Brava® Skin Barrier Spray

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Version 2.0

Safety Data Sheet

Based on template version 3.0

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

1.1 Product identifier

Product name:	Brava® Skin Barrier Spray
Product code:	12020
Product description:	Pump spray
Product content:	50 ml (~40 g)

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

Product information:	Medical device, Class 1. A skin barrier spray which provides a thin protective layer on the skin.

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
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Section 2
Hazards identification

This product is regulated as a medical device in 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.

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:
Flam. Liq. 2;H225 Aquatic Acute 1;H400

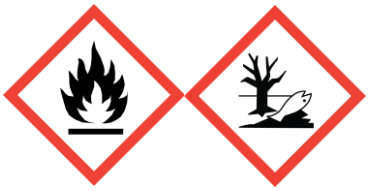
Wording of H-statements – see section 16.

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 MSDS and not necessarily present on the product labelling.

Pictogram(s):



Signal word:

Danger

Hazard statement(s):
H225: Highly flammable liquid and vapour.
H400: Very toxic to aquatic life.

Precautionary statement(s):
P210: Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233: Keep container tightly closed.
P243: Take precautionary measures against static discharge.
P273: Avoid release to the environment.

2.3. Other hazards: None.
PBT/vPvB: No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

Section 3
Composition/information on ingredients

3.2 Mixtures

The main ingredients are:

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (EC 1272/2008)
90-95	107-46-0	203-492-7	-	01-2119496108-31	Hexamethyl-disiloxane	Flam. Liq. 2;H225 Aquatic Acute 1;H400 (M=1)

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: This product is intended to be in contact with the skin when used as directed in the instructions for use. In case of skin problems: Seek medical advice.

Eye Contact: Immediately flush with water or physiological salt water, 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 dis-comfort: 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.

4.2 Most important symptoms and effects, both acute and delayed

May cause irritation to skin, eyes and respiratory tract.

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

Use water spray, carbon dioxide, dry chemical or foam.

5.2 Special hazards arising from the substance or mixture

Do not inhale smoke fumes.
In case of fire, the product may form hazardous decomposition products: Primarily oxides of carbon, nitrogen and silica. Vapours may form explosive mixtures with air. Take precautionary measures against static discharge.

5.3 Advice for firefighters

Remove containers if possible or keep containers cool by spraying with water.
Use breathing apparatus with an independent source of air.

Section 6
Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment - see section 8. Remove sources of ignition. Ventilate area of leak or spill.

6.2 Environmental precautions
Do not empty into drains - see section 12. Inform appropriate authorities in accordance with local regulations.

6.3 Methods and materials for containment and cleaning up
Absorb spilled liquid with absorbent material and place in a suitable container with a lid for disposal. The spilled product produces an extremely slippery surface. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

6.4. Reference to other sections
Reference to other sections: See references above.

Section 7
Handling and storage

7.1 Precautions for safe handling
Avoid breathing vapours/spray/mists. Provide adequate ventilation.
Keep this material out of reach of children
Avoid contact with eyes.
Never to be handled close to fire, sparks and hot surfaces - No smoking.
Do not empty into drains.
Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

7.2 Conditions for safe storage, including any incompatibilities
Store in a cool and ventilated area. Keep container tightly closed.
Storage must be in compliance with all regulatory requirements pertaining to flammable liquids. Fire class (DK): I-1. 1 Storage unit = 1 Liter.

Danish storage requirements: Keep locked up and out of reach of unauthorized personnel, and separated from food, feed etc.

7.3 Specific end use(s)
See section 1.2.

Section 8
Exposure controls/personal protection
8.1 Control parameters

Denmark (AT): None

PNEC:

Medium	Value
Freshwater	0,002 mg/l
Seawater	0,0002 mg/l
Intermittent release	0,003 mg/l
Sediment freshwater	1,7 mg/kg
Sediment seawater	0,17 mg/kg
Soil	0,083 mg/kg
STP	10 mg/l

DNEL:

Exposure	Value	Population	Effects
Long term, inhalation	890 mg/m^3	Worker	Systemic
Long term, dermal	126 mg/kg/bw/d	Worker	Systemic
Long term, inhalation	266 mg/m^3	Gen.Popul.	Systemic
Long term, dermal	25 mg/kg/bw/d	Gen.Popul.	Systemic

8.2 Exposure controls

Appropriate engineering measures: Provide adequate ventilation.
Personal protective measures:

Inhalation:	In case of inadequate ventilation: Use an approved mask (EN 140) with gas filter type A (brown - for organic vapors). The filter has a limited lifetime and must be changed. Read the instruction.
Skin:	Gloves are not normally required.
Eyes:	Tightly fitting safety goggles when there is risk of eye contact (EN 166).
Environmental exposure controls:	See section 6 and 13.

Section 9
Physical and chemical properties
9.1 Information on basic physical and chemical properties

Appearance:	Colorless liquid in Pump spray
Odour:	Characteristic
pH:	Not determined
Melting point / freezing point (°C):	-68 (Hexamethyldisiloxane)
Initial boiling point and boiling range (°C):	100 (Hexamethyldisiloxane)
Decomposition temperature (°C):	Not determined
Flash point (°C):	-3.3 (Hexamethyldisiloxane)
Evaporation rate:	Not determined
Flammability (solid, gas):	Not relevant
Upper/lower flammability or explosive limits (vol-%):	1.5-14.65 (Hexamethyldisiloxane)
Vapour pressure (kPa, 20°C):	4.2 (Hexamethyldisiloxane)
Vapour density (air=1):	Not determined
Relative density (g/ml, 25°C):	0.76 (Hexamethyldisiloxane)
Solubility:	Not miscible with water
Partition coefficient: n-octanol/water, Log K_{ow}:	4.76
Autoignition temperature (°C):	352 (Hexamethyldisiloxane)
Viscosity (mm2/s, 25°C):	0.65 (Hexamethyldisiloxane)
Explosive properties:	No. Vapours may form explosive mixtures with air
Oxidising properties:	Not relevant

9.2 Other information:
None relevant.

Section 10
Stability and reactivity

10.1 Reactivity
No available data.

10.2 Chemical stability
The product is stable under the advised storage conditions – see section 7.

10.3 Possibility of hazardous reactions
Vapors can be set on fire by sparks or hot surfaces. Vapors may form explosive mixtures with air. Vapors are at normal temperature heavier than air and may spread along the floor etc.

10.4 Conditions to avoid
Avoid creating sparks and hot surfaces including heating.

10.5 Incompatible materials
Exothermic reaction with oxidizing agents. Strong acid and strong alkali.

10.6 Hazardous decomposition products

When heated to high temperatures (decomposition), toxic gasses are formed such as oxides of carbon and nitrogen.

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:

Hazard class	**Data** (Hexamethyldisiloxane)	**Test**	**Reference**
Acute toxicity: Inhalation Dermal Oral	 LC_{50} (rat) = 106 mg/l/4H LD_{Lo} (rabbit) > 2000 mg/kg LD_{50} (rat) > 12160 mg/kg	 OECD 403 OECD 402 No info.	 ECHA diss. ECHA diss. ECHA diss.
Corrosion/irritation:	No skin irritation, rabbit No eye irritation, rabbit	No info. No info.	ECHA diss. ECHA diss.
Sensitization:	No skin sensitization, human	No info.	ECHA diss.
CMR:	No CMR effects.	Miscellaneous	ECHA diss.

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

Inhalation: May cause irritation of the respiratory tract.
Skin: May cause irritation.
Eyes: May cause irritation with redness.
Ingestion: May cause irritation of the gastrointestinal tract with discomfort.
Chronic effects: None known.

Section 12
Ecological information

12.1 Toxicity

Aquatic	**Data** (Hexamethyldisiloxane)	**Test (Mediu)**	**Reference**
Fish	LC_{50} (Oncorhynchus mykiss, 96h) = 0.46-3.02 mg/l	No info	ECHA diss.
Crustaceans	EC_{50} (Daphnia magna, 48h) = 0.2 mg/l	No info	ECHA diss.
Algea	EC_{50} (Pseudokirchnerella subcapitata, 70h) = 0.18 mg/l	No info	ECHA diss.

12.2 Persistence and degradability
Hexamethyldisiloxane: Poorly biodegradable. The substance may cause longterm effects in the aquatic environment, if not evaporated into air.

12.3 Bioaccumulative potential
Hexamethyldisiloxane: 3 ≤ Log Kow < 5 - moderate bioaccumulative effect may be expected for the substance, if not evaporated into air.

12.4 Mobility in soil
Hexamethyldisiloxane:
K_{oc} > 350 - Medium to very low mobility in soil, if not evaporated into air.

12.5 Results of PBT and vPvB assessment
No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

12.6 Other adverse effects
None known.

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

European Union: According to The European Waste Catalogue (EWC), in accordance with EC Directive 75/442/EEC, the following Waste Code can be used:
18 01 06 Chemicals containing hazardous substances.
15 02 02 absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances

However, if the waste in view of the prevention of infection needs special requirements, other Waste Codes should be used. It is the responsibility of the holder of the waste to determine the actual classification. Waste from private household may be disposed of together with other household waste.
Danish waste group (NORD): H

Section 14
Transport information ADR / IMDG / IATA

14.1 UN-no.:	1993
14.2 UN proper shipping name:	FLAMMABLE LIQUID, N.O.S. (HEXAMETHYLDISILOXANE)
14.3 Transport hazard class(es):	3
14.4 Packing group:	II
14.5 Environmental hazards:	Yes.
14.6 Special precautions for user:	None.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: None
EmS: F-E, S-E.

ADR
UN1993 FLAMMABLE LIQUID, N.O.S. (HEXAMETHYLDISILOXANE) 3, II
Classification code: F1
ADR limited Quantities 1 L

IMDG
UN1993 FLAMMABLE LIQUID, N.O.S. (HEXAMETHYLDISILOXANE) 3, II
IMDG limited quantities 1 Liter
EMS: F-E, S-E

IATA
UN1993 FLAMMABLE LIQUID, N.O.S. (HEXAMETHYLDISILOXANE) 3, II

Transportation on road in other countries than ADR-countries:
US: UN1993 FLAMMABLE LIQUID, N.O.S. (HEXAMETHYLDISILOXANE) 3, PGII, MP
Canada: UN1993 FLAMMABLE LIQUID, N.O.S./ LIQUIDE INFLAMMABLE, N.S.A. (HEXAMETHYLDISILOXANE) 3, PGII, MP
Brazil: UN1993 LÍQUIDO INFLAMMÁVEL, N.E. (HEXAMETHYLDISILOXANE) 3, PGII, MP
Australia: UN1993 FLAMMABLE LIQUID, N.O.S. (HEXAMETHYLDISILOXANE) 3, PGII, MP
New Zealand: UN1993 FLAMMABLE LIQUID, N.O.S. (HEXAMETHYLDISILOXANE) 3, PGII, MP
Hongkong / China: UN1993 FLAMMABLE LIQUID, N.O.S./ 易燃液体,未另列明的 (HEXAMETHYLDISILOXANE) 3, PGII, MP

Section 15
Regulatory information
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Medical devices (93/42) is exempt from classification and labelling according to CLP (1272/2008).
Other labelling:
The product must be labelled according to the provisions laid down in the Council directive 93/42/EEC on Medical devices. Class I.

15.2 Chemical Safety Assessment:
CSR has been prepared for Hexamethyldisiloxane.

Section 16
Other information
H-statements mentioned in section 2 and 3:

H225: Highly flammable liquid and vapour.
H400: Very toxic to aquatic life.

Abbreviations:
At. = Arbejdstilsynet
CMR = Carcinogenicity, mutagenicity and reproductive toxicity
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
EC_{50} = Effect Concentration 50 %
GPMT = Guinea Pig Maximization Test
LC_{50} = Lethal Concentration 50 %
MAK = Maximale ArbeitsplatzKonzentrationen
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative

Literature references:
ECHA diss. = REACH Registreringsdossier fra ECHA's hjemmeside.
IUCLID = International Uniform Chemical Database Information

Legislation reference:
This SDS is prepared to comply with EC regulation no. 1907/2006 (REACH). This product is assessed in accordance with Directive 93/42/EEC on Medical devices including Directive 1999/45/EC and Regulation (EC) no. 1272/2008 on classification, labelling and packaging.

Other information:
Prepared from the information, which was available to Altox a/s on December 18th 2013.

Changes since the previous edition:
Not relevant.

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Approved by	DKPLYM Peter Lynge Madsen Senior Biosafety Specialist Technical / Specialist 04-Aug-2015 07:36:20 GMT+0000

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