

Baza[®] Protect

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: Baza[®] Protect
Product code: 1873, 1877, 1880.

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.

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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2.1 Classification of the substance or mixture

The product is an OTC drug product and therefore not covered by the classification rules that apply to chemical products according to i.e. Regulation (EC) No 1272/2008.

2.2. Label elements

List of ingredients on label, listed with INCI-nomenclature according to Regulation (EC) No 1223/2009:

WATER (AQUA), PETROLATUM, ZINC OXIDE, LANOLIN OIL, PEG-40 STEARATE, PROPYLENE GLYCOL, CETYL ALCOHOL, GLYCERYL STEARATE, TRICONTANYL PVP, PEG-8 STEARATE, COD LIVER OIL (GADI LECUR OIL), TOCOPHERYL ACETATE, DIMETHICONE, BHT, QUATERNIUM-15, EDTA, FRAGRANCE(PARFUM).

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.

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: Zinc Oxide

Pictogram(s):

Signal word:



-

H411 Toxic to aquatic life with long lasting effects.

Section 3

Composition/information on ingredients

3.2 Mixtures

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

WATER (AQUA), PETROLATUM, ZINC OXIDE, LANOLIN OIL, PEG-40 STEARATE, PROPYLENE GLYCOL, CETYL ALCOHOL, GLYCERYL STEARATE, TRICONTANYL PVP, PEG-8 STEARATE, COD LIVER OIL (GADI LECUR OIL), TOCOPHERYL ACETATE, DIMETHICONE, BHT, QUATERNIUM-15, EDTA, FRAGRANCE(PARFUM).

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Section 4

First-AID measures

4.1 Description of first aid measures

Inhalation: Seek fresh air.

Skin Contact: The product is intended for skin application. Wash skin with soap and water.

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: 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

The product contains small amounts of Cis-1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (quaternium-15). 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.

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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.

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

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. Store at room temperature.

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.

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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: By handling of the product: Wear plastic or rubber protective gloves.

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

Appearance:	Semi-solid white cream
Odour:	Pleasant
pH:	6-7,5
Melting point / freezing point (°C):	0 °C
Initial boiling point and boiling range (°C):	-
Decomposition temperature (°C):	-
Flash point (°C):	-
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):	1,01
Solubility:	Solubility in water: Dispersible
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

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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 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 intended for skin application and has passed dermatological testing showing low risk of causing skin irritation and skin sensitisation.

In certain cases, the product may cause sensitization by skin contact. Especially, persons with a known allergy to quaternium-15 may exhibit an allergic response to the product. Symptoms include reddening, swelling, blistering and ulceration – often slowly developing. In case of these symptoms, discontinue use.

Other toxicological effects:

None known.

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Section 12

Ecological information

12.1 Toxicity

Toxic to aquatic life with long lasting effects.

Acute toxicity:

57-55-6-F:

Fish: Pimephales promelas: 96hLC50 = 710 mg/l

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

12.2 Persistence and degradability

3380-34-5-A: Readily biodegradable.

57-55-6-F: Readily 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

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

14.1 UN-no.:	3082
14.2 UN proper shipping name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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:	M6
- ADR limited Quantities:	5 l
- Hazard label:	9

Special provisions applicable to certain articles or substance: Not relevant

IMDG - Classification:

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

Special provisions applicable to certain articles or substance: Not relevant

IATA - Classification:

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

US: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

Canada: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc Oxide) / MATIÈRE DANGEREUSE DU POINT DE VUE DE L'ENVIRONNEMENT, LIQUIDE, N.S.A (Oxyde de zinc)

Brazil: UN3082 MÁTERIA PERIGOSA DO PONTO DE VISTA DO AMBIENTE, LÍQUIDA, N.S.A. (Óxido de zinco)

Australia: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

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

Hongkong / China: UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

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Section 15 Regulatory information

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.

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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