

## Gentle Rain® Extra Mild

09 August 2016  
Version 3.0

# Safety Data Sheet

Based on template version 4.0

### USA

Coloplast Corp.  
1601 West River Road N  
Minneapolis, MN 55411  
Telephone: +1-800-533-0464  
[www.coloplast.com](http://www.coloplast.com)

### Canada

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

### Europe

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

## Section 1

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

#### 1.1 Product identifier

Product name: Gentle Rain® Extra Mild  
Product code: 7229, 7230, 7231, 7233, 7234, 7235, 7236.

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

Product information: Cosmetic product. Moisturizing body wash, shampoo and hand wash for sensitive skin.

#### 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](mailto: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 a cosmetic 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.

#### 2.1 Classification of the substance or mixture

## Gentle Rain® Extra Mild

The product is a cosmetic 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 a cosmetic 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, AMMONIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, GLYCERIN, FRAGRANCE (PARFUM), IMIDAZOLIDINYL UREA, METHYLPARABEN, PROPYLPARABEN, CITRIC ACID, SODIUM CHLORIDE.

### 2.3 Other hazards

Assessment to determine PBT and vPvB has not been made (not required for cosmetic products).

---

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

## Gentle Rain® Extra Mild

### 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 a cosmetic product intended for body and hand washing.  
The product has passed dermatological testing.

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.

##### 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.

## Gentle Rain® Extra Mild

---

### 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 if there is a risk of eye splash. 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

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

Personal protective equipment, eye/face protection: Wear safety goggles if there is a risk of eye splash.

Personal protective equipment, skin protection:

Light use (small volume, short-term contact (below 10 min.)): Rinse off the product with water after use. Plastic or rubber gloves may be used.

Heavy use (high volume, long-term contact (more than 2 hours)): Wear plastic or rubber protective gloves.

## Gentle Rain® Extra Mild

Personal protective equipment, respiratory protection:  
Not required.

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

---

### Section 9

#### Physical and chemical properties

##### 9.1 Information on basic physical and chemical properties

Appearance:	Viscous liquid.
Odour:	-
pH:	5,5-6,5
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):	1-1,3
Solubility:	Solubility in water: Completely miscible.
Partition coefficient: n-octanol/water, Log K <sub>ow</sub> :	-
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

None known.

##### 10.4 Conditions to avoid

None known.

##### 10.5 Incompatible materials

None known.

## Gentle Rain® Extra Mild

### 10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

---

## Section 11

### Toxicological information

This product is a cosmetic 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 a cosmetic 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

#### 12.1 Toxicity

Test data not available.

#### 12.2 Persistence and degradability

Test data are not available.

#### 12.3 Bioaccumulative potential

Test data are not available.

#### 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.

## Gentle Rain® Extra Mild

### 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 RFT 261.4.B1.

#### European Union

Per The European Waste Catalogue (EWC), in accordance with EC Directive 75/422/ECC, 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.

### Section 14

#### Transport information

The product is not covered by the rules for transport of dangerous goods.

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

ADR - Classification:	
- 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:	
- IMDG limited Quantities:	Not relevant
- Hazard label:	Not relevant
- EMS:	Not relevant

Special provisions applicable to certain articles or substance: Not relevant

## Gentle Rain® Extra Mild

IATA - Classification:

- Hazard label: 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

#### 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

Training:

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



## Gentle Rain® Extra Mild

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.

Signature Page for VV-0097504 v3.0

Approved by	USJPB Jonathan Bogott Product Manager Management 09-Aug-2016 18:41:22 GMT+0000
-------------	---

Approved by	USBRDA Bronson Damjanovic Innovation Engineer Technical / Specialist 16-Aug-2016 14:21:16 GMT+0000
-------------	---

Approved by	DKPLYM Peter Lyng Madsen Senior Biosafety Specialist Technical / Specialist 05-Sep-2016 08:21:13 GMT+0000
-------------	--

Signature Page for VV-0097504 v3.0

Document Owner: DKPLYM Peter Lyng Madsen