

SAFETY DATA SHEET

Carell Patient Wipes

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

Issue Date: 13th September 2023

Version Number: 9

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

- 1.1 Product Identifier Product Name Carell Patient Wipes
- **1.2 Relevant identified uses of the substance or mixture and uses advised against** Identified Use Cleaning wipes for skin
- **1.3 Details of the supplier of the safety data sheet**
SupplierSupplierGAMA Healthcare

The Maylands Building Maylands Avenue, Hemel Hempstead Industrial Estate Hemel Hempstead Hertfordshire HP2 7TG Tel: +44 (0) 207 993 0030 Email: <u>info@gamahealthcare.com</u>

GAMA Healthcare Ireland 13 Upper Baggot Street 2nd Floor Dublin 4 D04 W7K5 T: +353 1 513 41 38 E: <u>info@gamahealthcare.com</u>

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** According to Cosmetics Regulation (EC) No. 1223/2009
- 2.2 Label Elements

Keep away from eyes.

2.3 Other hazards Microwave times may vary, test temperature before use. Do not reheat.

SECTION 3: Composition/information on ingredients

3.2 Mixtures



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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
2-phenoxyethanol	≤0.5	204- 589-7	122-99-6	Acute Tox. 4 (H302) Eye Irrit. 2 (H319)	Oral: ATE = 1394mg/kg bw
Benzalkonium chloride	≤1	270- 325-2	68424- 85-1	Skin Corr. 1B (H314) Acute Tox. 4 (H302, H312) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	-

Other Additives: <2%

Water: >95%

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

Full list of Hazard Statements is available in Section 16 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 designed for skin use. No adverse effects are anticipated during normal handling and use. If irritation occurs discontinue use, seek medical advice.

Eye

Avoid contact with eyes. Should the product come into contact with eyes, rinse well immediately. If irritation occurs, stop using and consult a doctor when necessary.

Ingestion

This product is for external use only and should be kept away from children. If incidentally swallowed in small amounts, may cause slight, transient irritation to the mouth and upper digestive tract. If swallowed, drink plenty of water and contact a doctor.

- **4.2 Most important symptoms and effects, both acute and delayed** May cause eye irritation.
- **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.



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5.2 Special hazards arising from the substance of mixture This product is water-based, therefore not flammable or explosive.

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 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



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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		
Propane-1,2-diol	ppm	mg/m ³	ppm	mg/m ³
Australia	150	474		
Ireland	150	470		
United Kingdom	150	474		

*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

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

Personal protective equipment

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 (eg rubber, neoprene, PVC) and safety goggles. Where more extensive contact may occur, wear suitable protective clothing (eg 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 spun-lace 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	No data available
рН	4 - 7
Kinematic viscosity	Not determined: water-based product
Solubility	Liquid is water soluble
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 Not available
- **10.2 Chemical stability** The product is considered stable under normal storage and handling conditions
- 10.3 Possibility of hazardous reactions None known
- **10.4 Conditions to avoid** Avoid excessive heat and light



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- 10.5 Incompatible materials None known
- **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

This preparation has not been tested for its toxicological effects.

Acute toxicity Not expected to be toxic by ingestion, skin contact or inhalation.

Skin corrosion/irritation Prolonged or repeated skin contact may cause irritation.

Serious eye damage/irritation Mild irritant to eyes.

Respiratory or skin sensitisation No data available

Germ cell mutagenicity None of the ingredients have exhibited confirmed mutagenic characteristics in the evaluation of their toxicity to date.

Carcinogenicity None of the ingredients have exhibited confirmed carcinogenic characteristics in the evaluation of their toxicity to date.

Reproductive toxicity No information available regarding toxicity to reproduction.

STOT-single exposure No data available

STOT-repeated exposure No data available

Aspiration hazard Not expected to be an aspiration hazard

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



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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** This formulation is not expected to be toxic to the aquatic environment.
- **12.2 Persistence and degradability** No information available
- **12.3 Bioaccumulative potential** No information available
- **12.4 Mobility in soil** No information available
- **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 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.



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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the mixture** This product is classified according to Regulation (EC) No 1223/2009 on cosmetic products.
- **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 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 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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