

Critic-Aid® Skin Paste

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: Critic-Aid® Paste
Product code: 1944, 1947

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

Product information: OTC moisture barrier drug product

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.

2.1 Classification of the substance or mixture

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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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.

Most serious harmful effects:

H411: Toxic to aquatic life with long lasting effects.

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:

PETROLATUM, SODIUM CARBOXYMETHYL CELLULOSE, ZINC OXIDE, DIMETHICONE.

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

According to Regulation (EC) No 1272/2008:

Pictogram(s):

Signal word:



Warning

Hazard statement(s):

H411: Toxic to aquatic life with long lasting effects.

Precautionary statement(s):

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Section 3

Composition/information on ingredients

3.2 Mixtures

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

PETROLATUM, SODIUM CARBOXYMETHYL CELLULOSE, ZINC OXIDE, DIMETHICONE.

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Section 4

First-AID measures

4.1 Description of first aid measures

Inhalation: Seek fresh air.

Skin Contact: Not relevant as the product is intended for skin application.

Eye Contact: Flush with water (preferably using eye wash equipment) if irritation occurs.

Ingestion:

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

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

None

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

The product is not directly flammable. Choose extinguishing agents based on the surrounding fire. Do not use water stream, as it may spread the fire.

5.2 Special hazards arising from the substance or mixture

The product is not directly flammable. Avoid inhalation of vapour and fumes – seek fresh air.

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: Stop leak if this can be done without risk.

For emergency responders: In addition to the above:

6.2 Environmental precautions

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Prevent spillage from entering drains and/or surface water. Normal protective clothing equivalent to EN 469 is recommended.

6.3 Methods and materials for containment and cleaning up:

Contain and absorb spill with sand or other absorbent 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

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

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

Legal basis: Commission Directive 2000/39/EC. 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 required.

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

State:	Paste
Colour:	Off -white
Odour:	Weak.
Odour threshold:	No data
pH (concentrate):	No data
pH (solution for use):	No data
Melting point / freezing point (°C):	No data
Initial boiling point and boiling range (°C):	No data
Decomposition temperature (°C):	No data
Flash point (°C):	>100 °C
Evaporation rate:	No data
Flammability (solid, gas):	No data
Upper/lower flammability or explosive limits (vol-%):	No data
Vapour pressure (hPa, 20°C):	No data
Vapour density (air=1):	No data
Relative density (25°C):	No data
Solubility:	No data
Partition coefficient: n-octanol/water, Log K _{ow} :	No data
Auto-ignition temperature (°C):	No data
Viscosity (mPa*s, 25°C):	No data
Explosive properties:	No data
Oxidising properties:	No data

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 know.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None known.

Section 11

Toxicological information

This product is an OTC drug product and has been subject to safety assessment in accordance with the requirements for medical devices according to ISO 10993-1.

The safety assessment also complies 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.

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11.1 Information on toxicological effects

Toxicological data:

The product is an OTC drug product intended for skin application.

The product has passed tests for skin irritation and skin sensitisation.

Other toxicological effects:

None known.

Section 12

Ecological information

12.1 Toxicity

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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.

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Section 14

Transport information

CRITIC BARRIER PASTE IS NOT RESTRICTED, AS PER SPECIAL PROVISIONS 375 (ADR/RID), A197 (IATA), AND SECTION 2.10.2.7 OF IMDG.

14.1 UN-no.:	3082
14.2 UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)
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:	M7
- ADR limited Quantities:	5 kg
- Hazard label:	9

IMDG - Classification:

- IMDG limited Quantities:	5 kg
- Hazard label:	9
EMS:	F-A, S-F

IATA - Classification:

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

US: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

Canada: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide) /MATIÈRE DANGEREUSE DU POINT DE VUE DE L'ENVIRONNEMENT, SOLIDE, N.S.A. (oxyde de zinc)

Brazil: MATÉRIA PERIGOSA DO PONTO DE VISTA DO AMBIENTE, SÓLIDA, N.S.A. (óxido de zinco)

Australia: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

New Zealand: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

Hongkong / China: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc oxide)

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Section 15

Regulatory information

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

Council Directive 96/82/EC (Seveso), Dangerous for the environment: Column 2: 200 t, Column 3: 500 t.

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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