

Comfeel Cleanser (Wipe)

8 April 2019
Version 3.0

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: Comfeel Cleanser (Wipe)
Product code: 04715
Product description: Sachet wipe

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

Product information: Medical device.
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

This product is regulated as a medical device in the European Economic Area (EEA). In other regions it may be regulated as a medical device, a cosmetic or not regulated. The product is assessed and supplied with a safety data sheet in accordance with Regulation (EC) no 1272/2008. Labelling of the product is prepared in accordance with Directive 93/42/EEC on medical devices and local legislation.

USA

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

Canada

Coloplast Canada Corporation
1380 Creditstone Road, Unit 6&7
Concord, ON, L4K 0J1
Telephone: +1-888-880-8605
www.coloplast.ca

Europe

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

Comfeel Cleanser (Wipe)

2.1 Classification of the substance or mixture

Classification according to Regulation (EC)

No 1272/2008:

Flammable Liquid 3;H226

Eye Irrit. 2;H319

Wording of H-statements – see section 16

Most serious harmful effects:

Irritating to eyes. Causes a burning sensation and tearing.

2.2. Label elements

The product is a medical device in EAA 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.

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

According to Regulation (EC) No 1272/2008:

Pictogram(s):

Signal word:

Warning



Hazard statement(s):

Flammable liquid and vapour.(H226)

Causes serious eye irritation. (H319)

Precautionary statement(s):

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. (P210)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.(P305/351/338)

If eye irritation persists: Get medical advice/attention.(P337/313)

Comfeel Cleanser (Wipe)

2.3 Other hazards

Assessment to determine PBT and vPvB has not been made.

Section 3

Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

The following substances have to be declared according to legislation:

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (EC 1272/2008)
10-15	67-63-0	200-661-7	-	-	Isopropyl alcohol	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336
<2	68650-39-5	272-39-5	-	-	Disodium Cocoamphodiacetate	Eye Irrit. 2;H319 Skin Irrit. 2;H315 Aquatic Chronic 3;H412

Wording of H-statements - see section 16.

Section 4

First aid measures

4.1 Description of first aid measures

Inhalation: Seek fresh air. Seek medical advice in case of persistent discomfort.

Skin Contact: This product is intended to be in contact with the skin when used as directed in the instructions for use. In case of skin problems: Seek medical advice.

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. Seek medical advice in case of persistent discomfort.

Burns: Flush with water until pain ceases. Remove clothing that is not stuck to the skin – seek medical advice/transport to hospital. If possible, continue flushing until medical attention is obtained.

Comfeel Cleanser (Wipe)

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

4.2 Most important symptoms and effects, both acute and delayed

Irritating to eyes. Causes a burning sensation and tearing.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms. No special immediate treatment required.

Section 5 Firefighting measures

5.1 Extinguishing media

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 chemical resistant gloves.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Stay upwind/keep distance from source. Stop leak if this can be done without risk. Smoking and naked flames prohibited.

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:

Sweep up/collect spills for possible reuse or transfer to suitable waste containers

6.4 Reference to other sections

See section 8 for type of protective equipment.

See section 13 for instructions on disposal.

Comfeel Cleanser (Wipe)

Section 7 Handling and storage

7.1 Precautions for safe handling

Running water and eye wash equipment must be available. Wash hands before breaks, before using restroom facilities, and at the end of work. Smoking and naked flames prohibited.

7.2 Conditions for safe storage, including any incompatibilities

Store safely and keep out of reach of children.

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) as subsequently amended. Last amended by Commission Directive 2017/164/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:

By handling of the product:

Wear safety goggles if there is a risk of eye splash.

Eye protection must conform to EN 166.

Personal protective equipment, skin protection:

By handling of the product: Plastic or rubber gloves recommended.

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

Comfeel Cleanser (Wipe)

Appearance:	Wipe (soaked in liquid)
Odour:	Alcohol
pH:	-
Melting point / freezing point (°C):	-
Initial boiling point and boiling range (°C):	-
Decomposition temperature (°C):	-
Flash point (°C):	37 (liquid)
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):	-
Solubility:	Solubility in water: Miscible (liquid)
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

None known.

10.4 Conditions to avoid

Avoid heating and contact with ignition sources.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

Section 11

Toxicological information

This product is a medical device and has been assessed in accordance with Directive 93/42/EEC on medical devices.

11.1 Information on toxicological effects

Information on likely routes of exposure: Inhalation, skin and ingestion

Symptoms:

Acute toxicity – oral: Ingestion may cause discomfort. The product does not have to be classified. Test data are not available for all substances.

Comfeel Cleanser (Wipe)

Acute toxicity - dermal:	CAS 67-63-0: LD ₅₀ (rat) = 5840 mg/kg (OECD Guideline 401) The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: LD ₅₀ (rabbit) = 13900 mg/kg (OECD Guideline 402)
Acute toxicity – inhalation:	The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: LC ₅₀ (rat), 6 hrs, vapour = 25000 mg/m ³ (OECD Guideline 403)
Skin corrosion/irritation:	May cause slight irritation. The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: May dry the skin (OECD404) The device has passed test for skin irritation according to ISO 10993-10
Serious eye damage/eye irritation:	Irritating to eyes. Causes a burning sensation and tearing. CAS 67-63-0: Irritating (OECD405)
Sensitisation:	The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: Not sensitizing (OECD406) The device has passed test for sensitization according to ISO 10993-10
Germ cell mutagenicity:	The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: Not expected to be a germ cell mutagen. (OECD 471, OECD 474, OECD 476)
Carcinogenic properties:	The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: Not expected to be a carcinogen. (OECD 451)
Reproductive toxicity:	The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: Not expected to be a reproductive toxicant. (OECD 414, OECD 415, OECD 416)
Single STOT exposure:	The product does not have to be classified. Test data are not available.
Repeated STOT exposure:	The product does not have to be classified. Test data are not available for all substances. CAS 67-63-0: Not expected to cause organ damage through prolonged or repeated exposure. (OECD 453)
Aspiration hazard:	The product does not have to be classified. Test data are not available.
Other toxicological effects:	None known.

Comfeel Cleanser (Wipe)

Section 12

Ecological information

12.1 Toxicity

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

CAS 67-63-0:

Acute toxicity:

LC₅₀ (Pimephales promelas, 96h) = 9640 mg/l

EC₅₀ (Daphnia magna, 48h) = 9714 mg/l

Chronic toxicity:

LOEC (Daphnia magna, 8d) = 1000 mg/l

12.2 Persistence and degradability

Not expected to be biodegradable.

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

Assessment to determine PBT and vPvB has not been made.

12.6 Other adverse effects

None known.

Section 13

Disposal considerations

13.1 Waste treatment methods

The recommended disposal technology at any approved facility. The disposal should always be in compliance with national, federal, state and local regulations. The product should not be discharged to the environment.

European Union

Avoid discharge to drain or surface water.

Collect spills and waste in closed, leak-proof containers for disposal at the local hazardous waste site.

EWC code: Depends on line of business and use, for instance 16 05 08* discarded organic chemicals consisting of or containing dangerous substances.

Absorbent/cloth contaminated with the product:

EWC code: 15 02 02 absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances.

Comfeel Cleanser (Wipe)

Section 14

Transport information

Comfeel Cleanser Wipes are individually packed sachets. Each sachet contains <10 ml of flammable liquid absorbed into a solid material. The product meets the special provisions SP216 (ADR/IMDG) and A46 (IATA) and does not need to be transported as fully regulated dangerous goods.

14.1 UN-no.:	3175
14.2 UN proper shipping name:	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)
14.3 Transport hazard class(es):	4.1
14.4 Packing group:	II
14.5 Environmental hazards:	No
14.6 Special precautions for user:	None
14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code:	Not applicable.

ADR - Classification:

- Classification code:	F1
- ADR limited Quantities:	1 kg
- Hazard label:	4

Special provisions applicable to certain articles or substance: 216, 274, 601.

IMDG - Classification:

- IMDG limited Quantities:	1 kg
- Hazard label:	4
EMS:	F-A, S-I

Special provisions applicable to certain articles or substance: 216, 274.

IATA - Classification:

- Hazard label:	4
-----------------	---

Transportation on road in other countries than ADR-countries:

US: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Canada: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)/ SOLIDES CONTENANT DU LIQUIDE INFLAMMABLE, N.S.A. (ISOPROPANOL)

Brazil: UN3175 SÓLIDOS CONTENDO LÍQUIDO INFLAMÁVEL, N.S.A. (ISOPROPANOL)

Australia: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

New Zealand: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Hongkong / China: UN3175 SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL)

Section 15

Regulatory information

Comfeel Cleanser (Wipe)

Covered by:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

Medical devices (93/42) are exempt from classification and labelling according to CLP (1272/2008).

Special provisions: None

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

Section 16

Other information

H-statements mentioned in section 2 and 3:

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H412 Harmful to aquatic life with long lasting effects.

Abbreviations:

PBT = Persistent, Bioaccumulative and Toxic

vPvB = Very Persistent and Very Bioaccumulative

STOT = Specific Target Organ Toxicity

Classification method:

Calculation based on the hazards of the known components.

Changes since the previous edition:

Not relevant.

Training:

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

Other information:

This safety data sheet has been prepared for and applies to this product only. It is based on our current knowledge and the information that the supplier was able to provide about the product 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.

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.

Comfeel Cleanser (Wipe)

The Change Log is added for the purpose of informing about the change between versions to Coloplast employees only.

Therefore, this page should not be printed or made available to customers outside of Coloplast

Change log

Version no.	Initials Issue Date (Month Year)	Short description of and reason for change
3.0	PLMITI, April 2019	Update to the Canadian address. Change log added. Change in the title from Material safety data sheet to Safety Data Sheet Alignment of version number between the document and Veeva. Several changes to the document.

Signature Page for VV-0097493 v3.0

Approved	DKMMB Maria Ahlm Matbjerg BioSafety Specialist Technical / Specialist 10-Apr-2019 13:48:29 GMT+0000
----------	--

Approved	DKAJL Anette Jansons Lauritzen Senior Specialist Biosafety and Chemical Compliance Technical / Specialist 25-Apr-2019 13:05:17 GMT+0000
----------	---

Signature Page for VV-0097493 v3.0
Document Owner: DKJDR Joan Drejer