

# SAFETY DATA SHEET

## Contiplan by Clinell

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

Issue Date: 8<sup>th</sup> June 2023

Version Number: 5

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

#### 1.1 Product Identifier

Product Name Contiplan by Clinell

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

Identified Use Wipes for the purpose of preventing incontinence associated dermatitis in individuals suffering from continence issues

#### 1.3 Details of the supplier of the safety data sheet

Supplier  
GAMA Healthcare Ltd  
The Maylands Building  
Maylands Avenue, Hemel Hempstead Industrial Estate  
Hemel Hempstead  
HP2 7TG  
United Kingdom  
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

This product is a medical device as defined in Directive 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and therefore is exempt from the requirements of classification and labelling according to Regulation (EC) No. 1272/2008 (CLP; Article 1, paragraph 5).

#### 2.2 Label Elements

Signal word Not applicable

Hazard statements Not applicable

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Precautionary statements      Not applicable

### 2.3 Other hazards

For external use only. Avoid contact with eyes, mouth and broken or bleeding skin. Discontinue use if irritation develops. If irritation persists for more than 72 hours seek medical advice. Store in a cool dry place.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

Declarable components	Conc. (%)	EC No.	CAS No.	Classification according to Regulation (EC) No. 1272/2008	Specific concentration limits according to Regulation (EC) No 1272/2008
Dimethicone	≤ 4.0		63148-62-9	Aquatic Chronic 4: H413	-
Glycerin	≤ 1.0	200-289-5	56-81-5	Eye Irrit. 2: H319	-
Benzalkonium chloride	≤ 0.1	270-325-2	68424-85-1	Acute Tox 4: H302, H312; Skin Corr 1B; H314; Aquatic Acute 1: H400	-

Although individual ingredients may be classified as hazardous, the levels contained in this mixture are not considered to be hazardous.

Parraffinum liquidum	6%
Other additives	<6%
Water	<75%

Full list of Hazard Statements are available in Section 16

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### Inhalation

For industrial use of the liquid, if adverse effects (e.g. irritation of the airways) occur, remove patient from exposure and give fresh air and rest. If the patient continues to feel unwell, obtain medical attention.

#### Skin

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.

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### Eye

For industrial use of the liquid, in case of contact with eyes, irrigate with water, occasionally lifting eyelids. Seek prompt medical attention.

### Ingestion

For industrial use of the liquid, if swallowed, wash out mouth thoroughly and give water to drink. Seek medical attention if significant amounts (e.g. 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 irritation. Seek medical attention if swallowed.

#### 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

When heated sufficiently, product may decompose to form smoke and toxic fumes, gases or vapours.

#### 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). Keep unauthorised personnel from the spillage area.

#### 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. Small spills can be mopped up with dry cloth. Collect larger spill using techniques such as sorbent

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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. Wear protective clothing as in Section 8. Good general ventilation is recommended.

### 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

National Limit

	Limit Value – Eight Hours		Limit Value – Short term *	
<b>Glycerol mist</b>				
Country	ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>
United Kingdom		10		

\* Short term is 15 minutes unless stated otherwise

### 8.2 Exposure controls

Engineering controls  
For industrial use of the liquid, good general ventilation is recommended.

Personal protective equipment  
Product is designed for skin use and is dermatologically tested.

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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 (e.g. rubber, neoprene, PVC) and safety goggles. Where more extensive contact may occur, wear suitable protective clothing (e.g. 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

Physical state	Moist non-woven wipe
Colour	White wipe with a clear, colourless eluate
Odour	Slight green tea perfume
Melting/freezing point	ca. 0°C
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	ca. 7
Kinematic viscosity	Not determined: water-based product
Solubility	Soluble in water
Partition coefficient n-octanol/water	No data available
Vapour pressure	No data available

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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

None known

#### 10.2 Chemical stability

Stable under recommended storage and handling conditions.

#### 10.3 Possibility of hazardous reactions

None known

#### 10.4 Conditions to avoid

None

#### 10.5 Incompatible materials

Oxidising agents. Contact with anionic substances will reduce effectiveness of the product.

#### 10.6 Hazardous decomposition products

None known.

### SECTION 11: Toxicological information

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

##### Acute toxicity

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

##### Skin corrosion/irritation

Not likely to cause dermal irritation.

##### Serious eye damage/irritation

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

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Respiratory or skin sensitisation  
Not likely to cause sensitisation.

Germ cell mutagenicity  
No data available

Carcinogenicity  
No data available

Reproductive toxicity  
Not available

STOT-single exposure  
No data available

STOT-repeated exposure  
No data available

Aspiration hazards  
Inhalation of vapours or liquid may cause drowsiness or dizziness.

### 11.2 Information on other hazard classes which relates to endocrine disrupting properties

Endocrine disrupting properties  
Not available

Other information  
Not applicable

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## SECTION 12: Ecological information

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### 12.1 Toxicity

Contains substances (dimethicone and benzalkonium chloride) which can be toxic to aquatic organisms.

### 12.2 Persistence and degradability

No information available

### 12.3 Bioaccumulative potential

No information available

### 12.4 Mobility in soil

No information available

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#### 12.5 Results of PBT and vPvB assessment

No information available

#### 12.6 Endocrine disrupting properties

No information available

#### 12.7 Other adverse effects

No information available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

This product may be disposed of via the landfill, or by incineration. 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.

The wipes are not flushable or maceratable.

### SECTION 14: Transport Information

Not classified for transport.

### 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

Basis of classification

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

List of hazard statements



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H302: harmful if swallowed  
H312: harmful in contact with skin  
H314: causes severe skin burns and eye damage  
H319: causes serious eye irritation  
H400: very toxic to aquatic life  
H413: May cause long lasting harmful effects to aquatic life

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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