# SAFETY DATA SHEET


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

<table>
<thead>
<tr>
<th>1.1</th>
<th>Product identifier</th>
<th>Sorbaderm Barrier Cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>Relevant identified uses of the substance or mixture and uses advised against</td>
<td>Medical Device; Medical skin barrier cream.</td>
</tr>
<tr>
<td>1.3</td>
<td>Details of the supplier of the safety data sheet</td>
<td>Aspen Medical Europe Ltd. Clinitron House, Ashby Park, Ashby-de-la-Zouch, Leicestershire, LE65 1JG, United Kingdom.</td>
</tr>
<tr>
<td></td>
<td>Company Identification</td>
<td>Aspen Medical Europe Ltd.</td>
</tr>
<tr>
<td></td>
<td>Telephone</td>
<td>+44 (0) 1530 411000</td>
</tr>
<tr>
<td></td>
<td>E-Mail (competent person)</td>
<td><a href="mailto:Customers@aspenmedicaleurope.com">Customers@aspenmedicaleurope.com</a></td>
</tr>
<tr>
<td>1.4</td>
<td>Emergency telephone number</td>
<td>+44 (0)1530 562216</td>
</tr>
</tbody>
</table>

## SECTION 2: HAZARDS IDENTIFICATION

<table>
<thead>
<tr>
<th>2.1</th>
<th>Classification of the substance or mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regulation (EC) No. 1272/2008 (CLP)</td>
</tr>
<tr>
<td></td>
<td>Hazard statement(s)</td>
</tr>
<tr>
<td></td>
<td>Risk Phrases</td>
</tr>
<tr>
<td>2.2</td>
<td>Label elements</td>
</tr>
<tr>
<td></td>
<td>Hazard pictogram(s)</td>
</tr>
<tr>
<td></td>
<td>Signal word(s)</td>
</tr>
<tr>
<td></td>
<td>Hazard statement(s)</td>
</tr>
<tr>
<td></td>
<td>Precautionary statement(s)</td>
</tr>
<tr>
<td>2.3</td>
<td>Other hazards</td>
</tr>
<tr>
<td>2.4</td>
<td>Additional information</td>
</tr>
</tbody>
</table>
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures
Description: Mixture, containing the following hazardous ingredients

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

*The exact percentage (concentration) of this composition has been withheld as a trade secret.

Dangerous components

EC Classification No. 1272/2008

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>EC Classification and Hazard statement(s)</th>
<th>%W/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

EC Classification No. 67/548/EEC

<table>
<thead>
<tr>
<th>Hazardous ingredient(s)</th>
<th>CAS No.</th>
<th>EC No.</th>
<th>REACH Registration No.</th>
<th>EC Classification and Risk Phrases</th>
<th>%W/W</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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: 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

5.1 Extinguishing media
   - Not Flammable
   - Suitable Extinguishing Media: 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

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.
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/bubbling 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.
SAFETY DATA SHEET

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

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
SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>14.1 UN number</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.2 Proper Shipping Name</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.3 Transport hazard class(es)</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.4 Packing Group</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.5 Environmental hazards</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.6 Special precautions for user</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

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.
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.

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.