SAFETY DATA SHEET

Revision: 1 Date: 18 July 2022

SECTION 1: Identification of the substance/mixture and company/undertaking

1.1 Product identifier — **Medi Derma-S Total Barrier Film Aerosol 50ml**

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

Medical product to provide a transparent, quick drying and long-lasting film protection from moisture-associated skin damage on intact and moderately damaged skin.

Uses advised against: not available.

1.3 Details of the supplier of the safety data sheet

Medicareplus International Limited, Chemilines House, Alperton Lane London HA0 1DX, UK.

Tel: +44 (0)20 8810 8811; email info@medicareplus.co.uk.

1.4 Emergency telephone number

Tel +44 (0)20 8810 8811 (UK business hours).

UK: 111 (public NHS number for less urgent medical problems). Medical professionals can contact the National Poisons Information Service (NPIS): 0344 892 0111.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to CLP Regulation (1272/2008): Aerosol 2, H223, H229; Aquatic Acute 1, H400; Aquatic Chronic 2, H411.

See Section 16 'Other information' for full text of the H-statements.

2.2 Label elements

Signal word: Warning

Hazard statements:

Flammable aerosol.

Pressurised container: May burst if heated.

Very toxic to aquatic life with long lasting effects.

Precautionary statements

prevention: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Do not spray on an open flame or other ignition source.

Do not pierce or burn, even after use.

response: None.

storage: None.

disposal: Dispose of contents/container in accordance with local/national regulation.

Supplemental information: None

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2.3 Other hazards

One ingredient (octamethyltrisiloxane) is considered to meet the criteria for very persistent and very bioaccumulative (vPvB).

The product does not contain any ingredient identified as having endocrine disrupting properties.

SECTION 3: Composition/information on ingredients

3.2 Mixtures [a,b]

Declarable components	*Conc. (wt%)*	*EC No.*	*CAS No.*	*REACH Reg. No.*	*Classification, supplemental hazards, ATE, M-factor, and SCL*
Hexamethyldisiloxane (HMDS)	50 to 75	203-492-7	107-46-0	NA	Flam Liq 2, H225; Aquatic Acute 1, H400; Aquatic Chronic 2, H411
Octamethyltrisiloxane (OMTS)	10 to 25	203-497-4	107-51-7	NA	Flam Liq 3, H226
Other components					
Not available					

[a] NA: not available.

[b] See Section 16 'Other information' for full text of the H-statements.

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation: If inhalation is suspected of causing respiratory effects (eg irritation or difficulties in breathing), remove product, and move person to fresh air and keep warm and at rest in a position comfortable for breathing. If symptoms continue, call a doctor.

Skin: Not expected to cause adverse effects. For skin contamination, wash affected area with soap and water. Call a doctor if irritation, rash, or other symptoms occur.

Eye: In case of contact with eyes, rinse eye with room-temperature water or eyewash solution, occasionally lifting eyelids. Call a doctor if irritation persists.

Ingestion: If in mouth, rinse mouth thoroughly with water and spit out rinsings. Water may be given to drink if product has been swallowed. Get medical attention for any symptoms. Do not induce vomiting, unless instructed by medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptoms as they occur.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable	Water spray, foam, carbon dioxide, or dry chemical powder are suitable for use with the product.
Unsuitable	Not available.

5.2 Special hazards arising from the substance or mixture

The product is supplied in small packages, but is classified as flammable. If involved in a fire, product will burn producing hazardous smoke, vapours and gases.

In bulk use, vapour at high concentration may form flammable or explosive mixture with air.

5.3 Advice for firefighters

Remove product from fire or cool them with water spray. Firefighters should wear self-contained breathing apparatus and full protective clothing.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Product is supplied in small packages (50 mL/item), which do not pose a hazard, and can be collected.

For bulk spills in professional setting, wear personal protection. Product spill may be slippery. Follow prescribed procedures for responding to all spillages.

6.2 Environmental precautions

Accidental release of the product is unlikely because it is placed on the market as small packages. The contains octamethyltrisiloxane which is considered to meet the criteria for very persistent and very bioaccumulative (vPvB).

Prevent spills of bulk material entering watercourses or drains.

6.3 Methods and material for containment and cleaning up

Clean up spill as soon as possible.

For small quantities, collect product or wipe off residue with cloth or paper.

For large quantities absorb onto inert material and sweep up.

Rinse contaminated surfaces with soap and water, and collect waste, washings, and contaminated materials for safe disposal.

6.4 Reference to other sections

For recommended personal protective equipment, see Section 8.

For disposal considerations, see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid eye contact with the product. Do not breathe spray. Wash hands after use.

7.2 Conditions for safe storage, including any incompatibilities

Store containers in a cool, dry place away from direct sunlight.

7.3 Specific end use(s)

Not available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

EU limit values	None.
National limit values	UK: none.
Monitoring procedure	Not applicable.
Other: human health (DNELs, DMELs)	HMDS: DNELs: workers, long-term exposure, systemic effects, inhalation, 53.4 mg/m^3; workers, long-term exposure, systemic effects, dermal, 333 mg/kg/day. OMTS: DNELs: workers, long-term exposure, systemic effects, inhalation, 78 mg/m^3; workers, long-term exposure, systemic effects, dermal, 1103 mg/kg/day.
Other: environmental (PNEC)	HMDS: PNECs: freshwater, 0.002 mg/L; sewage treatment plant, 10 mg/L; freshwater sediment, 8.9 mg/kg dry sediment; soil, 0.08 mg/kg dry soil; oral, 5.3 mg/kg food. OMTS: PNECs: freshwater sediment, 8.9 mg/kg dry sediment; oral, 1.7 mg/kg food.

8.2 Exposure controls

Engineering controls	Not required for normal use of the finished product. Use in a well-ventilated place (eg 3 air changes per hour) is recommended for bulk professional use.
Personal protective equipment	For handling in the workplace, the need for personal protective equipment should be based on a risk assessment for the particular use. Avoid skin contact by wearing chemical resistant gloves (eg nitrile rubber, 0.2 mm thickness). If extensive contact may occur, wear protective clothing (eg apron). Respiratory protective equipment not required for foreseen use. PPE should conform to British (EN) standards, eg gloves EN 420 and 374; eye protection EN 166. Consult PPE manufacturers concerning breakthrough times applicable to your particular use.
Environmental exposure controls	Not available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

(a)	Physical state	Liquid
(b)	Colour	Colourless
(c)	Odour	Characteristic
(d)	Melting/freezing point	Not available
(e)	Boiling point or initial boiling point and boiling range	100 °C
(f)	Flammability	Highly flammable liquid

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(g)	Lower and upper explosion limit	Not available
(h)	Flash point	– 3.3 °C (closed cup)
(i)	Auto-ignition temp.	Not available
(j)	Decomposition temp.	Not available
(k)	pH	Not available
(l)	Kinematic viscosity	1 mm^2/s at 25 °C
(m)	Solubility	Water: product: not available; HMDS: 0.034 mg/L at 23 °C
(n)	Partition coeff. n-octanol/water (log value)	HMDS: 6.6 at 25 °C
(o)	Vapour pressure	Product: not available; HMDS: 530 Pa at 25 °C
(p)	Density or rel. density	0.8
(q)	Relative vapour density	Not available
(r)	Particle characteristics	Not applicable to liquid
9.2	**Other information**	Not classified as explosive or oxidising

SECTION 10: Stability and reactivity

10.1	**Reactivity**	Not available.
10.2	**Chemical stability**	Stable under recommended storage and handling conditions. No hazardous polymerization.
10.3	**Possibility of hazardous reactions**	Not available.
10.4	**Conditions to avoid**	High temperatures, or direct sunlight. Vapours may form explosive mixture with air. Highly flammable liquid and vapour.
10.5	**Incompatible materials**	Strong acids, alkalis, and oxidising agents.
10.6	**Hazardous decomposition products**	Not available.

SECTION 11: Toxicological information

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

(a)	Acute toxicity	Based on available data, the classification criteria are not met. ATE_{mix} (oral) > 2000 mg/kg; ATE_{mix} (dermal) > 2000 mg/kg.
(b)	Skin corrosion/irritation	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
(c)	Serious eye damage/irritation	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.

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(d) Respiratory or skin sensitisation	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
(e) Germ cell mutagenicity	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
(f) Carcinogenicity	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
(g) Reproductive toxicity	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
(h) STOT-single exposure	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
(i) STOT-repeated exposure	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
(j) Aspiration hazard	Based on available data, the classification criteria are not met. No relevant ingredient has been classified for this effect.
11.2 Information on other hazards	Not available.

SECTION 12: Ecological information

12.1 Toxicity	Based on available data, the classification criteria are not met. HMDS: LC_{50} (fish, 96 h) 0.46 mg/L (NOEC 0.11 mg/L); EC_{50} (Daphnia magna, 48 h) > 1000 mg/L (water-accommodated fraction); E_rC_{50} (algae, 70 h) > 0.55 mg/L, NOEC, 0.09 mg/L.
12.2 Persistence and degradability	HDMS: Half-life for hydrolysis (method OECD 111) at 24.8 °C: 1.4 (pH 5), 116 (pH 7) and 12.4 h (pH 9). HMDS: Biodegradation: 2% in 28 d.
12.3 Bioaccumulative potential	One ingredient (octamethyltrisiloxane) is considered to meet the criteria for very persistent and very bioaccumulative (vPvB).
12.4 Mobility in soil	HMDS: log K_{oc} 3.0 at 20 to 25 °C (calculated) (moderate sorption to soil).
12.5 Results of PBT and vPvB assessment	One ingredient (octamethyltrisiloxane) is considered to meet the criteria for very persistent and very bioaccumulative (vPvB).
12.6 Endocrine disrupting properties	No ingredients have been identified with endocrine disrupting properties.
12.7 Other adverse effects	The mixture is not classified as hazardous to the ozone layer.

SECTION 13: Disposal considerations

13.1 Waste treatment methods	Small consumer items may be disposed of in landfill. Disposal via the drains is not recommended. The product is suitable for incineration. Bulk disposal must be via licensed waste disposal sites in accordance with national and local regulations. In a professional setting, chemical residues generally count as special waste, and their disposal may be regulated. General requirements are

given in the EU Waste Framework Directive (75/442/EEC) and the Hazardous Waste Directive (91/689/EEC), or GB equivalent.

SECTION 14: Transport information

14.1 UN Number	Not classified as dangerous goods for transport.
14.2 UN proper shipping name	Not applicable.
14.3 Transport hazard class(es)	Not applicable.
14.4 Packing group	Not applicable.
14.5 Environmental hazards	Classified as marine pollutant/environmentally hazardous.
14.6 Special precautions for user	UN 1950, AEROSOLS, flammable is applicable, but the product is supplied at < 50 mL per package according to Special Provision 190 and is below the minimum size of regulated aerosols.
14.7 Maritime transport in bulk according to IMO instruments	Not applicable.

SECTION 15: Regulatory information

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

UK: Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended.

COSHH Essentials: Easy Steps to Control Chemicals; HSE Books 2003 (also available on the HSE web site).

Workplace Exposure Limits EH40/2005 (Second edition, published 2011), Health and Safety Executive.

Product is regulated as a medical device according to EU Regulation 2017/745.

Council Directive Relating to Aerosol Dispensers (75/324/EEC) (as amended).

Community rolling action plan (CoRAP):

Octamethyltrisiloxane (L3), EC 203-497-4, CAS 107-51-7, has a substance evaluation conclusion (REACH Article 48) and is considered to meet the criteria for very persistent and very bioaccumulative (vPvB).

HMDS, EC 203-492-7, CAS 107-46-0, is being assessed for concerns over carcinogenicity and PBT.

15.2 Chemical safety assessment

Not available.

SECTION 16: Other information

Revisions

This SDS is the first version in EU format, using classification according to the CLP Regulation or GB equivalent.

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Abbreviations	ATE, acute toxicity estimate; DNEL, derived no-effect level; DMEL, derived minimum effect level; EC, effect concentration; LC, lethal concentration; OECD, Organisation for Economic Co-operation and Development; PBT, persistent, bioaccumulative, and toxic; PNEC, predicted no-effect concentration; vPvB, very persistent, very bioaccumulative.
References	Search for chemicals; available at the European Chemicals Agency website: http://echa.europa.eu/. This safety data sheet conforms to Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.
Basis of classification	The mixture is classified on the basis of available information on the ingredients.
List of hazard statements	H225: Highly flammable liquid and vapour; H226: Flammable liquid and vapour; H400: Very toxic to aquatic life; H411: Toxic to aquatic life with long lasting effects.

Safety data sheet compiled by Alchemy Compliance Ltd. on the basis of information provided by the supplier.