

Gentle Rain[®] Antibacterial

09. August 2016
Version 3.0

Safety Data Sheet

Based on template version 4.0

Section 1

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

1.1 Product identifier

Product name: Gentle Rain[®] Antibacterial
Product code: 7201, 7205, 7207.

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

Product information: OTC drug product. Antibacterial moisturizing body wash, shampoo and hand wash.

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

Coloplast Canada Corporation
3300 Ridgeway Drive, Unit 12
Mississauga, Ont. L5L 5Z9
Telephone: +1-877-820-7008
www.coloplast.ca

Europe

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Telephone: +45 49 11 11 11
www.coloplast.com

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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), AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, AMMONIUM LAURETH SULFATE, PROPYLENE GLYCOL, GLYCERIN, SODIUM CHLORIDE, IMIDAZOLIDINYL UREA, FRAGRANCE (PARFUM), METHYLPARABEN, PROPYLPARABEN, CITRIC ACID, TRICLOSAN.

The below illustrated pictograms, signal words and hazard statements are therefore only listed in the present SDS and not necessarily present on the product labelling.

According to Regulation (EC) No 1272/2008:

Pictogram(s):

Signal word:



None

Contains:

Triclosan 0,3%

Hazard statement(s):

Toxic to aquatic life with long lasting effects (H411).

Section 3

Composition/information on ingredients

3.2 Mixtures

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

WATER (AQUA), AMMONIUM LAURYL SULFATE, COCAMIDOPROPYL BETAINE, AMMONIUM LAURETH SULFATE, PROPYLENE GLYCOL, GLYCERIN, SODIUM CHLORIDE, IMIDAZOLIDINYL UREA, FRAGRANCE (PARFUM), METHYLPARABEN, PROPYLPARABEN, CITRIC ACID, TRICLOSAN.

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Section 4 First-AID measures

4.1 Description of first aid measures

Skin Contact: The product is a body and hand wash product intended to be rinsed off. Wash the skin with water.

Eye Contact: May sting or give rise to discomfort. Flush immediately with water for at least 5 minutes (preferably using eyewash equipment). Open eye wide. Remove any contact lenses. Seek medical advice in case of persistent discomfort.

Ingestion: Wash out mouth thoroughly and drink 1-2 glasses of water in small sips. Seek medical advice in case of persistent discomfort.

Inhalation: Not relevant

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

The product is an OTC drug product intended for body and hand washing. The product has passed dermatological testing showing low risk of causing skin irritation and skin sensitisation.

In certain cases, the product may cause sensitization by skin contact. Symptoms include reddening, swelling, blistering and ulceration – often slowly developing. In case of these symptoms, discontinue use.

Eye contact may result in stinging, pain, and discomfort. Risk of serious eye injury and loss of sight by excessive, prolonged exposure. Flush immediately with water for at least 5 minutes (preferably using eyewash equipment). Open eye wide. Remove any contact lenses. Seek medical advice in case of persistent discomfort.

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.

Unsuitable extinguishing media:

Do not use water stream, as it may spread the fire.

5.2 Special hazards arising from the substance or mixture

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

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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: Stop leak if this can be done without risk. Wear safety goggles/face protection. Wear gloves.
For emergency responders: In addition to the above: Protective suit equivalent to EN 368, type 3, is recommended.

6.2 Environmental precautions

Prevent spillage from entering drains and/or surface water.

6.3 Methods and materials for containment and cleaning up:

Contain and absorb spill with sand or other absorbent, non-combustible material and transfer to suitable waste containers. Wipe up minor spills with a cloth.

6.4 Reference to other sections:

See section 8 for type of protective equipment.
See section 13 for instructions on disposal.

Section 7 Handling and storage

7.1 Precautions for safe handling

The product is intended for rinse off. Use of running water is preferable. Wash hands after use.

7.2 Conditions for safe storage, including any incompatibilities

Store safely and keep out of reach of children. Store at temperatures below 40 °C.

7.3 Specific end use(s)

None.

Section 8 Exposure controls/personal protection

8.1 Control parameters

Commission Directive 2000/39/EC (Occupational Exposure Limits). Last amended by Commission Directive 2009/161/EU.

Contains no substances subject to reporting requirements.

8.2 Exposure controls

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Appropriate engineering controls: Wear the personal protective equipment specified below.

Personal protective equipment, eye/face protection: Wear safety goggles/face protection. Eye protection must conform to EN 166..

Personal protective equipment, skin protection: By handling of the product: Wear plastic or rubber protective gloves.

Personal protective equipment, respiratory protection: Not required.

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

Section 9

Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Viscous liquid.
Odour:	-
pH:	5-7
Melting point / freezing point (°C):	-
Initial boiling point and boiling range (°C):	-
Decomposition temperature (°C):	-
Flash point (°C):	-
Evaporation rate:	-
Flammability (solid, gas):	-
Upper/lower flammability or explosive limits (vol-%):	-
Vapour pressure (hPa, 20°C):	-
Vapour density (air=1):	-
Relative density (g/ml, 25°C):	Approx. 1
Solubility:	Solubility in water: Completely miscible.
Partition coefficient: n-octanol/water, Log K _{ow} :	-
Autoignition temperature (°C):	-
Viscosity (mPa*s, 25°C):	-
Explosive properties:	-
Oxidising properties:	-

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

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None known.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Carbonmonoxide and carbon dioxide.

Section 11

Toxicological information

This product is an OTC drug product and has been subject to safety assessment in accordance with the requirements in The Federal Food, Drug and Cosmetic Act and associated FDA guidance documents, as well as the Canadian and European cosmetic regulations.

The safety assessment also complies with the requirements for medical devices according to ISO 10993-1.

11.1 Information on toxicological effects

Toxicological data:

The product is an OTC drug product intended for body and hand washing.

The product has passed dermatological testing showing low risk of causing skin irritation and skin sensitisation.

In certain cases, the product may cause sensitization by skin contact. Symptoms include reddening, swelling, blistering and ulceration – often slowly developing. In case of these symptoms, discontinue use.

Eye contact may result in stinging, pain, and discomfort. Risk of serious eye injury and loss of sight by excessive, prolonged exposure. Flush immediately with water for at least 5 minutes (preferably using eyewash equipment). Open eye wide. Remove any contact lenses. Seek medical advice in case of persistent discomfort.

Other toxicological effects:

None known.

Section 12

Ecological information

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12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

Test data are not available for all substances.

3380-34-5-A: Readily biodegradable.

12.3 Bioaccumulative potential

Test data are not available for all substances.

3380-34-5-A: Partition coefficient n-octanol/water: 4,76.

12.4 Mobility in soil

Test data are not available.

12.5 Results of PBT and vPvB assessment

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.:	3082
14.2 UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triclosan)
14.3 Transport hazard class(es):	9
14.4 Packing group:	III
14.5 Environmental hazards:	The product must be labelled as an environmental hazard (symbol: fish and tree) in packaging sizes of more than 5 kg/l.
14.6 Special precautions for user:	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Not applicable.

ADR - Classification:

- Classification code:	M6
- ADR limited Quantities:	5 l
- Hazard label:	9

Special provisions applicable to certain articles or substance: Not relevant

IMDG - Classification:

- IMDG limited Quantities:	5 l
- Hazard label:	9

EMS: F-A, S-F

Special provisions applicable to certain articles or substance: Not relevant

IATA - Classification:

- Hazard label:	9
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Transportation on road in other countries than ADR-countries:

US: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triclosan)

Canada: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triclosan)/ MATIÈRE DANGEREUSE DU POINT DE VUE DE L'ENVIRONNEMENT, LIQUIDE, N.S.A (Triclosano)

Brazil: UN3082 MÁTERIA PERIGOSA DO PONTO DE VISTA DO AMBIENTE, LÍQUIDA, N.S.A. (Triclosan)

Australia: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triclosan)

New Zealand: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triclosan)

Hongkong / China: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Triclosan)

Section 15

Regulatory information

Regulatory information

Covered by: Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

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

No special training is required, but knowledge of this safety data sheet should be a prerequisite condition

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

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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