

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 Pro Skin Protectant Ointment Tube 115g
1.2 Relevant identified uses of the substance or mixture and uses advised against	Medical product to provide a protective waterproof barrier from severe moisture-associated skin damage. 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)	This product does not meet the criteria for classification in any hazard class according to the CLP Regulation, and it is not mandatory to supply a safety data sheet, but this document contains information and advice concerning safe handling of the product.
--	---

2.2 Label elements

Pictogram	None.
Signal word	None.
Hazard statements	None.
Precautionary statements	
Supplemental information	None.

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures ^a

Declarable components	Conc. (wt%)	EC No.	CAS No.	REACH Reg. No.	Classification, supplemental hazards, ATE, M-factor, and SCL
None					
<i>Other components</i>					
Polyethylene glycol (PEG)	50 to 75	NA	25322-68-3	NA	Not classified

SAFETY DATA SHEET

Revision: 1

Date: 18 July 2022

^a NA: not available.

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.

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, and is not classified as flammable. However, if involved in a fire, product will decompose producing hazardous smoke, vapours and gases.

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 (< 125 g/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.

SAFETY DATA SHEET

Revision: 1

Date: 18 July 2022

6.2 Environmental precautions	Accidental release of the product is unlikely because it is placed on the market as small packages containing viscous liquid (ointment). The product is not classified for environmental effects. 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. 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.

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)	Polyethylene glycol: DNELs: workers, long-term exposure, systemic effects, inhalation: 40 mg/m ³ ; workers, long-term exposure, systemic effects, dermal: 112 mg/kg/d.
Other: environmental (PNEC)	Polyethylene glycol: PNECs: freshwater, 273 mg/L; sewage treatment plant, 1030 mg/L; soil, 46.4 mg/kg dry soil.

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.

SAFETY DATA SHEET

Revision: 1

Date: 18 July 2022

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 | Viscous liquid |
| (b) Colour | Not available |
| (c) Odour | Not available |
| (d) Melting/freezing point | Not available |
| (e) Boiling point or initial boiling point and boiling range | Not available |
| (f) Flammability | Not classified as flammable |
| (g) Lower and upper explosion limit | Not available |
| (h) Flash point | Product: not available; PEG: 138.6 °C |
| (i) Auto-ignition temp. | Product: not available; PEG: 360 °C |
| (j) Decomposition temp. | Not available |
| (k) pH | Not available |
| (l) Kinematic viscosity | Not available |
| (m) Solubility | Water: product: not available; PEG: 256 g/L at 25 °C |
| (n) Partition coeff. n-octanol/water (log value) | Not available |
| (o) Vapour pressure | Product: not available; PEG: < 0.1 Pa at 20 °C |
| (p) Density or rel. density | Not available. |
| (q) Relative vapour density | Not available |
| (r) Particle characteristics | Not applicable to viscous liquid |

9.2 Other information Not expected to be 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.

SAFETY DATA SHEET

Revision: 1

Date: 18 July 2022

10.4 Conditions to avoid	High temperatures, or direct sunlight.
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.
(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. Product is a viscous liquid (ointment).
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.
12.2 Persistence and degradability	Not available.
12.3 Bioaccumulative potential	No relevant ingredient has been identified as bioaccumulative.
12.4 Mobility in soil	Not available.

SAFETY DATA SHEET

Revision: 1

Date: 18 July 2022

12.5 Results of PBT and vPvB assessment	No relevant ingredients have been identified with PBT or vPvB properties.
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	<p>Small consumer items may be disposed of in landfill. Disposal via the drains is not recommended. The product is suitable for incineration.</p> <p>Bulk disposal must be via licensed waste disposal sites in accordance with national and local regulations.</p> <p>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.</p>
-------------------------------------	--

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	Not classified as marine pollutant/environmentally hazardous.
14.6 Special precautions for user	Not available.
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	<p><i>UK:</i> Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended.</p> <p>COSHH Essentials: Easy Steps to Control Chemicals; HSE Books 2003 (also available on the HSE web site).</p> <p>Workplace Exposure Limits EH40/2005 (Second edition, published 2011), Health and Safety Executive.</p> <p>Product is regulated as a medical device according to EU Regulation 2017/745.</p>
15.2 Chemical safety assessment	Not available.

SAFETY DATA SHEET

Revision: 1

Date: 18 July 2022

SECTION 16: Other information

Revisions	This SDS is the first version in EU format, using classification according to the CLP Regulation or GB equivalent.
Abbreviations	ATE, acute toxicity estimate; DNEL, derived no-effect level; DMEL, derived minimum effect level; 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	None.

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