk. Prevent any run off water from extinguishing media entering the sewer 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

Contain spillage in suitable container(s) for examination and possible return to stock.
Unless packaging is broken, no eye/skin protection should be required.
If packaging is broken and continuous handling necessary, then approved eye protection must be worn and gloves/protective clothing are recommended.
If disposal is required, local/national regulations/guidelines should be adhered to.
Product must be disposed of as Hazardous Waste.
Avoid breathing any vapour or mist.
Wear appropriate personal protective equipment (see section 8).

6.2 Environmental precautions

Avoid dispersal of spilled material from entering the sewers or water courses.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Use in well ventilated areas.
Avoid breathing vapours.
Wear protective gloves when using the wipe.

7.2 Conditions for safe storage, including any incompatibilities

Store product in accordance with local regulations. Store in original packs protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10) and food and drink. Keep canisters tightly closed and sealed until ready for use. Canisters that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

Storage temperature : 0·C to 25·C

7.3 Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Components with workplace control parameters

Ingredient

Propan-2-ol WEL: Long term exposure limit (8hrs) 400ppm (999mg/m³)
Short term exposure limit (15 mins) 500ppm (1250mg/m³)

WEL = Workplace Exposure Limit

8.2 Exposure Controls

Hand protection

Protection should be used for prolonged or repeated skin contact, use suitable protective gloves. Disposable gloves are recommended, butyl or nitrile disposable gloves. Prolonged contact may cause skin to dry and possibly cause irritation.

Respiratory protection/equipment

Not necessary in normal use.

Eye protection.

Not necessary in normal use.

Hygiene Measures

When in contact do not eat, drink or smoke. Good personal hygiene is necessary. Wash hands and contaminated areas with water and soap before leaving the work site. Use appropriate cream to prevent drying of skin.

Environmental Exposures Controls

Avoid release to the environment. Users should be aware of environmental considerations and their duties under environmental protection act. Further information may be found on Government websites: www.dti.gov.uk/access/index/htm and www.envirowise.gov.uk.

Derived No-Effect Levels' (DNEL's) and Predicted No-Effect Concentrations' (PNEC's)

DNELS No information available.

PNECS No information available.

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.

Eye and face protection (EN 166) : No special protective equipment is required.

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

Hand protection (EN374) : No special protective equipment is required.

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

Environmental exposure controls

General advice : Consider the provision of containment around storage vessels.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.0 Information on basic physical and chemical properties

Appearance	White non-woven substrate dosed with liquid
Physical state	Clear colourless liquid provided as:
Colour	Liquid adsorbed on suitable wipes
Odour	Alcoholic
Odour threshold	Not applicable and/or not determined for the mixture
pH	Not applicable and/or not determined for the mixture
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	Flammable
Explosion limits	Not applicable and/or not determined for the mixture
Upper	
Lower	
Vapour pressure	Not applicable and/or not determined for the mixture
Vapour density	Not applicable and/or not determined for the mixture
Relative density	0.872 - 0.883 @ 20°C
Solubility	Highly soluble and miscible in water

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Reacts with strong oxidising agents and acids.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

Avoid exposure to heat, sparks, naked flames and other sources of ignition.

10.5 Incompatible materials

Strong oxidising agents and acids.

10.6 Hazardous decomposition products

Combustion may liberate carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

General Information

a) Acute toxicity

Oral

Ingestion of liquid may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

Dermal

Repeated exposure may cause skin dryness or cracking.

Inhalation

Inhalation of high concentrations of vapour or mist may cause irritation to the respiratory tract, headaches, dizziness, nausea, vomiting.

Other routes

No data.

(b) Skin corrosion/irritation

Repeated exposure may cause skin dryness or cracking.

(c) Serious eye damage/irritation

Causes serious eye irritation.

(d) Respiratory or skin sensitization

Vapours may cause drowsiness or dizziness.

(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

12.1 Toxicity

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)

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>

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.

12.2 Persistence and degradability

The product does not contain any PBT or vPvB substances.

12.3 Bioaccumulative potential

There is data on the degradability of this product. The surfactant(s) contained in this preparation comply with Detergent Regulation (EC) 648/2004; and readily biodegradability resulting to >90%.

12.4 Mobility in soil

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

12.5 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 containers or liners may retain some product residues. This material and its container 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. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Packaging is recyclable. Wash out containers with water before disposal.

Product : Do not flush to sanitary sewer.

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

Hazardous waste : The classification of the product meets the criteria for hazardous waste.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN number : 3175

14.2 UN proper shipping name : Solids containing flammable liquid,
n.o.s. (Isopropanol Alcohol)

14.3 Transport hazard class(es) : Class 4.1

14.4 Packing group : II

NB Limited quantity exemptions apply

14.5 Environmental hazards : Marine pollutant

14.6 Special precautions for user : DGN required for transport by Sea (IMDG/IMO)
and / or Air (IATA)

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

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