SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1	**Product identifier**	
	Trade name	Barrier Film
1.2	**Relevant identified uses of the substance or mixture and uses advised against**	
	Identified use(s)	Medical Device; Skin barrier film spray
1.3	**Details of the supplier of the safety data sheet**	
	Company Identification	AD Medical IDA Business Park, Balinalee Road, Longford, N39 DX73 Ireland
	Telephone	+353 43 33 49586
	E-Mail (competent person)	proudct.safety@eu.vaerydennison.com
1.4	**Emergency telephone number**	
	Emergency Phone No.	+353 43 33 49586

► SECTION 2: HAZARDS IDENTIFICATION

2.1	**Classification of the substance or mixture**	
	Regulation (EC) No. 1272/2008 (CLP)	Flam. Liq. 2
	Hazard statement(s)	H225: Highly flammable liquid and vapour.
	Directive 67/548/EEC & Directive 1999/45/EC	Highly flammable, Dangerous for the environment.
	Risk Phrases	R11: Highly flammable.
2.2	**Label elements**	According to Regulation (EC) No. 1272/2008 (CLP)
	Hazard pictogram(s)	
	Signal word(s)	
	Hazard statement(s)	Highly flammable liquid and vapour.
	Precautionary statement(s)	Keep out of reach of children. Keep away from heat, sparks, open flame, hot surfaces - No smoking
2.3	**Other hazards**	None
2.4	**Additional information**	As a finsihed medical device used in direct contact with the human body and in accordance with article 1.5 (d) of Regulation (EC) No. 1272/2008, the finished product is not within the scope of the classification, labelling and packaging provisions of the CLP Regulation.

► SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: Mixture, containing the following hazardous ingredients

Ingredients	CAS No.	%W/W
Hexamethyldisiloxane	107-46-0	70-99
Acrylate co-polymer	Trade secret*	1-30

*The specific chemical identity and/or exact percentage (concentration) of this composition has been withheld as a trade secret.

Dangerous components

EC Classification No. 1272/2008

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	EC Classification and Hazard statement(s)	%W/W
Hexamethyldisiloxane	107-46-0	203-492-7	Not available.	Flam Liq 2; H225 Aquatic Acute 1; H400 Aquatic Chronic 2; H411	70-99%

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	EC Classification and Risk Phrases	%W/W
Hexamethyldisiloxane	107-46-0	203-492-7	Not available.	F, N; R11-50	70-99%

3.3 Additional Information

For full text of R/H phrases see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: Remove persons affected by vapour to fresh air.

Skin Contact: Wash affected skin with soap and water. Remove soiled clothing and clean before re-use.

Eye Contact: If substance has got into the eyes, wash out with water.

Ingestion: IF SWALLOWED: Rinse mouth. Consult a doctor in case of complaint

4.2 Most important symptoms and effects, both acute and delayed: No significant effects anticipated

4.3 Indication of the immediate medical attention and special treatment needed: None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media: Water spray, foam, dry powder or CO_2.

Unsuitable Extinguishing Media: Direct water jet

5.2 Special hazards arising from the substance or: In case of fire, the following can be released: Silanes,

	mixture	Carbon oxides (CO_x).
5.3	**Advice for fire-fighters**	Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1	**Personal precautions, protective equipment and emergency procedures**	Remove all ignition sources. Ventilate area. Isolate spillage and clean up immediately. Refer to Section 8 for protective measures when handling the spillage.
6.2	**Environmental precautions**	Avoid release to the environment.
6.3	**Methods and material for containment and cleaning up**	Adsorb spillages onto sand, earth or any suitable adsorbent material. Dispose of contaminated material as waste according to Section 13.
6.4	**Reference to other sections**	8, 13

SECTION 7: HANDLING AND STORAGE

7.1	**Precautions for safe handling**	Keep away from heat, sparks, open flame, hot surfaces - No smoking When using do not eat or drink.
7.2	**Conditions for safe storage, including any incompatibilities**	Keep out of reach of children. Keep only in the original container in a cool, well-ventilated place away from: Heat and direct sunlight. Storage temperature (°C): 5…30
7.3	**Specific end use(s)**	Use as per instructions for use Use only in well-ventilated areas. Avoid breathing vapours/spray.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1	**Control parameters**	.
8.1.1	**Occupational Exposure Limits**	No Occupational Exposure Limit assigned.
8.2	**Exposure controls**	
8.2.1	**Appropriate engineering controls**	Not normally required
8.2.2	**Personal protection equipment**	
	Eye/face protection	Not normally required
	Hand protection (Hygiene Measures)	Disposable gloves (EN374)

Material of Gloves	Latex, Vinyl, Nitrile rubber.
Body protection	Not normally required
Respiratory protection	Not normally required
8.2.3 Environmental Exposure Controls	No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1	**Information on basic physical and chemical properties**	
	Appearance	Clear Liquid
	Colour	Colourless
	Odour	Slight..
	Odour Threshold (ppm)	Not determined
	pH (Value)	Not determined
	Melting Point (°C) / Freezing Point (°C)	~ -68
	Boiling point/boiling range (°C):	~ 100
	Flash Point (°C)	-1
	Evaporation rate (BA = 1)	Not available
	Flammability (solid, gas)	Not applicable
	Explosive limit ranges (Hexamethyldisiloxane)	0.5 – 21.8 %V
	Vapour Pressure (Hexamethyldisiloxane)	20 hPa @ 20°C, 175 hPa @ 50°C
	Vapour Density (Air=1)	Not determined
	Density (g/ml)	0.76 @ 20°C
	Solubility (Water)	Insoluble.
	Solubility (Other)	Not determined
	Partition Coefficient (n-Octanol/water)	Log P_{OW} > 3.16. (25°C) (Hexamethyldisiloxane)
	Auto Ignition Temperature (°C)	Not determined
	Decomposition Temperature (°C)	Not determined
	Viscosity	Not determined
	Explosive properties	Not explosive.
	Oxidising properties	Not oxidising
9.2	**Other information**	Not available

SECTION 10: STABILITY AND REACTIVITY

10.1	**Reactivity**	May form explosive mixture with air particularly in enclosed spaces.
10.2	**Chemical stability**	Stable under normal conditions.
10.3	**Possibility of hazardous reactions**	Hazardous polymerization will not occur.
10.4	**Conditions to avoid**	Keep away from flames and hot surfaces.
10.5	**Incompatible materials**	Strong oxidising agents, strong acids, strong alkalis.
10.6	**Hazardous Decomposition Product(s)**	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

11.1.1 Substances

Acute toxicity Hexamethyldisiloxane	LC_{50} oral Rat > 5,000 mg/kg

11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met.
Irritation	Based upon the available data, the classification criteria are not met.
Corrosivity	Based upon the available data, the classification criteria are not met.
Sensitisation	Based upon the available data, the classification criteria are not met.
Repeated dose toxicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Mutagenicity	Based upon the available data, the classification criteria are

	not met.
Toxicity for reproduction	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.
Health Effects and Symptoms	
Inhalation	Cough. Excessive exposure to vapours may cause drowsiness and dizziness.
Skin Contact	No known hazards are associated with the use of this material.
Eye Contact	No adverse effects anticipated
Ingestion	No adverse effects anticipated (quantity limitation).

11.2 Other information No information available

SECTION 12: ECOLOGICAL INFORMATION

12.1	**Toxicity**	
	Acute toxicity Hexamethyldisiloxane	96-hr LC_{50} (rainbow trout) = 0.46 mg/L
12.2	**Persistence and degradability**	pH dependent hydrolysis in water Not readily biodegradable (according to OECD criteria). Hexamethyldisiloxane: 2% at 28 days
12.3	**Bioaccumulative potential**	The product has high potential for bioaccumulation. BCF Hexamethyldisiloxane > 700
12.4	**Mobility in soil**	No data. Not expected to be highly mobile due to lack of water solubility
12.5	**Results of PBT and vPvB assessment**	No information available
12.6	**Other adverse effects**	No information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: This must be disposed of in compliance with anti-pollution and other laws of the country concerned. Contact your local service providers for further information.

Packaging: Disposal must be made in accordance with local waste management regulations. Outer packaging may be recycled **.** Contact your local service providers for further information.

13.2 Additional Information

European waste catalogue: Possible waste codes
18 01 06* WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH - chemicals consisting of or containing dangerous substances
or
20 01 13* MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS – solvents

SECTION 14: TRANSPORT INFORMATION

		ADR/RID	IMDG	ICAO/IATA
14.1	**UN number**	UN 1993	UN 1993	UN 1993
14.2	**Proper Shipping Name**	FLAMMABLE LIQUID, N.O.S. (Contains Hexamethyldisiloxane)	FLAMMABLE LIQUID, N.O.S. (Contains Hexamethyldisiloxane)	FLAMMABLE LIQUID, N.O.S. (Contains Hexamethyldisiloxane)
14.3	**Transport hazard class(es)**	Class 3, Flammable Liquid 	Class 3, Flammable Liquid 	Class 3, Flammable Liquid 
14.4	**Packing Group**	II	II	II
14.5	**Environmental hazards**	Yes	Marine Pollutant	Not applicable
14.6	**Special precautions for user**	Not applicable	Not applicable	Not applicable
14.7	**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable	Not applicable	Not applicable

14.8 Additional Information

Depending on package size, may be shipped under Limited Quantity or Excepted Quantity provisions

SECTION 15: REGULATORY INFORMATION

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

Medical Devices Directive 93/42/EEC

The product is CE-marked in accordance with the requirements of this directive.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

► SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Classification code(s):

F	HIGHLY FLAMMABLE
N	DANGEROUS FOR THE ENVIRONMENT
Flam. Liq. 2	Flammable liquid Category 2
Aquatic Acute 1	Hazardous to the aquatic environment, Acute, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, Chronic, Category 2

Risk Phrases

R11	Highly flammable.
R50	Very toxic to aquatic organisms.

Hazard statement(s)

H225	Highly flammable liquid and vapour.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

References:

Raw material safety data sheets
Manufacturer's safety data sheet.
REACH Dossier

Supersedes: Revision: 27/10/2021

Additional Information

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.