



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II as amended

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

- 1.1 Product identifier**
Trade name Sorbaderm Barrier Cream
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) Medical Device; Medical skin barrier cream.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Aspen Medical Europe Ltd.
Clinitron House, Ashby Park, Ashby-de-la-Zouch,
Leicestershire, LE65 1JG, United Kingdom.
- Telephone +44 (0) 1530 411000
+44 (0) 800 032 3399
- E-Mail (competent person) Customers@aspenmedicaleurope.com
- 1.4 Emergency telephone number**
Emergency Phone No. +44 (0)1530 562216

► SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
Regulation (EC) No. 1272/2008 (CLP)
- Hazard statement(s) Non Hazardous Material
- Directive 67/548/EEC & Directive 1999/45/EC**
- Risk Phrases P262: Avoid Contact With Eyes
- 2.2 Label elements** According to Regulation (EC) No. 1272/2008 (CLP)
- Hazard pictogram(s) None
Signal word(s) None
Hazard statement(s) None
Precautionary statement(s) Avoid Contact with Eyes
Avoid Ingestion
- 2.3 Other hazards** None
- 2.4 Additional information** As a 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.



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▶ SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: Mixture, containing the following hazardous ingredients

Ingredient Name	CAS Number	%wt or % Vol*
Purified Water	7732-18-5	>50%
Ethylhexyl Isonanoate	71566-49-9	5-10%
Hexamethyldisiloxane	107-46-0	5-10%
Polyisobutylene	90003-27-4	1-5%
VP Eicosene Copolymer	28211-18-9	1-5%
Hydroxyethyl Acrylate/ Sodium Acryloyl Dimethyl Taurate copolymer	111286-86-3	1-5%
Butylene Glycol	107-88-0	1-5%
Oleth-3 Phosphate	39464-69-2	1-5%
Phenoxyethanol	122-99-6	0.1-1%
Hydrogenated Styrene/Iosprene Copolymer	68648-89-5	0.1-1%
Allantoin	97-59-6	0.1-1%
Carbomer	9003-01-4	0.1-1%
Triethanolamine, 99% (TEA)	102-71-6	0.1-1%
Methylparaben	99-76-3	0.1-1%
Propylparaben, NF	94-13-3	<0.1%
EDTA Disodium Technical Grade	139-33-3	<0.1%

*The 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
N/A	N/A	N/A	N/A	N/A	N/A

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	EC Classification and Risk Phrases	%W/W
N/A	N/A	N/A	N/A	N/A	N/A

3.3 Additional Information

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

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SECTION 4: FIRST AID MEASURES



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| 4.1 Description of first aid measures | |
| Inhalation | Not a Hazard |
| Skin Contact | Not a Hazard |
| Eye Contact | In case of contact, immediately flush eyes with water for at least 15 minutes. Contact physician if irritation persists. |
| 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

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| 5.1 Extinguishing media | |
| Suitable Extinguishing Media | Not Flammable
Carbon Dioxide, Dry chemical, Foam |
| Unsuitable Extinguishing Media | Not known |
| 5.2 Special hazards arising from the substance or mixture | Not known |
| 5.3 Advice for fire-fighters | Protective clothing should be worn.
Use fire-extinguishing methods suitable to surrounding conditions.
Wear full protective suit and self-contained breathing apparatus when extinguishing fires.
Do not release runoff from fire control methods to sewers or waterways. |

SECTION 6: ACCIDENTAL RELEASE MEASURES

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| 6.1 Personal precautions, protective equipment and emergency procedures | Contain all spill and leaks to prevent discharge into environment. Ventilate area and evacuate area of all non-essential personnel.
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 | Small spills Soak up with absorbant, shovel into waste container, flush area with water.
Large Spills: Soak up with absorbant, shovel into waste container, flush area with water.
Containment: Recover material for proper disposal.
Dispose of contaminated material as waste according to Section 13. |

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6.4 Reference to other sections 8, 13

SECTION 7: HANDLING AND STORAGE

7.1	Precautions for safe handling	Spilled material is slippery. Wash thoroughly after handling. When using do not eat or drink.
7.2	Conditions for safe storage, including any incompatibilities	Store in a well ventilated area and between 5°C and 25°C. Avoid overheating and freezing.
7.3	Specific end use(s)	Use as per instructions for use. Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics.

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)	Not required for normal use.
	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	Cream
	Colour	White
	Odour	Slight
	Odour Threshold (ppm)	Not Applicable
	pH (Value)	Not Applicable
	Melting Point (°C) / Freezing Point (°C)	Not Determined
	Boiling point/boiling range (°C):	~ 100°C
	Flash Point (°C)	Not Determined
	Evaporation rate (BA = 1)	Not available
	Flammability (solid, gas)	Not applicable
	Explosive limit ranges (Hexamethyldisiloxane)	Not applicable
	Vapour Pressure (Hexamethyldisiloxane)	Not applicable
	Vapour Density (Air=1)	Not applicable
	Density (g/ml)	Not Determined
	Solubility (Water)	Soluble.

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Solubility (Other)	Not determined
Partition Coefficient (n-Octanol/water)	Not Determined
Auto Ignition Temperature (°C)	Not Determined
Decomposition Temperature (°C)	Not Determined
Viscosity	55,000 cps
Explosive properties	Not explosive.
Oxidising properties	Not oxidising
9.2 Other information	Not available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Product is Stable
10.2 Chemical stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	Hazardous polymerization will not occur.
10.4 Conditions to avoid	Avoid overheating and freezing
10.5 Incompatible materials	None Known
10.6 Hazardous Decomposition Product(s)	None Known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
11.1.1 Substances	
Acute Toxicity	Not Known
11.1.2 Mixtures	
Acute toxicity	Not Known
Irritation	Not an irritant
Corrosivity	Not Known
Sensitisation	Does not cause Sensitization
Repeated dose toxicity	Not Known
Carcinogenicity	Not Carcinogenic
Mutagenicity	Not Mutagenic
Toxicity for reproduction	Not Teratogenic
STOT-single exposure	Not Known
STOT-repeated exposure	Not Known
Aspiration hazard	Not Known
Health Effects and Symptoms	
Inhalation	Not Applicable
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	Not considered an environmental hazard.
12.2 Persistence and degradability	No information available.
12.3 Bioaccumulative potential	No information available.
12.4 Mobility in soil	No information available
12.5 Results of PBT and vPvB assessment	No information available

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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:** Not Known

SECTION 14: TRANSPORT INFORMATION

	ADR/RID	IMDG	ICAO/IATA
14.1 UN number	Not Applicable	Not Applicable	Not Applicable
14.2 Proper Shipping Name	Not Applicable	Not Applicable	Not Applicable
14.3 Transport hazard class(es)	Not Applicable	Not Applicable	Not Applicable
14.4 Packing Group	Not Applicable	Not Applicable	Not Applicable
14.5 Environmental hazards	Not Applicable	Not Applicable	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** Not Applicable

SECTION 15: REGULATORY INFORMATION

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Medical Devices Directive** The product is classified and labelled in accordance with EC Directive 1999/45/EC.
- 15.2 Chemical Safety Assessment** No Chemical Safety Assessment has been carried out.



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► SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

Classification code(s):

Not Applicable

Risk Phrases

P262 Avoid Contact with Eyes

Hazard statement(s)

Not Applicable

References:

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

Sources of key data used to compile this data sheet: EC Directive 67/548/EC resp. 99/45/EC as amended in each case. Regulation (EC) No 1907/2006 (REACH) as amended in each case. EC Directives 2000/39/EC, 2006/15/EC as amended in each case. National Threshold Limit Values of the corresponding countries as amended in each case. Transport regulations according to ADR, RID, IMDG, IATA as amended in each case. The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Reason for update:

N/A

Supersedes:

N/A

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.