

ANTI-MICROBIAL GAUZE KITS

Safety Data Sheet

According to Regulation (EC) No 1907/2006, Annex II, amended by COMMISSION REGULATION (EU) 2020/878
SDS Record Number: CSSS-TCO-010-162922

Issue date: 02-07-2024 Revision date: 28-10-2025 Version 2.0

Section 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Identification on the label/Trade name: ANTI-MICROBIAL GAUZE ONLY KITS
Additional identification: Nanoform is NOT covered by this SDS.
UFI: Not applicable.
Identification of the product: See section 3
Index Number: See section 3
REACH registration No.: See section 3

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

1.2.1 Identified uses:

Antimicrobial Gauze for use with PICO and RENASYS NPWT Systems 15.24cm x 17.15cm / 6in x 6.75in.

1.2.2 Uses advised against:

Not available.

1.3 Details of the supplier of the safety data sheet:

Supplier(Only representative): Smith & Nephew Operation B.V.
Address: Bloemlaan 2
2132 NP Hoofddorp
Netherlands

Supplier(Manufacturer): Smith & Nephew Medical Ltd
Address: 101 Hessle Road
Hull
HU3 2BN
Contact web address (all markets) <https://www.smith-nephew.com/en/contact-us#general>
Telephone: 01482 222200

1.4 Emergency telephone Number:

999 (UK) or 112 (EU) - 24 Hours
+1-703-527-3887 (Chemtrec 24 Hours)

Section 2 Hazards identification

2.1 Classification of the substance or mixture:

2.1.1 Classification of the mixture:

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

REGULATION (EC) No 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

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2.2 Label elements:

Hazard pictogram(s):	No hazard pictogram is used.
Signal word:	No signal word is used.
Hazard statement(s):	Not applicable.
Precautionary statement(s):	Not applicable.
Supplemental Hazard information (EU)	Not applicable.

2.3 Other hazards:

The mixture does not contain PBT/vPvB substance.

The mixture does not contain endocrine disruptor.

Section 3 Composition/information on ingredients

Substance/Mixture: Mixture

Ingredient(s):

Chemical Name	Registration No.	CAS No.	EC No.	Concentration	Classification	Specific Concentration limits, M-Factors, Acute Toxicity Estimates (ATE)
Poly(Hexamethylene biguanide) hydrochloride (PHMB)	N/A	N/A	N/A	0.20%	Not available	N/A

100% of the mixture consists of component (s) of unknown toxicity.

100% of components with unknown hazards to the aquatic environment.

Section 4 First aid measures

4.1 Description of first aid measures:

In all cases of doubt, or when symptoms persist, seek medical attention.

4.1.1 In case of inhalation:

If there is difficulty in breathing, give oxygen. Seek medical attention if symptoms persist.

4.1.2 In case of skin contact:

Wash skin thoroughly with soap and water. Obtain medical attention if blistering occurs or redness persists.

4.1.3 In case of eyes contact:

Contact may cause slight transient irritation. Immediately flood the eye with plenty of water for at least 15 minutes, holding the eye open. Obtain medical attention if soreness or redness persists.

4.1.4 In case of ingestion:

Do not induce vomiting. Have victim drink 1-3 glasses of water to dilute stomach contents. Never administer anything by mouth if a victim is losing consciousness, is unconscious or is convulsing. Obtain medical attention immediately.

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

The product is not classified as harmful to human health effect.

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

Symptomatic treatment.

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Section 5 Firefighting measures

5.1 Extinguishing media:

Suitable extinguishing media:

Use extinguishing agents appropriate for surrounding fire.

Unsuitable extinguishing media:

Not available.

5.2 Special hazards arising from the substance or mixture

Combustion may produce carbon monoxide, carbon dioxide and hydrogen chloride.

5.3 Advice for firefighters:

Wear self-contained breathing apparatus for firefighting if necessary.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel:

Use personal protective equipment. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.1.2 For emergency responders:

Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.

6.2 Environmental precautions:

Prevent the material from entering drains or watercourses. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up:

This product may be collected by carefully scooping into a pan, paper towel or other absorbent material. Transfer into suitable containers for recovery or disposal.

6.4 Reference to other sections:

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

Section 7 Handling and storage

7.1 Precautions for safe handling:

7.1.1 Protective measures:

Ensure good ventilation/exhaustion at the workplace. Wash thoroughly after handling.

7.1.2 Advice on general occupational hygiene:

Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities:

Keep container tightly closed when not in use. Storage area should be: Cool, Dry, Well-ventilated.

7.3 Specific end use(s):

Not available.

Section 8 Exposure controls/personal protection

8.1 Control parameters:

8.1.1 Occupational exposure limits:

Not available.

8.1.2 Additional exposure limits under the conditions of use:

Not available.

8.1.3 DNEL/DMEL and PNEC-Values:

Not available.

8.2 Exposure controls:

8.2.1 Appropriate engineering controls:

Use adequate ventilation to keep airborne concentrations low.

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8.2.2 Individual protection measures, such as personal protective equipment:

Eye/face protection: No special requirements.

Skin protection

Hand protection: No special requirements.

Body protection: No special requirements. Normal work wear.

Respiratory protection: No special requirements.

Thermal hazards: Wear suitable protective clothing to prevent heat.

8.2.3 Environmental exposure controls:

Avoid discharge into the environment. Dispose of rinse water in accordance with local and national regulations

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Physical state:	Non-woven cloth / sponge saturated with liquid (0.2% PHMB in water)
Colour:	Colorless - Pale Yellow
Odour:	Odorless
Odour threshold:	Not available
pH:	5-5.5 at 10% w/w in water
Melting point/freezing point (°C):	Not available
Boiling point or initial boiling point and boiling range (°C):	102°C
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (gas, liquid, solid):	Not available
Ignition temperature (°C):	Not available
Lower and upper explosion limit:	Not available
Vapour pressure (20°C):	Not available
Relative vapour density:	Not available
Relative Density (g/cm³):	~1.04
Bulk density (kg/m³):	Not available
Solubility in water (g/l, 20°C):	Liquid ingredients completely soluble
Solubility in other polar and non-polar solvents (g/l, 20°C):	Not available
Partition coefficient n-octanol/water (log Po/w, 20°C):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Kinematic viscosity (mm²/s):	Not available
Particle characteristics:	Not available
Explosive properties:	Not available
Oxidising properties:	Not available

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9.2. Other information:

Fat solubility(solvent- oil to be specified)	Not available
etc:	
Surface tension:	Not available
Dissociation constant in water(pKa):	Not available
Oxidation-reduction Potential:	Not available

Section 10 Stability and Reactivity

10.1 Reactivity:

The substance is stable under normal storage and handling conditions.

10.2 Chemical stability:

Stable at room temperature in closed containers under normal storage and handling conditions.

10.3 Possibility of hazardous reactions:

No dangerous reactions known.

10.4 Conditions to avoid:

Incompatible materials. Heat. High temperatures.

10.5 Incompatible materials:

Strong oxidizing agents.

10.6 Hazardous decomposition products:

Carbon monoxide, carbon dioxide and hydrogen chloride.

Section 11 Toxicological information

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

Acute toxicity:

LD50(Oral, Rat):	Not available
LD50(Dermal, Rabbit):	Not available
LC50(Inhalation, Rat):	Not available

Skin corrosion/irritation:

Not classified

Serious eye damage/irritation:

Not classified

Respiratory or skin sensitization:

Not classified

Germ cell mutagenicity:

Not classified

Carcinogenicity:

Not classified

Reproductive toxicity:

Not classified

STOT- single exposure:

Not classified

STOT-repeated exposure:

Not classified

Aspiration hazard:

Not classified

11.2 Information on other hazards

Endocrine disrupting properties

The mixture does not contain endocrine disruptor.

Other information

Not applicable

Section 12 Ecological information

12.1 Toxicity:

Acute (short-term) toxicity:

LC50(96h, Fish):	Not available
LC50(48h, Crustacea):	Not available
EC50(72h, Algae/aquatic plants):	Not available

Chronic (long-term) toxicity:

NOEC(Fish):	Not available
NOEC(Crustacea):	Not available
EC50(Algae/aquatic plants):	Not available

12.2 Persistence and degradability:

Not available.

12.3 Bioaccumulative potential:

Not available.

12.4 Mobility in soil:

Not available.

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12.5 Results of PBT and vPvB assessment: The mixture does not contain PBT / vPvB substance.

12.6 Endocrine disrupting properties: The mixture does not contain endocrine disruptor.

12.7 Other adverse effects: Not available.

12.8 Additional information Not available.

Section 13 Disposal considerations

13.1 Waste treatment methods: The material should be disposed of by incineration in a chemical incinerator in compliance with national and regional requirements.

Section 14 Transport Information

	Land transport (ADR/RID)	Inland waterways (ADN)	Sea transport (IMDG)	Air transport (ICAO/IATA)
14. 1 UN number or ID number	Not regulated	Not regulated	Not regulated	Not regulated
14.2 UN proper shipping name	Not regulated	Not regulated	Not regulated	Not regulated
14.3 Transport hazard class(es)	Not regulated	Not regulated	Not regulated	Not regulated
14.4 Packing group	Not regulated	Not regulated	Not regulated	Not regulated
14.5 Environmental hazards	No	No	No	No
14.6 Special precautions for user	See section 2.2	See section 2.2	See section 2.2	See section 2.2
14.7 Maritime transport in bulk according to IMO instruments	Not regulated	Not regulated	Not regulated	Not regulated

Section 15 Regulatory information

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

Relevant information regarding authorization: Not applicable.

Relevant information regarding restriction: Not applicable.

Other EU regulations: Employment restrictions concerning young person must be observed.

Other National regulations: For use only by technically qualified individuals.

Not applicable

15.2 Chemical Safety Assessment

YES

NO

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Section 16 Other information

16.1 Indication of changes:

Version 1.0 Amended by (EU) 2020/878, (EU) 2023/707

16.2 Abbreviations and acronyms:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: Code international maritime dangerous goods code

ICAO: International Civil Aviation Organization

IATA: International Air Transport Association

UFI: Unique Formula Identifier

LC50: median lethal concentration

EC50: The effective concentration of substance that causes 50% of the maximum response.

NOEC: No Observed Effect Concentration

DNEL: derived no-effect level

PNEC: predicted no-effect concentration

16.3 Key literature references and sources for data

ECHA Registered substances data

16.4 Training instructions:

Not applicable.

16.5 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

16.6 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees.

This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

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