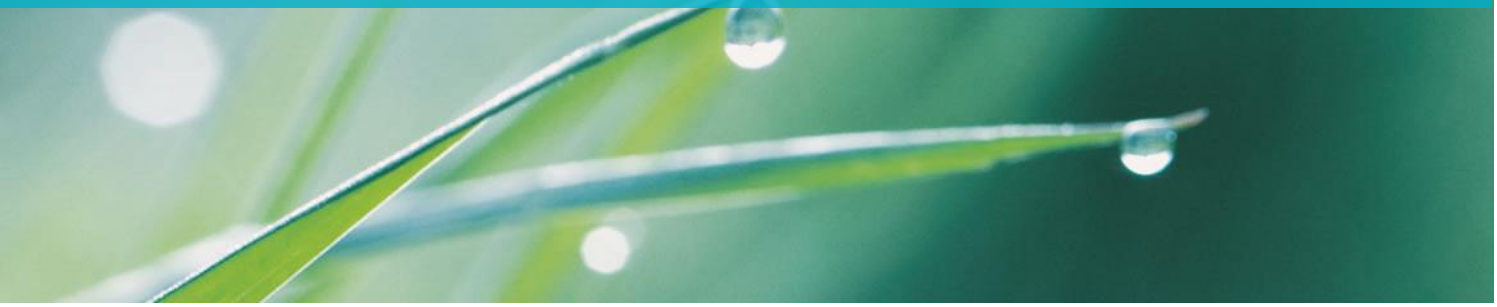
Brava® Adhesive Remover Spray



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Version 4.0

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® Adhesive Remover Spray
Product code:	12010
Product description:	Aerosol Dispenser
Net Content	50 ml

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

Product information:	Medical device. Aerosol dispenser used for removal of adhesive residues left 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
(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 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:
Aerosol 1;H222
Aerosol 3;H229
Aquatic Acute 1;H400 Aquatic Chronic 2; H411

Wording of H-statements – see section 16.

Most serious harmful effects:
May cause slight irritation to the skin and eyes.
Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.
Vapours may form explosive mixtures with air.

Other labeling

H229: Pressurised container: May burst if heated.

According to Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to Aerosol Dispensers:

Compliance with Aerosol Dispenser Directive 75/324/EEC

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:

Pictogram(s):

Signal word:
Danger

Hazard statement(s):
Extremely flammable aerosol.(H222)
Pressurised container: May burst if heated.(H229)
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 no expose to temperatures exceeding 50 °C/122°F.(P410/412)
Avoid release to the environment. (P273)
Collect spillage. (P391)

2.3 Other hazards
The product contains a PBT/vPvB substance (cyclopentasiloxane).

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 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
95-100	107-46-0	203-492-7	-	01-2119496108-31	Hexamethyldisiloxane	Flam. Liq. 2;H225 Aquatic Acute 1;H400 Aquatic Chronic 2;H411	*
0,1-2	541-02-6	208-764-9	-	01-2119511367-43	Cyclopentasiloxane	Not classified.	**, ***

Wording of H-statements - see section 16.

*: 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.

Section 4
First aid measures

4.1 Description of first aid measures
Inhalation: Seek fresh air. Seek medical advice in case of persistent discomfort.

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: 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: Flush with water until pain ceases. Remove clothing that is not stuck to the skin – seek medical advice/transport to hospital. If possible, continue flushing until medical attention is obtained.

Other information: When obtaining medical advice, show the safety data sheet or label.

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
Treat symptoms. No special immediate treatment required.

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
Heating will cause a rise in pressure in packaging with a risk of bursting.
CAUTION! Aerosol containers may explode.

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: Stay upwind/keep distance from source. Provide adequate ventilation. Smoking and naked flames prohibited.

For emergency responders: In addition to the above: Normal protective clothing equivalent to EN 469 is recommended.

6.2 Environmental precautions

Avoid unnecessary release to the environment.

6.3 Methods and materials for containment and cleaning up:

Wipe up drops and splashes 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

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)

None.

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) systemic (long term)	890 mg/m³, 134 ppm
Consumer:	
Dermal; systemic (acute) systemic (long term)	25 mg/kg/day
By inhalation; systemic (acute) systemic (long term)	266 mg/m³, 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/m³
By inhalation; local (acute) local (long term)	24,2 mg/m³
Consumer:	
By inhalation; systemic (acute) systemic (long term)	17,3 mg/m³
By inhalation; local (acute) local (long term)	4,3 mg/m³
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

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: Plastic or rubber gloves recommended.

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:	aerosol
Odour:	characteristic
pH:	-
Melting point / freezing point (°C):	-68 (Hexamethyldisiloxane)
Initial boiling point and boiling range (°C):	100 (Hexamethyldisiloxane)
Decomposition temperature (°C):	-
Flash point (°C):	-6 (Hexamethyldisiloxane)
Evaporation rate:	-
Flammability (solid, gas):	-
Upper/lower flammability or explosive limits (vol-%):	0,68-26 (Hexamethyldisiloxane)
Vapour pressure (hPa, 20°C):	44 (Hexamethyldisiloxane)
Vapour density (air=1):	-
Relative density (g/ml, 25°C):	approx. 0,76 (Hexamethyldisiloxane)
Solubility:	<0,001 g/l (Hexamethyldisiloxane)
Partition coefficient: n-octanol/water, Log K_{ow}:	>4 (25 °C) (Hexamethyldisiloxane)
Autoignition temperature (°C):	340 (Hexamethyldisiloxane)
Viscosity (mPa*s, 25°C):	0,5 (Hexamethyldisiloxane)
Explosive properties:	Vapours may form explosive mixtures with air.
Oxidising properties:	-

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
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.

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

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

Symptoms:

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. CAS 107-46-0: NOAEC: >= 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: >= 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 air-ways. 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: >= 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.

Section 12
Ecological information

12.1 Toxicity
Very toxic to aquatic life with long lasting effects.

CAS 107-46-0:
Acute toxicity:
LC_{50} (Oncorhynchus mykiss, 96h) = 0,46 mg/l (test report, OECD 203)
EC_{50} (Daphnia magna, 48h) = 0,35 mg/l (test report, OECD 202)
IC_{10} (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:
LC_{50} (Oncorhynchus mykiss, 96h) = 16 µg/l (test report, OECD 204)
EC_{50} (Daphnia magna, 48h) > 2,9 mg/l (test report, OECD 202)
ErC_{50} (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 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
Avoid unnecessary release to the environment.
Do not dispose of aerosol sprays in refuse collection, even when empty. The sprays must be sent to the municipal chemical waste collection facility.

EWC code: 16 05 04* Gases in pressure containers containing dangerous substances.

Absorbent/cloth contaminated with the product:
EWC code: 15 02 02 absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances.

Section 14
Transport information

14.1 UN-no.: 1950
14.2 UN proper shipping name: AEROSOLS
14.3 Transport hazard class(es): 2.1
14.4 Packing group: -
14.5 Environmental hazards: Yes. 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 and the IBC Code: Not applicable.

ADR - Classification:
- Classification code: 5F
- ADR limited Quantities: 1 L
- Hazard label: 2

Special provisions applicable to certain articles or substance:
190, 327, 344, 625.

IMDG - Classification:
- IMDG limited Quantities: 1 L
- Hazard label: 2
EMS: F-D, S-U

Special provisions applicable to certain articles or substance:
63, 190, 277, 327, 344, 381, 959.

IATA - Classification:
- Hazard label: 2

Transportation on road in other countries than ADR-countries:

US: UN1950 AEROSOLS
Canada: UN1950 AEROSOLS / AÉROSOLS
Brazil: UN1950 AEROSSÓIS
Australia: UN1950 AEROSOLS
New Zealand: UN1950 AEROSOLS
Hong Kong / China: UN1950 AEROSOLS

Section 15
Regulatory information

Covered by:
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work.

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).

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.
Directive 2012/18/EU (Seveso), P3a FLAMMABLE AEROSOLS: Column 2: 150 (net) t, Column 3: 500 (net) 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.

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:

H222 Extremely flammable aerosol.
H225 Highly flammable liquid and vapour.
H229 Pressurised container: May burst if heated.
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:
DNEL = Derived No-Effect Level
PNEC = Predicted No-Effect Concentration
PBT = Persistent, Bioaccumulative and Toxic
vPvB = Very Persistent and Very Bioaccumulative
STOT = Specific Target Organ Toxicity

Classification method:
Calculation based on the hazards of the known components.

Changes since the previous edition:
Not relevant.

Training:
No special training is required, but a thorough knowledge of this safety data sheet should be a prerequisite condition.

Other information:
This safety data sheet has been prepared for and applies to this product only. It is based on our current knowledge and the information that the supplier was able to provide about the product 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.

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.

Brava® Adhesive Remover Spray

The Change Log is added for the purpose of informing about the change between versions to Coloplast employees only.

Therefore, this page should not be printed or made available to customers outside of Coloplast

Change log

Version no.	Initials Issue Date (Month Year)	Short description of and reason for change
4.0	PLMITI, 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.

Signature Page for VV-0097295 v4.0

Approved	DKAJL Anette Jansons Lauritzen Senior Specialist Biosafety and Chemical Compliance Technical / Specialist 12-Apr-2019 08:57:27 GMT+0000

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