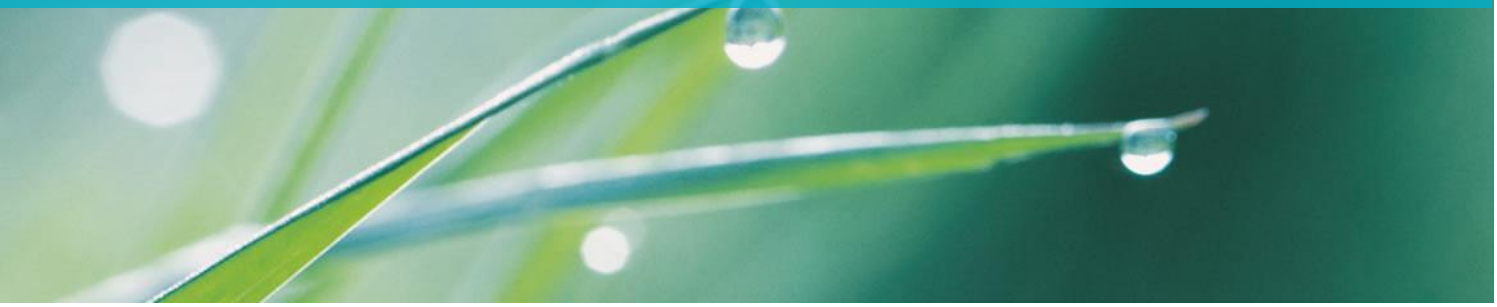
Critic Aid Clear Skin Protectant Barrier



13. March 2016
Version 3.0

Safety Data Sheet

Based on template version 3.0

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

Section 1
Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: Critic Aid Clear Skin Protectant Barrier
Product code: 7565, 7566, 7567, 7573.

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

Product information: OTC skin protectant/barrier drug.

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

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.

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, CELLULOSE GUM, DIMETHICONE, ZINC OXIDE, TOCOPHERYL ACETATE.

Section 3
Composition/information on ingredients

3.1 Substances
N/A

3.2 Mixtures

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

PETROLATUM, CELLULOSE GUM, DIMETHICONE, ZINC OXIDE, TOCOPHERYL ACETATE.

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. 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: Not relevant.

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
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.

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: 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 material and transfer to suitable waste containers Wipe up minor spills with a cloth.

6.4 Reference to other sections
See section 13 for instructions on disposal.

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.

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 measures: 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

Appearance:	Ointment
Colour:	Off-white
Odour:	Weak
Melting point / freezing point (°C):	60˚C
Initial boiling point and boiling range (°C):	No data
Decomposition temperature (°C):	No data
Flash point (°C):	No data
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 (g/ml, 25°C):	No data
Solubility:	No data
Partition coefficient: n-octanol/water, Log K_{ow}:	No data
Autoignition 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 known
10.5 Incompatible materials
None known.
10.6 Hazardous decomposition products
Carbon monoxide and carbon dioxide.

Section 11
Toxicological information
This product is an OTC drug product resembling 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 an OTC drug product resembling a cosmetic product and is intended for skin application. The product has passed dermatological testing showing low risk of causing skin irritation and skin sensitisation.

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
The product does not have to be classified. Test data are not available.
12.3 Bioaccumulative potential
The product does not have to be classified. Test data are not available.
12.4 Mobility in soil
The product does not have to be classified. Test data are not available
12.5 Results of PBT and vPvB assessment
The product does not have to be assessed. 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 Conversation 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.: Not relevant
14.2 UN proper shipping name: Not relevant
14.3 Transport hazard class(es): Not relevant
14.4 Packing group: Not relevant
14.5 Environmental hazards: Not relevant
14.6 Special precautions for user: Not relevant
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not relevant

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

Special provisions applicable to certain articles or substance: Not relevant

IATA - Classification: 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

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
None

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.

Signature Page for VV-0097501 v2.0

Approved by	DKPLYM Peter Lynge Madsen Senior Biosafety Specialist Technical / Specialist 17-Mar-2016 07:00:51 GMT+0000

Approved by	USDLG Donald Gerrish Innovation Support Manager Technical / Specialist 17-Mar-2016 15:50:21 GMT+0000

Signature Page for VV-0097501 v2.0
Document Owner: DKPLYM Peter Lynge Madsen