SAFETY DATA SHEET
Clinell Universal Spray
According to Regulation (EU) No 453/2010

Issue Date: 25th April 2016 Version Number: 7

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

1.1 Product Identifier

Product Name: Clinell Universal Spray

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

Identified Use: Disinfectant spray for surface disinfection and cleaning of non-invasive medical devices

1.3 Details of the supplier of the safety data sheet

Supplier:
GAMA Healthcare Ltd
2 Regal Way
Watford
Hertfordshire 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: Mixture not classified as hazardous

2.2 Label Elements

Contains PHMB. May produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1 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)
Polyhexamethyl ene 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 affects following exposure to this product via the inhalation route are not anticipated during normal handling and use.

Skin
This product is not intended for skin use. However, it has been dermatologically tested and approved safe for contact with skin. The use of gloves is recommended for prolonged use. If irritation develops, seek medical advice.

Although this product contains components classified as corrosive and sensitive to skin, due to the high volume of water also present in the formulation, the dilution effect means the classification of the formulation through CLP does not results in the hazards being carried through to the product.

A toxicological risk assessment considers this product unlikely to cause dermal irritation.

Eye
This 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
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.

4.2 Most important symptoms and effects, both acute and delayed

This product contains PHMB which may produce 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.

7.3 Specific end use
Identified in Section 1.2

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters
EU Limit No applicable EU occupational exposure limit values.

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	Clear liquid
Odour	Slight green tea perfume
Odour threshold	Not available
pH	5-8
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	Liquid is water soluble
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 the effectiveness f the product. Contact with oxidising agents should be avoided.

10.2 Chemical stability
This 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
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 a toxicology risk assessment.

11.1 Information of toxicological effects

Acute toxicity
Not likely to be acutely toxic.

Irritancy
Not likely to cause significant dermal irritation.

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

Sensitisation
Not likely to cause significant sensitisation or delayed hypersensitivity.

Repeated dose toxicity
No data available on the repeat dose toxicity of this product.

Carcinogenicity
No data on the carcinogenicity of this product.

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

Toxicity for reproduction
No data available on the toxicity to reproduction of this product.

SECTION 12: Ecological information

Ecotoxicological data have not been determined specifically for this product. Based on the 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 hazards are not carried through to the product.

12.2 Persistence and degradability

Two components of the formulation (DDAC and BAC) have been found to readily degrade 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 in not expected.

12.4 Mobility soil

No information available on the mobility of active substances in soil.

12.5 Results of PBT and vPVP assessment
The formulation does not contain substances that meet the PBT or vPvB criteria of REACH annex XIII.

12.6 Other adverse effects
No information available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
This product may be disposed of via the drains, by 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 regulations. 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

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

15.2 Chemical safety assessment
Not applicable

SECTION 16: Other Information

Revisions
Currently in sixth version to bring in line with new regulations.

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

This Safety Data Sheet was compiled using ECHA Guidance on the compilation of Safety Data Sheets, Version 1.1 December 2011.

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