

SAFETY DATA SHEET

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

1.1. Product identifier:

Derma Shield Lotion

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

Medical device (lotion) for industrial, consumer, professional use.

EuPCS: PC-MED

The product is classified as medical device (finished products intended for end users). Such products are exempted of Title IV of Regulation (EC) No. 1907/2006 (REACH), and the preparation of a safety data sheet is not required. Information below is for informative purposes.

1.3. Details of the supplier of the safety data sheet:

Information about the manufacturer:

Unigloves (UK) Limited

3 Ambley Green, Gillingham Business Park, Gillingham, ME8 0NJ

United Kingdom

Tel: +44 (0)800 049 6602

1.3.1. Responsible person:

Technical Department

E-mail:

technical@unigloves.co.uk

1.4. Emergency telephone number:

United Kingdom: National Poisons Information Service (NPIS)

NHS 111 (England), NHS 24 (Scotland) or NHS Direct (Wales) – dial 111

In Northern Ireland contact your local GP

Healthcare Professionals: UK NPIS 0344 892 0111

Ireland:

National Poisons Information Centre (NPIC)

Tel: 353 (1) 809 2166 (8.00 a.m. to 10.00 p.m. 7 days a week).

Healthcare Professionals: +353 (1) 809 2566 (24 hour service)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture:

Classification is not required, since the product is a medical device.

Hazard statements: No hazard statements.

2.2. Label elements:

The product should be labelled according to Regulation (EU) 2017/745.

Hazard statements: No hazard statements

Precautionary statements: No precautionary statements.

2.3. Other hazards:

The product has no other known specific hazards for human or environment.

Results of PBT and vPvB assessment: No data available.

Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances:

Not applicable.

3.2. Mixtures:

Chemical description: Water based skin lotion.

INGREDIENTS: Aqua, Palmitic Acid, Dimethicone, Palm Kernel Acid, Isopropyl Myristate, Glycerin, VP/VA Copolymer, Triethanolamine, Cetyl Alcohol, Cetearyl Alcohol, Ceteareth-20, Hydroxyethylcellulose, Polyperfluoromethylisopropyl Ether, Tocopheryl Acetate, Lanolin, Disodium EDTA, Aloe Barbadensis Leaf Juice, Propylene Glycol, Diazolidinyl Urea, Methylparaben, Propylparaben, Citric Acid, Sodium Benzoate, Potassium Sorbate.

Ingredients having occupational exposure limit value:

Glycerol (CAS: 56-81-5)

Triethanolamine (CAS: 102-71-6)

Propylene glycol (CAS: 57-55-6)

For more information, see Section 8.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

INGESTION:

Measures:

- If irritation or discomfort occur, obtain medical advice.

INHALATION:

Measures:

- If symptoms are experienced, remove source of contamination, or move victim to fresh air.
- Obtain medical advice.

SKIN CONTACT:

Measures:

- No health effects expected.
- If irritation does occur, flush with lukewarm, gently flowing water for 5 minutes.
- If irritation persists, obtain medical advice.

EYE CONTACT:

Measures:

- No health effects expected.
- If irritation does occur, flush with lukewarm, gently flowing water for 5 minutes.
- If irritation persists, obtain medical advice.

4.2. Most important symptoms and effects, both acute and delayed:

No acute and delayed symptoms and effects known.

4.3. Indication of any immediate medical attention and special treatment needed:

No special treatment needed; treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media:

5.1.1. Suitable extinguishing media:

Use fire extinguishing media appropriate for surrounding materials.

5.1.2. Unsuitable extinguishing media:

No data available.

5.2. Special hazards arising from the substance or mixture:

No hazardous combustion products expected under normal conditions.

5.3. Advice for firefighters:

No special firefighting procedures necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. **Personal precautions, protective equipment and emergency procedures:**
- 6.1.1. **For non-emergency personnel:**
Allow only well-trained experts wearing suitable protective clothing to abide in the field of accident.
- 6.1.2. **For emergency responders:**
No special precautions required.
- 6.2. **Environmental precautions:**
Dispose of the spillage and the resulting waste according to the applicable environmental regulations. Do not allow the product and the resulting waste to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.
- 6.3. **Methods and material for containment and cleaning up:**
No special measures or equipment required for cleaning up the spills.
- 6.4. **Reference to other sections:**
For further and detailed information see Sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

- 7.1. **Precautions for safe handling:**
Observe conventional hygiene precautions.
Technical measures:
No special measures required.
Precautions against fire and explosion:
No special measures required.
- 7.2. **Conditions for safe storage, including any incompatibilities:**
Technical measures and storage condition:
Keep container closed to prevent spillage.
Store in a cool, dry place out of the reach of children.
Protect from extremes of temperature.
Keep only in original packaging.
Incompatible materials: See Section 10.5.
Packaging material: Bottle: 100 ml, 1000 ml. Pouch: 800 ml.
- 7.3. **Specific end use(s):**
No specific instructions available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. **Control parameters:**

Occupational exposure limit values:

United Kingdom (EH40/2005 Workplace Exposure Limits):

Glycerol, mist (CAS: 56-81-5): 8-hr TWA: 10 mg/m³

Propylene glycol (CAS: 57-55-6): 8-hr TWA: 150 ppm, 474 mg/m³ (total vapour and particulates)
8-hr TWA: 10 mg/m³ (particulates)

Ireland (2024 Code of Practice for the Safety, Health and Welfare at Work):

Triethanolamine (CAS: 102-71-6): 8-hr: 5 ppm

Propylene glycol (CAS: 57-55-6): 8-hr: 150 ppm, 474 mg/m³ (total vapour and particulates)
8-hr: 10 mg/m³ (particulates)

DNEL values		Oral exposure		Dermal exposure		Inhalative exposure	
		Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)	Short term (acute)	Long term (chronic)
Consumer	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data
Worker	Local	no data	no data	no data	no data	no data	no data
	Systemic	no data	no data	no data	no data	no data	no data

PNEC values		
Compartment	Value	Note(s)
Freshwater	no data	no notes
Marine water	no data	no notes
Freshwater sediment	no data	no notes
Marine water sediment	no data	no notes
Sewage Treatment Plant (STP)	no data	no notes
Intermittent release	no data	no notes
Secondary poisoning	no data	no notes
Soil	no data	no notes

8.2. Exposure controls:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1. Appropriate engineering controls:

In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes.
Ensure good ventilation of the workstation.

8.2.2. Individual protection measures, such as personal protective equipment:

- Eye/face protection:** Not required.
- Respiratory protection:** Not required.
- Thermal hazards:** No thermal hazards known.

8.2.3. Environmental exposure controls:

Avoid release to the environment.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions, an expert's advice is necessary before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties:

Parameter	Value / Test method / Remarks
1. Physical state	liquid
2. Colour	white
3. Odour, odour threshold	slight
4. Melting point/freezing point	no data*
5. Boiling point or initial boiling point and boiling range	no data*
6. Flammability	no data*
7. Lower and upper explosion limit	no data*
8. Flash point	no data*
9. Auto-ignition temperature	no data*
10. Decomposition temperature	no data*
11. pH	6.5 – 7.5
12. Kinematic viscosity	no data*
13. Solubility in water in other solvents	soluble no data*
14. Partition coefficient n-octanol/water (log value)	no data*
15. Vapour pressure	no data*
16. Density and/or relative density	no data*
17. Relative vapour density	no data*
18. Particle characteristics	no data*

9.2. Other information:

9.2.1. Information with regard to physical hazard classes:

No further data available or not applicable for the product.

9.2.2. Other safety characteristics:

No other characteristics available.

*: The manufacturer did not carry out any tests on this parameter for the product or the results of the tests are not available at the time of publication of the data sheet, or the property is not applicable for the product.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

No reactivity known.

10.2. Chemical stability:

Stable under ambient storage conditions.

10.3. Possibility of hazardous reactions:

No hazardous reactions known during recommended use.

10.4. Conditions to avoid:

No conditions to avoid known.

10.5. Incompatible materials:

No incompatible materials known.

10.6. Hazardous decomposition products:

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity: Based on available data, the classification criteria are not met.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure: Based on available data, the classification criteria are not met.

STOT-repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

11.1.1. Summaries of the information derived from the test conducted:

No data available.

11.1.2. Relevant toxicological properties:

No data available.

11.1.3. Information on likely routes of exposure:

Ingestion, inhalation, skin contact, eye contact.

11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:

No data available.

11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:

No data available.

11.1.6. Interactive effects:

No data available.

11.1.7. Absence of specific data:

No information.

11.2. Information on other hazards:

Endocrine disrupting properties:

Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.

Other information:

No data available.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. **Toxicity:**
Non-hazardous liquid so not regarded as hazardous for the environment.
- 12.2. **Persistence and degradability:**
No data available.
- 12.3. **Bioaccumulative potential:**
No data available.
- 12.4. **Mobility in soil:**
No data available.
- 12.5. **Results of PBT and vPvB assessment:**
No data available.
- 12.6. **Endocrine disrupting properties:**
Endocrine disrupting property: Based on available data, does not contain endocrine disruptors.
- 12.7. **Other adverse effects:**
No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. **Waste treatment methods:**
Disposal according to the local regulations.
- 13.1.1. **Information regarding the disposal of the product:**
Dispose in a safe manner in accordance with local/national regulations.
List of Waste Code:
No waste disposal key according to the List of Waste Code (LoW code) can be determined for this product, as only the purpose of application defined by the user enables an allocation. The LoW code number has to be determined after a discussion with a waste disposal specialist.
- 13.1.2. **Information regarding the disposal of the packaging:**
Dispose of in accordance with applicable regulations.
- 13.1.3. **Physical/chemical properties that may affect waste treatment options shall be specified:**
No data available.
- 13.1.4. **Sewage disposal:**
No data available.
- 13.1.5. **Special precautions for any recommended waste treatment:**
No data available.

SECTION 14: TRANSPORT INFORMATION

ADR/RID; ADN; IMDG; IATA:
Not subject to the conventions of carriage of dangerous goods.

- 14.1. **UN number or ID number:**
No UN or ID number.
- 14.2. **UN proper shipping name:**
No proper shipping name.
- 14.3. **Transport hazard class(es):**
No transport hazard classes.
- 14.4. **Packing group:**
No packing group.
- 14.5. **Environmental hazards:**
Not applicable.
- 14.6. **Special precautions for user:**
No relevant information 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:

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive (EC) No 1999/45 and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive (EEC) No 76/769 and Commission Directives (EEC) No 91/155, (EEC) No 93/67, (EC) No 93/105 and (EC) No 2000/21

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives (EEC) No 67/548 and (EC) No 1999/45, and amending Regulation (EC) No 1907/2006

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The mixture does not contain any substance listed in Annex XIV of Regulation (EC) No 1907/2006 (REACH) (List of substances subject to authorisation).

15.2. Chemical safety assessment: Has not been carried out.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet:

The safety data sheet has been revised according to Regulation (EU) 2020/878 (Section 1-16).

The composition and hazard classification of the mixture were not modified compared to the previous version.

This safety data sheet supersedes all previous versions according to Annex II of Regulation (EC) No 1907/2006.

Literature references / data sources:

Previous version of the safety data sheet (26. 04. 2023, version 6).

Methods used for the classification according to Regulation (EC) No 1272/2008:

Classification is not required, since the product is a medical device.

Relevant hazard statements (code and full text) of Sections 2 and 3: No relevant statements.

Training advice: No data available.

Full text of the abbreviations in the safety data sheet:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.

ADR: Agreement concerning the International Carriage of Dangerous Goods by Road.

ATE: Acute Toxicity Estimate.
AOX: Adsorbable organic halides.
BCF: Bioconcentration factor.
BOD: Biological Oxygen Demand.
CAS number: Chemical Abstract Service number.
CLP: Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.
CMR effects: Carcinogenic, mutagenic, reprotoxic effects.
COD: Chemical Oxygen Demand.
CSA: Chemical Safety Assessment.
CSR: Chemical Safety Report.
DNEL: Derived-No-Effect-Level.
ECHA: European Chemical Agency.
EC: European Community.
EC number: EINECS and ELINCS numbers (see also EINECS and ELINCS).
EEC: European Economic Community.
EEA: European Economic Area (EU + Iceland, Liechtenstein and Norway).
EINECS: European Inventory of Existing Commercial Chemical Substances.
ELINCS: European List of Notified Chemical Substances.
EN: European Norm.
EU: European Union.
EuPCS: European Product Categorisation System.
EWC: European Waste Catalogue (replaced by LoW – see below).
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.
IATA: International Air Transport Association.
ICAO-TI: Technical Instructions for the Safe Transport of Dangerous Goods by Air.
IMDG: International Maritime Dangerous Goods.
IMO: International Maritime Organization.
IMSBC: International Maritime Solid Bulk Cargoes.
IUCLID: International Uniform Chemical Information Database.
IUPAC: International Union of Pure and Applied Chemistry.
Kow: n-Octanol - Water Partition Coefficient.
LC50: Lethal concentration resulting in 50 % mortality.
LD50: Lethal dose resulting in 50 % mortality (median lethal dose).
LoW: List of Waste.
LOEC: Lowest Observed Effect Concentration.
LOEL: Lowest Observed Effect Level.
NOEC: No Observed Effect Concentration.
NOEL: No Observed Effect Level.
NOAEC: No Observed Adverse Effect Concentration.
NOAEL: No Observed Adverse Effect Level.
OECD: Organization for Economic Cooperation and Development.
OSHA: Occupational Safety and Health Administration.
PBT: Persistent, Bioaccumulative and Toxic.
PNEC: Predicted No Effect Concentration.
QSAR: Quantitative Structure Activity Relationship.
REACH: Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.
RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.
SCBA: Self Contained Breathing Apparatus.
SDS: Safety Data Sheet.
STOT: Specific Target Organ Toxicity.
SVHC: Substances of Very High Concern.
UN: United Nations.
UVCB: Chemical Substances of Unknown or Variable Composition, Complex Reaction Products or of Biological Materials.
VOC: Volatile Organic Compound.
vPvB: very Persistent and very Bioaccumulative.

This safety data sheet had been prepared on the basis of information provided by the manufacturer/supplier and conform to the relevant regulations.



The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information.

The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required.

Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product.

It is the responsibility of the user to fully comply with local, national and international regulations concerning the use of this product.