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SAFETY DATA SHEET:

Reference: This SDS is prepared in compliance with: Regulation (EC) No 1907/2006 with amendments.

**SECTION 1. ----- IDENTIFICATION OF THE SUBSTANCE/MIXTURE
AND OF THE COMPANY/UNDERTAKING -----**

Product identifier:

Product Name: Adhesive Remover Spray

Product Code: 12010

Product Information:

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

Medical device (spray) used for removal of adhesives from skin.

Details of the supplier of the safety data sheet:

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Denmark
Telephone: +45 4911 1111
Fax: +45 4911 2260
Responsible person for the safety data sheet (e-mail): MSDS@coloplast.com

Emergency telephone number:

+45 4911 1111 (Within office hours. Local emergency number is given on the packaging)

SECTION 2. ----- HAZARDS IDENTIFICATION -----

This product is assessed in accordance with Directive 93/42/EEC on medical devices and Directive 1999/45/EC and Regulation (EC) no 1272/2008 on classification, labelling and packaging of substances and mixtures.

Classification of the substance or mixture:

Classification according to Directive 67/548/EEC F+;R12
or 1999/45/EC and later amendments:

Classification according to Regulation (EC) No 1272/2008: Flam. Aer. 1;H222

Physical and Chemical hazards: Extremely flammable aerosol.

Hazards to Humans: None.

Hazards to environment: None.

Label elements:

According to Regulation (EC) No 1272/2008:

Contains: -

Pictogram(s): **Signal word:**



Danger

Hazard statement(s):

H222: Extremely flammable aerosol.

Precautionary statement(s):

P102: Keep out of reach of children.

P260: Do not breathe vapours/spray.

Other labelling:

Pressurized container: Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition - No smoking. Keep out of the reach of children.

Other hazards:

No known.

PBT/vPvB: No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

SECTION 3. ----- COMPOSITION/INFORMATION ON INGREDIENTS -----

Mixtures:

The main ingredients are: Hexamethyldisiloxane

The following substances have to be declared according to legislation:

w/w %	CAS No	EC No	Index No	REACH reg. No	Chemical Name	Classification (67/548/EEC)	Classification (EC 1272/2008)
> 80	107-46-0	203-492-7	None	None	Hexamethyl-disiloxane	F;R11	Flam. Liq. 2;H225

Wording of R-sentences and H-statements - see section 16.

SECTION 4. ----- FIRST AID MEASURES -----

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 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.

Most important symptoms and effects, both acute and delayed:

May cause irritation to skin, eyes and respiratory tract.

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 -----

- Extinguishing Media:** Use water spray, carbon dioxide, dry chemical or foam.
- 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.
Risk of explosion if heated under confinement.
- Advice for firefighters:** Remove containers if possible or keep containers cool by spraying with water. Wear self contained breathing apparatus when generation of smoke is vigorous.

SECTION 6. ----- ACCIDENTAL RELEASE MEASURES -----

- Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment - see section 8.
Remove sources of ignition.
Ventilate area of leak or spill.
- Environmental precautions:** Do not empty into drains - see section 12. Inform appropriate authorities in accordance with local regulations.

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.

Reference to other sections:

See references above.

SECTION 7. ----- HANDLING AND STORAGE -----

Precautions for safe handling:

Avoid breathing vapours/aerosols. Provide adequate ventilation. Avoid contact with skin, eyes and clothing. Change contaminated clothes. Wash contaminated skin with water and mild soap. Never to be handled close to fire, sparks and hot surfaces - No smoking.

Conditions for safe storage, including any incompatibilities:

Store in a cool place. Heating may result in increased pressure and risk of container bursting. Protect from sunlight and do not expose to temperatures exceeding 50°C, i.e. electric lights. Do not pierce or burn, even after use. Do not spray on flames or red-hot objects. Observe official regulations on storage of pressurized containers.

Specific end use(s):

See section 1.

SECTION 8. ----- EXPOSURE CONTROLS/PERSONAL PROTECTION -----

Control parameters:

USA (ACGIH)	None
Germany (MAK)	None
Denmark (AT)	None
DNEL	No CSR
PNEC	No CSR

Exposure controls:

Appropriate engineering controls: Avoid inhalation of vapors/aerosols. Provide adequate ventilation.

Personal protective equipment:

Inhalation:
Respiratory equipment is normally not required. In case of extensive use and inadequate ventilation: Use an approved mask with gas filter type A (Brown - for organic vapours). The filter has a limited lifetime and must be changed. Read the instruction.

Skin:
Wear protective gloves of nitril (> 0.3 mm). Break through time: app. 1 hour.

Eyes:
Tightly fitting safety goggles when there is risk of contact with eyes.

Environmental exposure controls: See section 6 and 13.

SECTION 9. ----- PHYSICAL AND CHEMICAL PROPERTIES -----

Information on basic physical and chemical properties:

Appearance:	Aerosol
Odour:	Characteristic
Odour threshold:	Not determined
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):	≤ 4 (Hexamethyldisiloxane)
Evaporation rate:	Not determined
Flammability (solid, gas):	Not relevant
Upper/lower flammability or explosive limits (vol-%):	0,5-22 (Hexamethyldisiloxane)
Vapour pressure (hPa, 20°C):	20 (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}:	Not determined
Autoignition temperature (°C):	340 (Hexamethyldisiloxane)
Viscosity (mPa*s, 25°C):	0,5 (Hexamethyldisiloxane)
Explosive properties:	Not relevant
Oxidising properties:	Not relevant

Other information:

None relevant.

SECTION 10. ----- STABILITY AND REACTIVITY -----

Reactivity: No available data.

Chemical stability: The product is stable under the advised storage conditions – see section 7.
Vapours can be set on fire by sparks or hot surfaces.
Vapours may form explosive mixtures with air.

Possibility of hazardous reactions: No known.

Conditions to avoid: Strong heat, sparks and flames.

Incompatible materials: Strong acids, bases and oxidizing agents.

Hazardous decomposition products: When heated to high temperatures (decomposition), toxic gasses are formed such as oxides of carbon.

SECTION 11. ----- TOXICOLOGICAL INFORMATION -----

Information on toxicological effects:

Toxicological data: Hexamethyldisiloxane:
No acute toxicity (rodents), skin- or eye irritation (rabbit), sensitization (guinea pig, GPMT) or evidence of CMR effects (animal tests) [IUCLID].

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: No known.

SECTION 12. ----- ECOLOGICAL INFORMATION -----

Toxicity: Hexamethyldisiloxane is toxic to aquatic organisms:
LC₅₀ (Oncorhynchus mykiss, 96h) = 3 mg/l [IUCLID] *
EC₅₀ (Daphnia magna, 24h) = 314 mg/l [IUCLID] *
* The solubility of the substance is lower than these reported effect concentrations.

Persistence and degradability: Hexamethyldisiloxane:
No available data. The substance may cause long-term effects in the aquatic environment, if not evaporated into air.

Bioaccumulative potential: Hexamethyldisiloxane:
Log K_{ow} = 4,2 - Moderate bioaccumulative effect may be expected for the substance, if not evaporated into air.

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

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

Other adverse effects: No known.

SECTION 13. ----- DISPOSAL CONSIDERATIONS -----

Waste treatment methods:

The recommended disposal technology is incineration at any approved facility. The disposal should always be in compliance with National, Federal, State and local regulations. The project should not be discharged into the environment.

US: If this product as supplied becomes a waste, it 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: According to The European Waste Catalogue (EWC), in accordance with EC Directive 75/442/EEC, the following Waste Code can be used: 16 05 04 pressurized containers containing hazardous 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.

SECTION 14. ----- TRANSPORT INFORMATION -----

UN-no.: 1950
UN proper shipping name: AEROSOLS
Transport hazard class(es): 2
Packing group: -
Environmental hazards: None.
Special precautions for user: None.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not relevant.

ADR - Classification: UN 1950 AEROSOLS, 2
- Classification code: 5F
- ADR limited Quantities: LQ2: 1L
- Hazard label:



IMDG - Classification: UN 1950 AEROSOLS, 2
- Classification code: -
- IMDG limited Quantities: 1L
- Hazard label:



IATA - Classification: UN 1950 AEROSOLS, 2
- Hazard label:



SECTION 15. ----- REGULATORY INFORMATION -----

Safety, health and environmental regulations/legislation specific for the substance or mixture:
Must not be used by persons under 18 years of age.

The propellant used in this product is prohibited in aerosols in Denmark, according to Bek. 552 from 02.07.2002. However, aerosols for medical use are exempted.

Chemical Safety Assessment:

No CSR.

SECTION 16. ----- OTHER INFORMATION -----

R-sentences and H-statements mentioned in section 2 and 3:

- R 11: Highly flammable.
- R 12: Extremely flammable.
- H222: Extremely flammable aerosol.
- H225: Highly flammable liquid and vapour.

Abbreviations:

- At. = Arbejdstilsynet.
- 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

Changes since the previous edition:

Not relevant.

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