SAFETY DATA SHEET
Clinell Universal Wipes
According to Regulation (EU) No 2020/878 & Regulation (EC) No 1272/2008

Issue Date: 01 April 2021 Version Number: 12

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
Prinsessegracht 20
2514 AP The Hague
The Netherlands
Tel: +31 (0) 70 345 8570

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: Mixture not classified as hazardous

2.2 Label Elements

Contains PHMB. May produce an allergic reaction. Wear appropriate PPE

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 No1272/2008
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) Carc. 2 (H351) STOT RE 1 (H372) Aquatic acute 1 (H400) Aquatic chronic (H410)

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
The product contains components classified as damaging to eyes. Due to the high volume of water also present in the formulation, the dilution effect means that the classification through CLP does not result in the hazard being carried through to the product.

Nevertheless, 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*	
2-phenoxyethanol	**ppm**	**mg/m^3**	**ppm**	**mg/m^3**
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

Appearance	Moist non woven wipe
Odour	Slight green tea perfume
Odour threshold	Not available
pH	4-7

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Melting/freezing point	Ca. 0°C
Initial boiling point/range	Ca. 100°C
Flash point	Not determined: water based product
Evaporation rate	Not determined: water based product
Flammability (solid, gas)	Not determined: water based product
Flammability or explosive limits	Not determined: water based product
Vapour pressure	24 mmHg (25°C) (water)
Relative density	Not determined: water based product
Solubility	Not determined: water based product
Partition coef	No data available
Auto-ignition temperature	Not determined: water based product
Decomposition temperature	Not determined: water based product
Viscosity	Not determined: water based product
Explosive properties	Not determined: water based product
Oxidising properties	Not determined: water based product

9.2 Other information 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

10.4 Conditions to avoid

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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 of toxicological effects

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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SECTION 12: Ecological information

Ecotoxicological data has not been determined specifically for this product. Based on classification of the formulation through CLP, the environmental hazards are not carried through to the product.

12.1 Toxicity
Components are classified as toxic to the environment but are not present in the formulation at sufficient levels. The hazard is not carried through to the product.

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-octonal/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 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.

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.

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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

Revisions
Currently in its twelfth revision.

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
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

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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