

Prep Barrier Film

08. May 2017
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: Prep Barrier Film
Product code: 62041

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

Product information: Medical device.
The wipes are used for cleaning the skin area before application of stoma.

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.
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Minneapolis, MN 55411
Telephone: +1-800-533-0464
www.coloplast.com

Canada

Coloplast Canada Corporation
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Mississauga, Ont. L5L 5Z9
Telephone: +1-877-820-7008
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Europe

Coloplast A/S
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DK-3050 Humlebaek
Telephone: +45 49 11 11 11
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2.1 Classification of the substance or mixture

Classification according to Regulation (EC)

No 1272/2008:

Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3;
H336.

Wording of H-statements – see section 16.

Most serious harmful effects:

Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness.

Persons with a known allergy to Terpenes and terpenoids, sweet orange-oil may exhibit an allergic response to the product.

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 hazard statements are therefore only listed in the present MSDS and not necessarily present on the product labelling.

Hazard statement(s):

Highly flammable liquid and vapour.(H225)

Causes serious eye irritation.(H319)

May cause drowsiness or dizziness.(H336)

Precautionary statement(s):

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

Wear protective gloves.(P280)

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)

Supplemental information:

Contains Terpenes and terpenoids, sweet orange-oil. May produce an allergic reaction.
(EUH208)

2.3 Other hazards

Assessment to determine PBT and vPvB has not been made.

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Section 3

Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (EC 1272/2008)
50-75	67-63-0	200-661-7	-	-	Propan-2-ol	Flam. Liq. 2;H225 Eye Irrit. 2;H319 STOT SE 3;H336
0.1-1	71-36-3	200-751-6	-	-	Butan-1-ol	Flam. Liq. 3;H226 Acute Tox. 4; H302 STOT SE 3;H335 Skin Irrit. 2;H315 Eye Dam. 1;H318 STOT SE 3;H336
0,1-1	68647-72-3	-	-	-	Terpenes and terpenoids, sweet orange-oil	Flam. Liq. 3;H226 Skin Irrit. 2;H315 Skin Sens. ;H317 Aquatic Acute 1;H400 Aquatic Chronic 1;H410

Wording of H-statements - see section 16.

Section 4

First-AID measures

4.1 Description of first aid measures

Inhalation: Seek fresh air.

Skin Contact: Remove contaminated clothing. Wash the skin with water. Seek medical advice in case of persistent discomfort.

Eye Contact: Flush immediately with water (preferably using eye wash equipment) for at least 5 minutes. Open eye wide. Remove any contact lenses. Seek medical advice.

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.

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

4.2 Most important symptoms and effects, both acute and delayed

3/10

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Irritating to eyes. Causes a burning sensation and tearing. Inhalation of vapours may cause irritation to the upper airways. The product releases organic solvent vapours which may cause lethargy and dizziness. At high concentrations, the vapours may cause headache and intoxication. The product contains small amounts of Terpenes and terpenoids, sweet orange-oil. Persons with a known allergy may exhibit an allergic response to the product.

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. Extinguishing water which has been in contact with the product may be corrosive. 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: Stay upwind/keep distance from source. 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.

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Section 7 Handling and storage

7.1 Precautions for safe handling

Running water and eye wash equipment should be available. Wash hands before breaks, before using restroom facilities, and at the end of work. Use the product under well-ventilated conditions. Smoking and naked flames prohibited.

7.2 Conditions for safe storage, including any incompatibilities

Store safely and keep out of reach of children. Do not store with the following: Strong oxidisers.

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: Not required.

Personal protective equipment, skin protection: 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

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Appearance:	Yellow liquid (contained in wipes)
Odour:	Alcohol
pH:	-
Melting point / freezing point (°C):	-
Initial boiling point and boiling range (°C):	82 °C (liquid)
Decomposition temperature (°C):	-
Flash point (°C):	10 °C (liquid)
Evaporation rate:	-
Flammability (solid, gas):	-
Upper/lower flammability or explosive limits (vol-%):	20 - 120
Vapour pressure (hPa, 20°C):	-
Vapour density (air=1):	33 mmHg
Relative density (g/ml, 25°C):	0,85 (liquid)
Solubility:	Solubility in water: miscible (liquid)
Partition coefficient: n-octanol/water, Log K _{ow} :	-
Autoignition temperature (°C):	399 °C
Viscosity (mPa*s, 25°C):	-
Explosive properties:	-
Oxidising properties:	-

9.2 Other information:

None.

Section 10

Stability and reactivity

10.1 Reactivity

Reacts with the following: Strong oxidisers.

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

Strong oxidisers.

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

Toxicological data: None

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

Symptoms:

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Acute toxicity – oral:	Ingestion may cause discomfort. The product does not have to be classified. Test data are not available.
Acute toxicity - dermal:	The product does not have to be classified. Test data are not available.
Acute toxicity – inhalation:	The product does not have to be classified. Test data are not available.
Skin corrosion/irritation:	The product does not have to be classified. Test data are not available. Repeated exposure may cause skin dryness or cracking.
Serious eye damage/eye irritation:	Irritating to eyes. Causes a burning sensation and tearing.
Sensitisation:	The product contains small amounts of Terpenes and terpenoids, sweet orange-oil. Persons with a known allergy may exhibit an allergic response to the product. The product does not have to be classified.
Mutagenicity:	The product does not have to be classified. Test data are not available.
Carcinogenic properties:	The product does not have to be classified. Test data are not available.
Reproductive toxicity:	The product does not have to be classified. Test data are not available.
Single STOT exposure:	The product releases organic solvent vapours which may cause lethargy and dizziness. At high concentrations, the vapours may cause headache and intoxication.
Repeated STOT exposure:	The product does not have to be classified. Test data are not available.
Aspiration hazard:	The product does not have to be classified. Test data are not available.
Other toxicological effects:	None known.

Section 12 Ecological information

12.1 Toxicity

The product does not have to be classified. Test data are not available. The product contains small quantities of environmentally hazardous substances.

67-63-0:

Fish: Pimephales promelas: 96hLC50 = 5770 - 7450 mg/l

Crustacea: Daphnia magna: 48hEC50 = >10000 mg/l

71-36-3:

Fish: Lepomis macrochirus: 96hLC50 = 100 - 500 mg/l

Crustacea: Daphnia magna: 48hEC50 = 1897 - 2072 mg/l

12.2 Persistence and degradability

Expected to be biodegradable.

71-36-3: Readily biodegradable. (OECD 301E)

12.3 Bioaccumulative potential

67-63-0-I: Partition coefficient n-octanol/water: 0,05

71-36-3: Partition coefficient n-octanol/water: 0,88

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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.

67-63-0-I: COD (Chemical Oxygen Demand) = 0,00209 mg/g

71-36-3: COD (Chemical Oxygen Demand) = 2,45 mg/g

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. Contact the local authorities.

Absorbent/cloth contaminated with the product:

EWC code: 15 02 03 Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02.

Section 14

Transport information

14.1 UN-no.:	3175
14.2 UN proper shipping name:	-
14.3 Transport hazard class(es):	-
14.4 Packing group:	-
14.5 Environmental hazards:	-
14.6 Special precautions for user:	-
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	-

ADR - Classification:

- Classification code: -
- ADR limited Quantities: -
- Hazard label: -

Special provisions applicable to certain articles or substance: SP216

IMDG - Classification:

- IMDG limited Quantities: -

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- Hazard label: -
EMS: -

Special provisions applicable to certain articles or substance: SP216

IATA - Classification:
- Hazard label: -

Transportation on road in other countries than ADR-countries:

US: -
Canada: -
Brazil: -
Australia: -
New Zealand: -
Hongkong / China: -

Section 15 Regulatory information

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

Special provisions: None

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

Section 16 Other information

R-sentences and H-statements mentioned in section 2 and 3:

R10 Flammable.
R11 Highly flammable.
R22 Harmful if swallowed.
R36 Irritating to eyes.
R37/38 Irritating to respiratory system and skin.
R38 Irritating to skin.
R41 Risk of serious damage to eyes.
R43 May cause sensitisation by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R67 Vapours may cause drowsiness and dizziness.

H225 Highly flammable liquid and vapour.
H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.

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H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H400 Very toxic to aquatic life.
H410 Very toxic 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:

1-16

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.

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