

# 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](mailto: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

# 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 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)<br>Acute Tox 4 (H302, H312)<br>Aquatic Acute 1 (H400)                                                                               |
| Didecyl dimethyl ammonium chloride | ≤0.5      | 230-525-2 | 7173-51-5  | Acute Tox 4 (H302)<br>Skin Corr 1B (H314)                                                                                                               |
| Polyhexamethylene biguanide (PHMB) | ≤0.10     | NA        | 27083-27-8 | Acute tox 4 (H302)<br>Skin sens 1B (H317)<br>Eye dam 1 (H318)<br>Carc. 2 (H351)<br>STOT RE 1 (H372)<br>Aquatic acute 1 (H400)<br>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

# 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

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.

# 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

### 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 <sup>3</sup> | ppm                       | mg/m <sup>3</sup> |
| 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                      |

# 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

|                                  |                                     |
|----------------------------------|-------------------------------------|
| 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

# 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

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.

# 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 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-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 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.

# 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 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.

*Disclaimer: This information is furnished without warranty express or implied, except that it is accurate to the best of our knowledge.*

*It relates to the specific material designated herein, and does not relate to the use in combination with any other material or in any process. We assume no legal responsibility for use or reliance upon this information.*