

SAFETY DATA SHEET

Clinell Alcoholic 2% Chlorhexidine Wipes

According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 22nd May 2023

Version Number: 13

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

1.1 Product Identifier

Product Name Clinell Alcoholic 2% Chlorhexidine Wipes for Medical Devices

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

Identified Use Disinfection of non-invasive medical devices

1.3 Details of the supplier of the safety data sheet

Supplier GAMA Healthcare Ltd
The Maylands Building
Maylands Avenue, Hemel Hempstead Industrial Estate
Hemel Hempstead
HP2 7TG
United Kingdom
Tel: +44 (0) 207 993 0030
Email: info@gamahealthcare.com

Authorised Representative Emergo Europe BV
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
Tel: +31 (0) 70 345 8570

1.4 Emergency telephone number

Tel: +44 (0) 207 9930 035
Monday-Thursday, 9-5pm; Friday, 9-4pm (excluding UK bank holidays)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008 Flam. Liq. 2: H225, Eye irrit. 2: H319

2.2 Label Elements



Signal Word



Danger

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Hazard statements:	H225: Highly flammable liquid and vapour H319: Causes serious eye irritation
Precautionary statements:	P403 + P235: Store in a well-ventilated place. Keep cool. P305 + P351 + P338: IF IN EYES: Rinse cautiously for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.

2.3 Other hazards Not applicable

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Declarable components	Conc. (%)	EC No.	CAS No.	Classification of individual components under Regulation (EC) No 1272/2008	Specific concentration limits according to Regulation (EC) No 1272/2008
Propan-2-ol	68-75	200-661-7	67-63-0	Flam Liq. 2: H225, Eye Irrit. 2: H319, STOT SE 3: H336.	-
Chlorhexidine digluconate*	2-2.5	242-354-0	18472-51-0	Eye Dam. 1: H318, Aquatic Acute 1: H400; Aquatic Chronic: H410	-

Other components: Water – 22.5 – 30%

* EU name: D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1).

Full list of Hazard Statements is available in Section 16

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation

If adverse effects (e.g. irritation of the airways, drowsiness, or dizziness) occur, remove patient from exposure and give fresh air and rest. Obtain prompt medical attention.

Skin

For industrial use of the liquid, remove contaminated clothing and wash affected area with soap and water. If irritation occurs, seek medical attention. Launder contaminated clothing before re-use.

Eye

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In case of contact with eyes irrigate with water, occasionally lifting eyelids. Seek prompt medical attention for signs of irritation.

Ingestion

For industrial use of the liquid, if swallowed, wash out mouth thoroughly and give water to drink. Seek medical attention if significant amounts (e.g. more than a teaspoonful) are ingested, or for any symptoms occurring after ingestion. Do not induce vomiting, unless instructed by medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

May cause eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms as they occur.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Water spray, carbon dioxide, dry chemical and foam are compatible with the product. Remove containers from fire or cool them with water.

5.2 Special hazards arising from the substance or mixture

The liquid is expected to be flammable. Vapour may produce explosive mixture in air in confined space.

When heated sufficiently, product may decompose to form smoke and toxic fumes, gases or vapours, including oxides of carbon and nitrogen, hydrogen chloride, ammonia, and small amounts of p-chloroaniline.

5.3 Advice for firefighters

Fire fighters should wear an approved self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For industrial spills of the liquid, ensure full personal protection is worn (see Section 8). Ensure all sources of ignition are extinguished. Keep unauthorised personnel from the spillage area.

6.2 Environmental precautions

Prevent leakage of product into water-courses or drainage system by diking with sand or other absorbent material. Contact authorities, water company, and waste-water treatment plant as appropriate if significant contamination occurs.

6.3 Methods and material for containment and cleaning up

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Stop the source of leak or release. Clean up spill as soon as possible using non-sparking equipment and machinery. Small spills can be mopped up with dry cloth. Collect larger spill using techniques such as sorbent materials or pumping. Place material in suitable container for disposal in accordance with local and national regulations. Wash contaminated surfaces with water and collect washings for safe disposal. Follow prescribed procedures for responding to large spills and reporting to appropriate authorities.

6.4 Reference to other sections

For recommended personal protective equipment see Section 8.
For disposal considerations see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For industrial use of the liquid, avoid contact with skin and eyes. Remove sources of ignition. Wear protective clothing as in Section 8. Good general ventilation is recommended.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well-ventilated place, away from direct sunlight. Do not allow to freeze. Keep container closed when not in use.

7.3 Specific end use

Identified in Section 1.2

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters

EU Limit: None

National Limit:

	Limit Value – Eight hours		Limit value – Short term*	
	ppm	mg/m ³	ppm	mg/m ³
United Kingdom	400	999	500	1250

*Short term is 15 minutes unless states otherwise

8.2 Exposure controls

Engineering controls

For industrial use of the liquid, good general ventilation is recommended. Where exposure limits may be exceeded, local exhaust ventilation may be necessary.

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Personal protective equipment

For professional use of the liquid, the need for personal protective equipment should be based on a workplace risk assessment for the particular use. Prevent skin and eye contact by wearing chemical resistant gloves (eg rubber, neoprene, PVC) and safety goggles. Where more extensive contact may occur, wear suitable protective clothing (eg apron, sleeves, boots). PPE should be to European (EN) standards. Consult manufacturers concerning breakthrough times

Environmental exposure controls

Not available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Moist non-woven wipe
Colour	White wipe with a clear, colourless eluate
Odour	Alcohol
Melting/freezing point	-88 to -90°C (propan-2-ol)
Initial boiling point/range	82 to 83°C (propan-2-ol)
Flammability	Not available
Lower and upper explosion limit	Not determined: water-based product
Flash point	ca. 18°C (70% propan-2-ol)
Auto-ignition temperature	Not available
Decomposition temperature	Not available
pH	5.0-8.0
Kinematic viscosity	Not available
Solubility	Soluble in water
Partition coefficient n-octanol/water	Not available
Vapour pressure (20°C)	4.3 kPa (propan-2-ol)

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Density and/or relative density	Not available
Relative vapour density	Not available
Particle characteristics	Not applicable

9.2 Other information

Explosive limits (in air)	1.8-12% (propan-2-ol)
Explosive properties	Vapours may form explosive mixtures with air

SECTION 10: Stability and reactivity

10.1 Reactivity

Not available

10.2 Chemical stability

Stable under recommended handling conditions

10.3 Possibility of hazardous reactions

Not available

10.4 Conditions to avoid

Sources of ignition (e.g. heat, spark, flame).

10.5 Incompatible materials

Oxidising agents, ammonia, and chlorine. Contact with anionic substance will reduce effectiveness of the product

10.6 Hazardous decomposition products

Not available

SECTION 11: Toxicological information

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

Acute toxicity

Not classified as harmful by ingestion or skin contact. Ingestion of liquid may cause intoxication.

Skin corrosion/irritation

Not likely to cause dermal irritation.

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Serious eye damage/irritation
May cause eye irritation. Prolonged or repeat exposure may cause skin irritation.

Respiratory or skin sensitisation
Not likely to cause sensitisation.

Germ cell mutagenicity
No data available

Carcinogenicity
No data available

Reproductive toxicity
Not available

STOT-single exposure
No data available

STOT-repeated exposure
No data available

Aspiration hazards
No data available

11.2 Information on other hazard classes which relates to endocrine disrupting properties

Endocrine disrupting properties
Not available

Other information
Not applicable

SECTION 12: Ecological information

12.1 Toxicity

Contains a substance (chlorhexidine digluconate) which can be toxic to aquatic organisms.

12.2 Persistence and degradability

Contains a substance (Chlorhexidine digluconate) which is not readily biodegradable.

12.3 Bioaccumulative potential

Not available

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12.4 Mobility in soil

Not available

12.5 Results of PBT and vPvB assessment

Not available

12.6 Endocrine disrupting properties

No information available

12.7 Other adverse effects

Not available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

For large-scale industrial use, the liquid should be disposed of by incineration. Do not dispose of via the drains, or by landfill. Disposal must be in accordance with current national and local regulations. In industry, chemical residues generally count as special waste, and their disposal may be regulated in the EC member countries through corresponding laws and regulations. We recommend that you contact either the authorities or approved waste disposal companies who will advise you on how to dispose of special waste.

General EU requirements are given in the Waste Framework Directive (75/442/EEC) and the Hazardous Waste Directive (91/689/EEC).

The wipes are not flushable or maceratable.

SECTION 14: Transport Information

14.1 UN Number

3175 with special provisions: IATA A46, ADR 216 & 274, IMDG 216 & 274.

14.2 UN Proper Shipping Name

SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S (contains isopropanol)

14.3 Transport hazard class(es)

4.1

14.4 Packing groups

II

14.5 Environmental hazards

Marine pollutant

14.6 Special precautions for user

Not available

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14.7 Maritime transport in bulk according to IMO instruments

Not available

SECTION 15: Regulatory information

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

Classification and Labelling of Substances and Preparation Dangerous for Supply. Workplace Exposure Limits EH40. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 with amendments.

15.2 Chemical safety assessment

Not available

SECTION 16: Other Information

Basis of classification

The mixture is self-classified on the basis of available information on the ingredients

List of hazard statements

H225: Highly flammable liquid and vapour

H318: Causes serious eye damage

H319: Causes serious eye irritation

H336: May cause drowsiness or dizziness

H400: Very toxic to aquatic life

H410: Very toxic to aquatic life with long lasting effects

This safety data sheet was compiled using the ECHA Guidance on the compilation of Safety Data Sheets, Version 4.0, December 2020.

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