

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Mixture
Trade name	: PREVANTICS® 2% CHG SWAB - DEVICE
Product code	: ISW4040, ISW4050, XP00220, XP00314
Other means of identification	: 5398 solution

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category	: Professional use
Use of the substance/mixture	: Disinfection of Medical Devices

1.2.2. Uses advised against

Restrictions on use	: For external use only
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1.3. Details of the supplier of the safety data sheet

PDI
PDI
PDI EMEA LTD, Pywell Road, Willowbrook East Industrial Estate
NN17 5XJ Corby – Northants
United Kingdom
T +44 (0)8081 697 945
contact@PDI-EMEA.com - <https://pdi-intl.com>

1.4. Emergency telephone number

Emergency number	: +44 (0) 8081 697 945
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 2	H225
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity – Single exposure, Category 3, Narcosis	H336
Hazardous to the aquatic environment – Chronic Hazard, Category 2	H411

Full text of H- and EUH-statements: see section 16

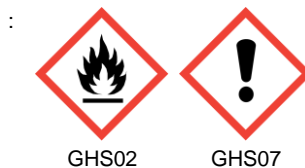
Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. May cause drowsiness or dizziness. Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)	: Danger
Contains	: PROPAN-2-OL; CHLORHEXIDINE DIGLUCONATE.
Hazard statements (CLP)	: H225 - Highly flammable liquid and vapour. H319 - Causes serious eye irritation. H336 - May cause drowsiness or dizziness.
Precautionary statements (CLP)	: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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P280 - Wear protective gloves.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for packages of a capacity of 125ml or less

Hazard pictograms (CLP) :



GHS02

GHS07

Signal word (CLP) :

Danger

Hazardous ingredients :

PROPAN-2-OL; CHLORHEXIDINE DIGLUCONATE.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
PROPAN-2-OL substance with national workplace exposure limit(s) (AT, BE, BG, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, LT, LV, PL, PT, RO, SE, SI, SK, IS, NO, MK, CH)	CAS-No.: 67-63-0 EC-No.: 200-661-7 EC Index-No.: 603-117-00-0 REACH-no: 01-2119457558-25	≥ 70	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
CHLORHEXIDINE DIGLUCONATE.	CAS-No.: 18472-51-0 EC-No.: 242-354-0 REACH-no: 01-211994658-22	< 4	Eye Dam. 1, H318 STOT RE 1, H372 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Rinse skin with water/shower. Take off immediately all contaminated clothing.
First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : May cause drowsiness or dizziness.
Symptoms/effects after eye contact : Eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Ground/bond container and receiving equipment.
Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

PROPAN-2-OL (67-63-0)	
United Kingdom - Occupational Exposure Limits	
Local name	Propan-2-ol
WEL TWA (OEL TWA) [1]	999 mg/m ³
WEL TWA (OEL TWA) [2]	400 ppm
WEL STEL (OEL STEL)	1250 mg/m ³
WEL STEL (OEL STEL) [ppm]	500 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

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8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Appearance	: Liquid dosed onto swabstick.
Odour	: Alcoholic.
Odour threshold	: Not available
Melting point	: No data available.
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Highly flammable liquid and vapour.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: < 23 °C
Auto-ignition temperature	: No data available.
Decomposition temperature	: Not available
pH	: Approx. 7
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: No data available.
Relative vapour density at 20°C	: No data available.
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

PROPAN-2-OL (67-63-0)

LD50 oral rat	5840 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity)
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CHLORHEXIDINE DIGLUCONATE. (18472-51-0)

LD50 dermal rabbit	> 5000 mg/kg bodyweight Animal: rabbit, Guideline: other:
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Skin corrosion/irritation : Not classified
pH: Approx. 7

CHLORHEXIDINE DIGLUCONATE. (18472-51-0)

pH	5.91 Temp.: 20 °C Concentration: 200 g/L
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Serious eye damage/irritation : Causes serious eye irritation.
pH: Approx. 7

CHLORHEXIDINE DIGLUCONATE. (18472-51-0)

pH	5.91 Temp.: 20 °C Concentration: 200 g/L
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Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : May cause drowsiness or dizziness.

PROPAN-2-OL (67-63-0)

STOT-single exposure	May cause drowsiness or dizziness.
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STOT-repeated exposure : Not classified

CHLORHEXIDINE DIGLUCONATE. (18472-51-0)

LOAEL (oral, rat, 90 days)	8.88 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 452 (Chronic Toxicity Studies)
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STOT-repeated exposure	Causes damage to organs through prolonged or repeated exposure.
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Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Toxic to aquatic life with long lasting effects.

Not rapidly degradable

CHLORHEXIDINE DIGLUCONATE. (18472-51-0)

LC50 - Fish [1]	2.08 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 - Crustacea [1]	0.087 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	0.0187 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
EC50 72h - Algae [2]	0.0101 mg/l Test organisms (species): Raphidocelis subcapitata (previous names: Pseudokirchneriella subcapitata, Selenastrum capricornutum)
NOEC chronic fish	0.065 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '28 d'

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Additional information : Flammable vapours may accumulate in the container.

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HP Code	: HP3 - "Flammable:" – flammable liquid waste: liquid waste having a flash point below 60 °C or waste gas oil, diesel and light heating oils having a flash point > 55 °C and ≤ 75 °C; – flammable pyrophoric liquid and solid waste: solid or liquid waste which, even in small quantities, is liable to ignite within five minutes after coming into contact with air; – flammable solid waste: solid waste which is readily combustible or may cause or contribute to fire through friction; – flammable gaseous waste: gaseous waste which is flammable in air at 20 °C and a standard pressure of 101.3 kPa; – water reactive waste: waste which, in contact with water, emits flammable gases in dangerous quantities; – other flammable waste: flammable aerosols, flammable self-heating waste, flammable organic peroxides and flammable self-reactive waste. HP5 - "Specific Target Organ Toxicity (STOT)/Aspiration Toxicity:" waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration. HP4 - "Irritant – skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye. HP14 - "Ecotoxic:" waste which presents or may present immediate or delayed risks for one or more sectors of the environment
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SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

ADR:	Not subject to ADR under SP 216 NOT SUBJECT
IATA:	Not subject to IATA under SP A46 NOT SUBJECT
IMDG:	Not subject to IMDG under SP 216 NOT SUBJECT
RID:	Not subject to RID under SP 216

14.1. UN number or ID number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable
:



IMDG

Transport hazard class(es) (IMDG) : Not applicable
:



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IATA

Transport hazard class(es) (IATA) : Not applicable



RID

Transport hazard class(es) (RID) : Not applicable



14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : Yes

Marine pollutant : Yes

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

No data available

Air transport

No data available

Rail transport

No data available

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

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POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes

Section	Changed item	Change	Comments
	Revision date	Modified	
	Supersedes version of	Modified	

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level

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Abbreviations and acronyms:

NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Narcosis

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU - PDI