

Bedside-Care® Perineal Wash

09. August 2016
Version 2.0

Safety Data Sheet

Based on template version 3.0

Section 1

Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: Bedside-Care® Perineal Wash
Product code: 1452, 1453, 1455.

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

Product information: OTC drug, no-rinse skin cleanser.

1.3 Details of the supplier of the safety data sheet:

Manufacturer: Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark
Telephone +45 49111111
msds@coloplast.com

1.4 Emergency telephone number:

(DK) +45 82 12 12 12
(US) 1-800-222-1222
(CA) 1-877-820-7008

Section 2

Hazards identification

The product is an OTC drug product and therefore not covered by the classification and labelling rules that apply to chemical products. This safety data sheet is supplied as an additional service to the customer.

USA

Coloplast Corp.
1601 West River Road N
Minneapolis, MN 55411
Telephone: +1-800-533-0464
www.coloplast.com

Canada

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Mississauga, Ont. L5L 5Z9
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Europe

Coloplast A/S
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DK-3050 Humlebaek
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2.1 Classification of the substance or mixture

The product is an OTC drug product and therefore not covered by the classification and labelling rules that apply to chemical products according to i.e. Regulation (EC) No 1272/2008.

2.2. Label elements

The product is an OTC drug product and therefore the labelling elements from the CLP regulations do not apply, according to Regulation (EC) No 1272/2008, Title I, Article 1, Section 5.

List of ingredients on label, listed with INCI-nomenclature according to Regulation (EC) No 1223/2009:

WATER (AQUA), SODIUM LAUROAMPHOACETATE, COCAMIDOPROPYL BETAINE, GLYCERIN, POLYSORBATE 20, QUATERNIUM 52, CITRIC ACID, QUATERNIUM 15, BENZETHONIUM CHLORIDE, TETRASODIUM EDTA.

2.3 Other hazards

None

Section 3

Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

List of ingredients according to Regulation (EC) No. 1223/2009 on cosmetic products (INCI-nomenclature):

WATER (AQUA), SODIUM LAUROAMPHOACETATE, COCAMIDOPROPYL BETAINE, GLYCERIN, POLYSORBATE 20, QUATERNIUM 52, CITRIC ACID, QUATERNIUM 15, BENZETHONIUM CHLORIDE, TETRASODIUM EDTA.

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Section 4

First-AID measures

4.1 Description of first aid measures

Inhalation: Seek fresh air.

Skin Contact: Not relevant, as the product is an OTC drug product intended for skin application.

Eye Contact: Flush with water (preferably using eye wash equipment) until irritation subsides. Seek medical advice if symptoms persist

Ingestion: Wash out mouth thoroughly and drink 1-2 glasses of water in small sips.

Burns: Not relevant.

Other information: When obtaining medical advice, show the safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

None

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms. No special immediate treatment required.

Section 5

Fire fighting measures

5.1 Suitable extinguishing media

Extinguish with powder, foam, carbon dioxide or water mist.
Use water or water mist to cool non-ignited stock.

5.2 Special hazards arising from the substance or mixture

Can generate harmful flue gases containing carbon monoxide in the event of fire.

5.3 Advice for firefighters

Move containers from danger area if it can be done without risk. Avoid inhalation of vapour and flue gases – seek fresh air. Wear Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely.

Section 6

Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: No special requirements

For emergency responders: In addition to the above: Normal protective clothing equivalent to EN 469 is recommended.

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6.2 Environmental precautions

Do not discharge large quantities of concentrated spills and residue into drains.

6.3 Methods and materials for containment and cleaning up:

Wipe up minor spills with a cloth.

6.4 Reference to other sections

See section 13 for instructions on disposal.

Section 7

Handling and storage

7.1 Precautions for safe handling

No special requirements.

7.2 Conditions for safe storage, including any incompatibilities

No special storage requirements.

7.3 Specific end use(s)

None.

Section 8

Exposure controls/personal protection

8.1 Control parameters

Legal basis: Commission Directive 2000/39/EC. Last amended by Commission Directive 2009/161/EU.

Contains no substances subject to reporting requirements.

8.2 Exposure controls

Appropriate engineering controls:

Wear the personal protective equipment specified below .

Personal protective measures: Not relevant, as the product is a cosmetic product.

Environmental exposure controls: Ensure compliance with local regulations for emissions.

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Section 9

Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Liquid
Colour:	Clear
Odour:	No data
pH (solution for use):	5-7
Melting point / freezing point (°C):	0 °C
Initial boiling point and boiling range (°C):	100 °C
Decomposition temperature (°C):	No data
Flash point (°C):	No data
Evaporation rate:	No data
Flammability (solid, gas):	No data
Upper/lower flammability or explosive limits (vol-%):	No data
Vapour pressure (hPa, 20°C):	No data
Vapour density (air=1):	No data
Relative density (g/ml, 25°C):	1,01
Solubility:	Miscible with the following: Water.
Partition coefficient: n-octanol/water, Log K _{ow} :	No data
Autoignition temperature (°C):	No data
Viscosity (mPa*s, 25°C):	No data
Explosive properties:	No data
Oxidising properties:	No data

9.2 Other information:

None

Section 10

Stability and reactivity

10.1 Reactivity

Not reactive.

10.2 Chemical stability

The product is stable when used in accordance with the supplier's directions

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None known.

Section 11

Toxicological information

This product is a cosmetic product and has been assessed in accordance with Directive 1223/2009 on cosmetic products.

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11.1 Information on toxicological effects

The product is an OTC drug product resembling a cosmetic product. Based on the inherent toxicity of the ingredients, the product is considered to have low risk of evoking toxicological effects. In certain cases the product may cause sensitization by skin contact to sensitive individuals. Symptoms include reddening, swelling, blistering – often slowly developing. In case of these symptoms discontinue use

Section 12

Ecological information

12.1 Toxicity

The product does not have to be classified. Test data are not available.

12.2 Persistence and degradability

The product does not have to be classified. Test data are not available.

12.3 Bioaccumulative potential

The product does not have to be classified. Test data are not available.

12.4 Mobility in soil

The product does not have to be classified. Test data are not available.

12.5 Results of PBT and vPvB assessment

The product does not have to be assessed. No assessment has been made.

12.6 Other adverse effects

None known.

Section 13

Disposal considerations

Dispose the product according to the recommended disposal technology at any approved facility. Under normal private use the product may be disposed of together with other household waste unless local regulations set special requirements. The disposal should always be in compliance with national, federal, state and local regulations. The product should not be discharged to the environment.

US

This product does not meet the criteria for hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261. Under normal private use the product may be disposed of together with other household waste per RCRA 40 CFR 261.4.B1.

European Union

Per The European Waste Catalogue (EWC), in accordance with EC Directive 75/422/EEC, the following Waste Code can be used: 18 01 04 00 wastes whose collection and disposal is not subject to special requirements in view of the prevention of infection (e.g. dressings, plaster casts, linen, disposable clothing, diapers). However, if the waste in view of the prevention of infection needs special requirements, other Waste Codes should be used. Under normal private use the product may be disposed of together with other household waste unless local regulations set special requirements.

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Section 14

Transport information

14.1 UN-no.:	Not relevant
14.2 UN proper shipping name:	Not relevant
14.3 Transport hazard class(es):	Not relevant
14.4 Packing group:	Not relevant
14.5 Environmental hazards:	Not relevant
14.6 Special precautions for user:	Not relevant
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Not relevant

ADR - Classification: Not relevant
- Classification code: Not relevant
- ADR limited Quantities: Not relevant
- Hazard label: Not relevant
Special provisions applicable to certain articles or substance: Not relevant

IMDG - Classification: Not relevant
- Classification code: Not relevant
- IMDG limited Quantities: Not relevant
- Hazard label: Not relevant

Special provisions applicable to certain articles or substance: Not relevant

IATA - Classification: Not relevant

Transportation on road in other countries than ADR-countries:

US: Not relevant
Canada: Not relevant
Brazil: Not relevant
Australia: Not relevant
New Zealand: Not relevant
Hongkong / China: Not relevant

Section 15

Regulatory information

Covered by:

US Cosmetics Regulations: Federal Food, Drug and Cosmetic Act (FD&C Act) Chapter VI - Cosmetics and Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

None

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

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Section 16 Other information

This safety data sheet is supplied as an additional service to the customer. The product has been evaluated according to the requirements of medical devices. For further information please contact Coloplast A/S.

This safety data sheet has been prepared for and applies to this product only. It is based on our current knowledge and the information available at the time of preparation. The safety data sheet complies with applicable law on preparation of safety data sheets in accordance with 1907/2006/EC (REACH) as subsequently changed.

Abbreviations:

PBT = Persistent, Bioaccumulative and Toxic

vPvB = Very Persistent and Very Bioaccumulative

THE ABOVE INFORMATION HAS BEEN COMPILED FROM SOURCES BELIEVED TO BE RELIABLE AND IS ACCURATE TO THE BEST OF OUR KNOWLEDGE. HOWEVER, COLOPLAST CORP. CANNOT GIVE ANY GUARANTEES REGARDING INFORMATION FROM OTHER SOURCES AND EXPRESSLY DOES NOT MAKE ANY WARRANTIES, NOR ASSUMES ANY LIABILITY, FOR ITS USE.

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