

SAFETY DATA SHEET

Clinell Universal Wipes

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

Issue Date: 31st July 2023

Version Number: 14

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

1.1 Product Identifier

Product Name Clinell Universal Wipes

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

Identified Use Wipes for surface disinfection and cleaning of non-invasive medical devices.

1.3 Details of the supplier of the safety data sheet

Supplier GAMA Healthcare
The Maylands Building
Maylands Avenue, Hemel Hempstead Industrial Estate
Hemel Hempstead
Hertfordshire
HP2 7TG
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) No 1272/2008 Mixture not classified as hazardous

2.2 Label Elements

Contains PHMB. May produce an allergic reaction.

2.3 Other hazards

Not applicable

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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
Benzalkonium chloride	≤0.5	270-325-2	68424-85-1	Skin Corr 1B (H314) Acute Tox 4 (H302, H312) Aquatic Acute 1 (H400)	-
Didecyl dimethyl ammonium chloride	≤0.5	230-525-2	7173-51-5	Acute Tox 4 (H302) Skin Corr 1B (H314)	-
Polyhexamethylene biguanide (PHMB)	≤0.10	NA	27083-27-8	Acute tox 4 (H302) Skin sens 1B (H317) Eye dam 1 (H318) Acute tox 2 (H330) Carc. 2 (H351) STOT RE 1 (H372) Aquatic acute 1 (H400) Aquatic chronic (H410)	M=10
2-phenoxyethanol	≤0.10	204-589-7	122-99-6	Acute tox 4 (H302) STOT SE 3 (H335) Eye Dam. 1 (H318)	Oral: ATE = 1394mg/kg bw

Other components:

Water >75
Additives Each <1

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation

Acute effects following exposure to this product via the inhalation route are not anticipated during normal handling and use.

Skin

This product is not intended for use on skin. If skin irritation occurs, get medical advice.

Both a toxicological risk assessment and dermatological patch test conclude that Clinell Universal Wipes are well tolerated and pose a negligible risk of developing an allergic reaction when used as intended.

Eye

Should eye irritation be experienced, this effect would likely be transient. But should symptoms persist, seek medical advice.

Ingestion

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This product is for external use only and should be kept away from children. No adverse effects are anticipated from the formulation via the oral route during normal handling and use of the product.

4.2 Most important symptoms and effects, both acute and delayed

This product contains PHMB which may cause an allergic reaction.

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. No unsuitable extinguishing media are known.

5.2 Special hazards arising from the substance of mixture

The product is water based, therefore not flammable or explosive.

5.3 Advice for fire fighters

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

None anticipated or expected to be required.

6.2 Environmental precautions

None anticipated or expected to be required.

6.3 Methods and material for containment and cleaning up

None anticipated or expected to be required.

6.4 Reference to other sections

For recommended personal protective equipment see Section 8.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

For prolonged use wear gloves to avoid drying of the skin.

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.

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7.3 Specific end use

See directions for use on pack.

Identified in Section 1.2

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters

EU Limit: No applicable EU occupational exposure limit values

National Limits:

	Limit Value – Eight hours		Limit value – Short term*	
	ppm	mg/m ³	ppm	mg/m ³
2-phenoxyethanol				
Germany (AGS)	1 (1)	5,7 (1)	1 (1)	5,7 (1)
Germany (DFG)	1 (1)	5,7 (1)	1 (1)	5,7 (1)
Poland		230		

*Short term is 15 minutes unless states otherwise

Germany (AGS): (1) Inhalable fraction and vapour

Germany (DFG): (1) Inhalable fraction and vapour

8.2 Exposure controls

Engineering controls

None anticipated or expected to be required.

Personal protective equipment

For prolonged use, wear gloves.

Environmental exposure controls

None anticipated or expected to be required.

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	Characteristic odour
Melting/freezing point	Ca. 0°C

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Initial boiling point/range	Ca. 100°C
Flammability	Not determined: water-based product
Lower and upper explosion limit	Not determined: water-based product
Flash point	Not determined: water-based product
Auto-ignition temperature	Not determined: water-based product
Decomposition temperature	Not determined: water-based product
pH	4-7
Kinematic viscosity	Not determined: water-based product
Solubility	Not determined: water-based product
Partition coefficient n-octanol/water	No data available
Vapour pressure	24 mmHg (25°C) (water)
Density and/or relative density	Not determined: water-based product
Relative vapour density	Not determined: water-based product
Particle characteristics	Not applicable
9.2.1 Other information	Not available
9.2.2 Other safety characteristics	Not available

SECTION 10: Stability and reactivity

10.1 Reactivity

Contact with ionic substances for example oils and dyes, may reduce effectiveness of the product. Contact with oxidising agents should be avoided.

10.2 Chemical stability

The product is considered stable under normal ambient storage and handling conditions or temperature and pressure.

10.3 Possibility of hazardous reactions

No hazardous reactions anticipated

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10.4 Conditions to avoid

None known

10.5 Incompatible materials

Oxidizing agents and anionic formulations.

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological information

This preparation has undergone toxicology risk assessment.

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

Acute toxicity

Not likely to be acutely toxic.

Skin Corrosion/Irritation

Not likely to cause significant dermal irritation.

Serious eye damage/irritation

No risk of dermal corrosivity identified under normal handling and use.

Respiratory or skin sensitisation

Not likely to cause significant sensitisation or delayed hypersensitivity.

Germ cell mutagenicity

None of the components have exhibited confirmed mutagenic characteristics in the evaluation of their toxicity to date.

Carcinogenicity

No data available on the carcinogenicity of this product.

Reproductive toxicity

No data available on reproductive toxicity of this product.

STOT-single exposure

No data available on the STOT-single exposure of this product.

STOT-repeated exposure

No data available on the STOT-repeated exposure of this product.

Aspiration hazards

No data available on the aspiration hazards for this product.

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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

Ecotoxicological data has not been determined specifically for this product.

12.1 Toxicity

Contains substances (Benzalkonium chloride and PHMB) which can be toxic to aquatic organisms.

12.2 Persistence and degradability

Two components of the formulation (DDAC and BAC) have been found to readily biodegrade in OECD 301D closed bottle tests. However, PHMB was found not to be readily biodegradable under the same protocol.

12.3 Bioaccumulative potential

Due to the distribution coefficient of n-octanol/water, accumulation in organisms is not expected.

12.4 Mobility soil

No information available on mobility of active substance in soil.

12.5 Results of PBT and vPvB assessment

The formulation does not contain substances that meet the PBT or vPvB criteria of REACH annex XIII.

12.6 Endocrine disrupting properties

No information available

12.7 Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

This product may be disposed of landfill, or by incineration. Disposal must be in accordance with current national and local regulations.

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In the Healthcare Industry, chemical residues, biocides and infectious substances generated as a result of medical and nursing care may require classification as hazardous waste.

Waste disposal is regulated in the EC member countries through corresponding laws and regulation. In the UK, we recommend that you consult the List of Wastes available through the Environment Agency. In other countries, contact either the authorities or approved waste disposal companies for advice on disposal of used waste.

SECTION 14: Transport Information

Not classified for transport

SECTION 15: Regulatory information

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

This product is classified under the Classification, Labelling and Packaging of Substances and Mixtures (EC) No 1272/ 2008 it contains substances which are notified and under the Biocidal Products Regulation (EU). No 528/2012.

15.2 Chemical safety assessment

Not applicable

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

H302: Harmful if swallowed

H312: Harmful in contact with skin

H314: Causes severe skin burns and eye damage

H317: May cause an allergic skin reaction

H318: Causes serious eye damage

H330: Fatal if inhaled

H335: May cause respiratory irritation

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

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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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