

SAFETY DATA SHEET

Clinell Alcoholic 2% Chlorhexidine Wipes

According to Regulation (EU) No 453/2010

Issue Date: 16-April-2019

Version Number: 9

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
2 Regal Way
Watford
WD24 4YJ
United Kingdom
Tel: +44 (0) 207 993 0030
Email: info@gamahealthcare.com

1.4 Emergency telephone number

Tel: +44 (0) 207 9930 035

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 Flam Liq. 2: H225, Eye Irrit. 2: H319, Eye Dam. 1: H318, STOT SE 3: H336, Aquatic. Acute 1: H400

Classification according to Directive 1999/45/EEC F: R10, Xi: R36, R41, R67, N: R50

Human Health

Risk of serious damage to eyes. Vapours may cause drowsiness and dizziness.

Environment

Contains a substance (chlorhexidine digluconate) which can be toxic to aquatic organisms, but at the levels contained in this mixture it is not considered to be toxic.

Physical and Chemical Hazards

Flammable

2.2 Label Elements

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Signal Word

Danger

Hazard statements

Highly flammable liquid and vapour

Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces

Avoid breathing vapours

IF IN EYES: Rinse with water for 15 minutes. Seek prompt medical attention for signs of irritation.

2.3 Other hazards

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Declarable components	Conc. (%)	EC No.	CAS No.	Classification	
				67/548/EEC	1272/2008
Propan-2-ol	68-75	200-661-7	67-63-0	F: R10, Xi: R36, R67	Flam Liq. 2: H225, Eye Irrit. 2: H319, STOT SE 3: H336.
Chlorhexidine digluconate*	2-2.5	242-354-0	18472-51-0	Xi: R41, N: R50	Eye Dam. 1: H318, Aquatic Acute 1: H400

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).

For the full test of all R-Phrases and Hazard Statements are available in Section 16

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation

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

Skin

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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

In case of contact with eyes, irrigate with water for 15 minutes, 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 (eg 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. Vapours may cause drowsiness or dizziness.

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 of 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.

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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

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

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

UK Limit: Propan-2-ol: long-term exposure limit (8 h), 999 mg/m³ (400 ppm); short-term exposure limit (15 min), 1250 mg/m³ (500 ppm).

8.2 Exposure controls

Engineering controls

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

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

Appearance	Moist non-woven wipe
Odour	Alcohol
Odour threshold	Not available
pH	5.0-8.0
Melting/freezing point	-88 to -90°C (propan-2-ol)
Initial boiling point/range	82 to 83°C (propan-2-ol)
Flash point	ca. 18°C (70% propan-2-ol)
Evaporation rate	Not available
Explosive limits (in air)	1.8-12% (propan-2-ol)
Vapour pressure (20°C)	4.3 kPa (propan-2-ol)
Solubility	Soluble in water
Partition coef	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available

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Viscosity Not available

Explosive properties Vapours may form explosive mixtures with air

9.2 Other information Not available

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 of toxicological effects

Acute toxicity
Not classified as harmful by ingestion or skin contact. Inhalation may cause drowsiness or dizziness. Ingestion of liquid may cause intoxication.

Irritancy
May cause eye irritation. Prolonged or repeat exposure may cause skin irritation.

Corrosivity
Not available

Sensitisation
Not available

Repeated dose toxicity

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Not available

Carcinogenicity
Not available

Mutagenicity
Not available

Toxicity for reproduction
Not available

SECTION 12: Ecological information

12.1 Toxicity

Contains a substance (chlorhexidine digluconate) which can be toxic to aquatic organisms, but at the levels contained in this mixture it is not considered to be toxic.

12.2 Persistence and degradability

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

12.3 Bioaccumulative potential

Not available

12.4 Mobility soil

Not available

12.5 Results of PBT and vPVB assessment

Not available

12.6 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.

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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

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

Revisions

Currently in eighth revision.

Basis of classification

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

List of R-phrases

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F: Flammable, Xi: Irritant, N: Dangerous for the environment, R10: Flammable, R36: Irritating to eyes, R41: Risk of serious damage to eyes, R50: Very toxic to aquatic organisms

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.

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