

Coloplast Paste

08 May 2017
Version 5.0

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: Coloplast Paste
Product code: 02650

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

Product information: Coloplast Paste medical device used as an ostomy care accessory.

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 a medical device 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.

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.

USA

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Canada

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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:

FLAMMABLE SOLID; H228

Wording of H-statements – see section 16.

The product is a medical device and therefore not covered by the classification and labelling rules that apply to chemical products.

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 SDS and not necessarily present on the product labelling.

According to Regulation (EC) No 1272/2008:

Contains: Ethanol

Pictogram(s):

Signal word:



Danger

Hazard statement(s):

FLAMMABLE SOLID; H228

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Section 3

Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

The main ingredients are: Ethanol, Guar Gum, Isopropanol and Guar Gum.

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)
40-60	64-17-5-	200- 578-6-	603-002- 00-5-	None-	Ethanol-	Flam. Liq 2; H225-
3-6	67-63-0	200- 661-7	603-117- 00-0	None	Isopropanol	Flam. Liq. 2 H225

Wording of H-statements - see section 16.

Section 4

First-AID measures

4.1 Description of first aid measures

Inhalation: Move the affected person to fresh air. Keep at rest. If needed: Get medical attention.

Skin Contact: In case of skin problems: Seek medical advice.

Eye Contact: 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.

Immediately flush with water or physiological salt water for at least 15 minutes, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. Do not induce vomiting. If vomiting occurs keep head down to avoid vomit in the lungs. In case of discomfort: Seek medical advice.

Burns: Flush with water until pain ceases. Remove clothes that are not burnt to the skin. If needed seek medical attention, continue to flush on the way.

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

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4.2 Most important symptoms and effects, both acute and delayed

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

Show this Safety Data Sheet to a physician or emergency ward.

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 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.

Wear gloves.

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

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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). 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: Not relevant, as the product is intended for skin application product.

Personal protective equipment, respiratory protection: Not required.

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:	Paste
Odour:	Alcohol
pH:	Not relevant
Melting point / freezing point (°C):	Not relevant
Initial boiling point and boiling range (°C):	Not relevant
Decomposition temperature (°C):	Not determined
Flash point (°C):	Not determined
Evaporation rate:	Not determined
Flammability (solid, gas):	Not determined
Upper/lower flammability or explosive limits (vol-%):	Not determined
Vapour pressure (hPa, 20°C):	Not determined
Vapour density (air=1):	Not determined
Relative density (g/ml, 25°C):	Not determined
Solubility:	Not determined
Partition coefficient: n-octanol/water, Log K _{ow} :	Not relevant
Autoignition temperature (°C):	Not determined
Viscosity (mPa*s, 25°C):	Not determined
Explosive properties:	Not determined
Oxidising properties:	Not determined

9.2 Other information:

Not relevant

Section 10

Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

The product is stable under the advised storage condition – see section 7.

10.3 Possibility of hazardous reactions

No known

10.4 Conditions to avoid

No known

10.5 Incompatible materials

No known

10.6 Hazardous decomposition products

No known

Section 11

Toxicological information

This product is a medical device and has been subject to safety assessment in accordance with the requirements in ISO 10993-1.

11.1 Information on toxicological effects

The product is intended for skin application and has passed preclinical testing showing low risk of causing skin irritation and skin sensitisation.

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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

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.

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.

Section 14

Transport information

14.1 UN-no.:

1325

14.2 UN proper shipping name:

FLAMMABLE SOLID, ORGANIC,
N.O.S. (contains Ethanol)

14.3 Transport hazard class(es):

4.1

14.4 Packing group:

III

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14.5 Environmental hazards:

The product should not be labelled as an environmental hazard (symbol fish and tree)

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: F1
- ADR limited Quantities: 5 kg
- Hazard label: 4.1

Special provisions applicable to certain articles or substance: Not relevant

IMDG - Classification:

- IMDG limited Quantities: 5kg
- Hazard label: 4.1
- EMS: F-A, S-G

Special provisions applicable to certain articles or substance: Not relevant

IATA - Classification:

Hazard Label: 4.1

Transportation on road in other countries than ADR-countries:

US: 49 CFR: 1170 UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (contains Ethanol), 4.1, III. LQ=5kg

Canada: TDG: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (contains Ethanol), 4.1, III. LQ=5kg

Brazil: ANTT. 420 2004/2/12 with ammendments: UN1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (contains Ethanol), 4.1, III. LQ=5kg

Australia: ADG7: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (contains Ethanol), 4.1, III. LQ=5kg

Turkey: UN1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (contains Ethanol), 4.1, III. LQ=5kg

New Zealand: NZS 5433: UN 1325 FLAMMABLE SOLID, ORGANIC, N.O.S. (contains Ethanol), 4.1, III. LQ=5kg

Hongkong / China: As ADR

Section 15

Regulatory information

Covered by: 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

Special provisions: None

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

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Section 16

Other information

H-statements mentioned in section 2:

H228 Flammable solid

Abbreviations:

PBT = Persistent, Bioaccumulative and Toxic

vPvB = Very Persistent and Very Bioaccumulative

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.

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