

Brava[®] Skin Barrier Spray

2. December 2022
Version 6.0

Safety Data Sheet

Based on template version 8.0

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
Net Content	50 ml

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

Product information:	Medical device. A skin barrier spray which provides a thin protective layer on the skin.
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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
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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 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. Labelling of the product is prepared in accordance with European Union Medical Device Regulation (EU) 2017/745

USA

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Canada

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Europe

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2.1 Classification of the substance or mixture

Classification according to Regulation (EC)

No 1272/2008:

Flammable Liquid 2; H225

Aquatic Acute 1; H400 Aquatic Chronic 2; H411

Classification according to Directive 67/548/EEC or
1999/45/EC and later amendments: not classified

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.

According to Regulation (EC) No 1272/2008:

Contains: Hexamethyldisiloxane

Pictogram(s):

Signal word:
Danger



Hazard statement(s):

Highly flammable liquid and vapour (H225)

Very toxic to aquatic life with long lasting effects (H410)

Precautionary statement(s):

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking (P210)

Do not spray on an open flame or other ignition source (P211)

Do not pierce or burn, even after use (P251)

Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122°F (P410/412)

Avoid release to the environment (P273)

Collect spillage (P391)

Other labelling:

Not relevant

2.3 Other hazards

The product contains a PBT/vPvB substance (Cyclopentasiloxane).

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Section 3

Composition/information on ingredients

The product contains Substance of Very High Concern (SVHC) in a concentration above 0.1% w/w according to the candidate list, article 59 (10) European REACH regulation (EC) No. 1907/2006.

This substance is cyclopentasiloxane D5 (CAS # 541-02-6) and it is of concern due to environmental toxicity.

3.1 Substances

N/A

3.2 Mixtures

The main ingredients are: Hexamethyldisiloxane, Cyclopentasiloxane

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)	Note
85-95	107-46-0	203-492-7	-	01-2119496108-31	Hexamethyl-disiloxane	Flam. Liq. 2;H225 Aquatic Acute 1;H400 Aquatic Chronic 2;H411	*
5-10	541-02-6	208-764-9	-	01-2119511367-43	Cyclopentasiloxane	Not classified.	**, ***

*: M factor (acute) = 1

**: The substance is included in the candidate list (SVHC), Regulation 1907/2006/EC, Article 59.

***: The substance is comprised by Regulation 1907/2006/EC, Annex XVII concerning restrictions.

Wording of H-statements - see section 16.

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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 stated in the instructions for use. In case of skin problems: Seek medical advice.

Eye Contact:

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.

4.2 Most important symptoms and effects, both acute and delayed

May cause slight irritation to the skin and eyes. Inhalation of spray mist may cause irritation to the upper air-ways.

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

Firefighting measures

5.1 Extinguishing media

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.

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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 paper towel. Place in a suitable container for disposal. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

6.4 Reference to other sections.

Please see the references above

Section 7

Handling and storage

7.1 Precautions for safe handling

Use the product under well-ventilated conditions. 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. Pressurized container: Protect from sunlight and do not expose to temperatures exceeding 50°C/122°F.

7.3 Specific end use(s)

See section 1.2.

Section 8

Exposure controls/personal protection

8.1 Control parameters

Commission Directive 2000/39/EC (Occupational Exposure Limits) as subsequently amended. Last amended by Commission Directive 2017/164/EU.

Contains no substances subject to reporting requirements.

Derived No-Effect Level (DNEL):

CAS 107-46-0:

Worker:

Dermal; systemic (acute) systemic (long term) 126 mg/kg/day

By inhalation; systemic (acute) 890 mg/m³, 134 ppm

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systemic (long term)

Consumer:

Dermal; systemic (acute) systemic (long term)	25 mg/kg/day
By inhalation; systemic (acute) systemic (long term)	266 mg/m ³ , 40 ppm
Oral; systemic (long term)	25 mg/kg/day

CAS 541-02-6:

Worker:

By inhalation; systemic (acute) systemic (long term)	97,3 mg/m ³
By inhalation; local (acute) local (long term)	24,2 mg/m ³

Consumer:

By inhalation; systemic (acute) systemic (long term)	17,3 mg/m ³
By inhalation; local (acute) local (long term)	4,3 mg/m ³
Oral; systemic (acute) systemic (long term)	5 mg/kg/day

Predicted No Effect Concentration (PNEC):

CAS 107-46-0:

Freshwater	0,008 mg/l
Marine water	0,0008 mg/l
Intermittent release	0,05 mg/l
Sediment (freshwater)	0,065 mg/kg wet weight
Sediment (marine water)	0,0065 mg/kg wet weight
Soil	0,25 mg/kg wet weight
Sewage treatment plant	10 mg/l
Secondary poisoning	67 mg/kg food

CAS 541-02-6:

Fresh water	> 0,0012 mg/l
Marine water	> 0,00012 mg/l
Fresh water sediment	2,4 mg/kg
Marine sediment	0,24 mg/kg
Soil	1,1 mg/kg
Sewage treatment plant	10 mg/l

8.2 Exposure controls

Engineering measures: Wear the personal protective equipment specified below.

Personal protective measures:

Personal protective equipment, eye/face protection: Not required.

Personal protective equipment, skin protection: By handling of the product: Plastic or rubber gloves recommended.

Personal protective equipment, respiratory protection: Not required.

Exposure hazard: 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

Physical state:	Liquid
Colour:	-
Odour:	characteristic
pH:	-
Melting point / freezing point (°C):	-68 (Hexamethyldisiloxane)
Boiling point or initial boiling point and boiling range (°C):	100 (Hexamethyldisiloxane)
Flammability:	-
Lower and upper explosion limit (°C):	0,68-26 (Hexamethyldisiloxane)
Flash point (°C):	-6 (Hexamethyldisiloxane)
Auto-ignition temperature (°C):	340 (Hexamethyldisiloxane)
Decomposition temperature (°C):	-
pH:	-
Kinematic viscosity (mm ² /s):	-
Solubility:	<0,001 g/l (Hexamethyldisiloxane)
Partition coefficient: n-octanol/water (log value):	>4 (25 °C) (Hexamethyldisiloxane)
Vapour pressure (hPa, 0°C):	44 (Hexamethyldisiloxane)
Density and/or relative density (g/cm ³):	approx. 0,76 (Hexamethyldisiloxane)
Relative vapour density (g/cm ³ , 20°C):	-
Particle characteristics:	-

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 – see section 7.

10.3 Possibility of hazardous reactions

Vapours may form explosive mixtures with air.

10.4 Conditions to avoid

Avoid heating and contact with ignition sources. Avoid direct sunlight. Store at temperatures below 50°C/122°F.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

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Section 11

Toxicological information

This product is a medical device and has been assessed in accordance with European Union Medical Device Regulation (EU) 2017/745.

11.1 Information on hazard classes as defined in Regulation (EC) No. 1272/2008

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

Symptoms related to the physical, chemical and toxicological characteristics:

Acute toxicity – oral:	Spray mist in mouth may irritate mucous membranes in mouth and throat. The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 107-46-0: LD ₅₀ (rat) > 16 ml/kg (test report) CAS 541-02-6: LD ₅₀ (rat) > 34 600 mg/kg (estimated)
Acute toxicity - dermal:	The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 107-46-0: LD ₅₀ (rabbit) > 2000 mg/kg (test report, OECD402)
Acute toxicity – inhalation:	The product does not have to be classified. Based on existing data, the classification criteria are deemed not to have been met. CAS 107-46-0: LC ₅₀ (rat) = 106 mg/l/4h (test report, OECD403) CAS 541-02-6: LC ₅₀ (rat) = 8,67 mg/l/4h (dust/mist)
Skin corrosion/irritation:	May cause slight irritation. The product does not have to be classified. Test data are not available for all substances. CAS 107-46-0: Rabbit – not irritating (test report, OECD404) The device has passed test for skin irritation according to ISO 10993-10
Serious eye damage/eye irritation:	Temporary irritation. The product does not have to be classified. Test data are not available for all substances. CAS 107-46-0: Rabbit – not irritating (test report, OECD405)
Sensitisation:	The product does not have to be classified. Test data are not available for all substances. CAS 107-46-0: Human – not sensitizing (test report, human skin patch test) The device has passed test for sensitization according to ISO 10993-10
Germ cell mutagenicity:	The product does not have to be classified. Test data are not available for all substances. CAS 107-46-0: Negative - mutation assay (in vitro) (test report, OECD 471, OECD 476) Negative – chromosome aberration assay (in vitro, in vivo) (test report, OECD 473, OECD 475)
Carcinogenic properties:	The product does not have to be classified. Test data are not available for all substances.

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	CAS 107-46-0: NOAEC: $\geq 33,2$ mg/l (test report, OECD 453)
Reproductive toxicity:	The product does not have to be classified. Test data are not available for all substances.
	CAS 107-46-0: NOAEC: $\geq 33,2$ mg/l, two generation study, rat (test report, EPA OPPTS 870.3800 + 870.6300)
Single STOT exposure:	Inhalation of spray mist may cause irritation to the upper airways. The product does not have to be classified. Test data are not available.
Repeated STOT exposure:	The product does not have to be classified. Test data are not available for all substances.
	CAS 107-46-0: NOAEC: $\geq 33,2$ mg/l (test report, OECD 453) NOAEL: ≥ 1000 mg/kg (test report, OECD 407, OECD 410)
Aspiration hazard:	The product does not have to be classified. Test data are not available.
Other toxicological effects:	None known.
Inhalation:	Inhalation of aerosols may cause irritation of the respiratory tract.
Skin:	Prolonged contact may cause slight irritation.
Eyes:	May cause irritation with redness.
Ingestion:	In general, not relevant
Chronic effects:	Not known

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not relevant

11.2.2 Other information

None

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Section 12

Ecological information

12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

CAS 107-46-0:

Acute toxicity:

LC₅₀ (Oncorhynchus mykiss, 96h) = 0,46 mg/l (test report, OECD 203)

EC₅₀ (Daphnia magna, 48h) = 0,35 mg/l (test report, OECD 202)

IC₁₀ (Selenastrum capricornutum, 96h) = 0,14 mg/l (test report, OECD 201)

Chronic toxicity:

NOEC (Daphnia magna, 21d) = 0,85 mg/l (test report, OECD 211)

CAS 541-02-6:

Acute toxicity:

LC₅₀ (Oncorhynchus mykiss, 96h) = 16 µg/l (test report, OECD 204)

EC₅₀ (Daphnia magna, 48h) > 2,9 mg/l (test report, OECD 202)

ErC₅₀ (Pseudokirchneriella subcapitata, 96h) > 0,012 mg/l

Chronic toxicity:

NOEC (Oncorhynchus mykiss, 90d) > 0,014 mg/l

NOEC (Daphnia magna, 21d) = 0,15 mg/l

12.2 Persistence and degradability

Not expected to be biodegradable.

CAS 107-46-0: Not readily biodegradable. (test report, OECD 301C)

CAS 541-02-6: Not readily biodegradable. (test report, OECD 310)

12.3 Bioaccumulative potential

The product is potentially bioaccumulative.

CAS 107-46-0: Log_{KOW} >4

CAS 541-02-6: Log_{KOW} 5,2 (measured)

12.4 Mobility in soil

Expected to be mobile in soil.

CAS 107-46-0: Log_{KOC}: 2,53

CAS 541-02-6: Log_{KOC}: >5000 (estimated)

12.5 Results of PBT and vPvB assessment

The product contains a PBT/vPvB substance (Cyclopentasiloxane).

12.6 Endocrine disrupting properties

Not relevant

12.7 Other adverse effects

No additional adverse effects to add

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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

Avoid discharge to drain or surface water.

Collect spills and waste in closed, leak-proof containers for disposal at the local hazardous waste site.

EWC code: Depends on line of business and use, for instance 16 05 08* discarded organic chemicals consisting of or containing dangerous substances.

Section 14

Transport information

14.1 UN number or ID number:	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 Maritime transport in bulk according to IMO instruments:	Not relevant

ADR - Classification: UN1993 FLAMMABLE LIQUID,
N.O.S. (HEXAMETHYL-
DISILOXANE) 3, II

- Classification code: F1
- ADR limited Quantities: 1 L
- Hazard label:



Special provisions applicable to certain articles or substance:

IMDG - Classification: UN1993 FLAMMABLE LIQUID,
N.O.S. (HEXAMETHYL-
DISILOXANE) 3, II

- Classification code:
- IMDG limited Quantities: 1 Liter

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- Hazard label:



Special provisions applicable to certain articles or substance:

IATA - Classification: UN1993 FLAMMABLE LIQUID,
N.O.S. (HEXAMETHYL-
DISILOXANE) 3, II

Hazard Label:



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

Covered by:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

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

Medical devices are exempt from classification and labelling according to CLP (1272/2008).

Special provisions:

Directive 2012/18/EU (Seveso), E1 Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1: Column 2: 100 t, Column 3: 200 t.

Special care should be applied for employees under the age of 18. Young people under the age of 18 may not carry out any work causing harmful exposure to this product.

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The product contains at least one substance comprised by Regulation 1907/2006/EC, Article 59 (SVHC).

The product contains at least one substance comprised by Regulation 1907/2006/EC, Annex XVII concerning restrictions.

15.2 Chemical safety assessment:

Chemical safety assessment has not been performed.

Section 16

Other information

H-statements mentioned in section 2 and 3:

H225 Highly flammable liquid and vapour.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC₅₀ = Effect Concentration 50 %

GPMT = Guinea Pig Maximization Test

LC₅₀ = Lethal Concentration 50 %

MAK = Maximale ArbeitsplatzKonzentrationen

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

Literature references:

IUCLID = International Uniform Chemical Database Information

Legislation reference:

This SDS is prepared to comply with EC regulation no. 1907/2006 (REACH) and Commission Regulation (EU) 2020/878

Changes since the previous edition:

Not relevant.

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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Change log

Version no.	Issue Date (Month Year)	Short description of and reason for change
3.0	March 2019	Update to the Canadian address. Change log added. Change in the title from Material safety data sheet to Safety Data Sheet Alignment of version number between the document and Veeva. Several changes to the document due to an ingredient has entered the REACH list for Substances of Very high Concern, and has environmental concern.
4.0	August 2019	UN number in section 14.1 has been corrected.
5.0	August 2019	Section 14 has been corrected.
6.0	December 2022	Updated to template 8.0