

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

1.1. Product identifier

| | |
|--|--|
| Trade name or designation of the mixture | Sorbaderm Barrier Film (Foam Applicator) |
| Registration number | - |
| Synonyms | None. |
| Issue date | 10-March-2017 |
| Version number | 01 |
| Revision date | - |
| Supersedes date | - |

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

| | |
|----------------------|--|
| Identified uses | Medical device; skin barrier film foam applicator. |
| Uses advised against | None known. |

1.3. Details of the supplier of the safety data sheet

| | |
|---------------------------------|---|
| Company name | Aspen Medical Europe Ltd. |
| Address | Clinitron House, Ashby Park, Ashby-de-la-Zouch, Leicestershire, LE65 1JG |
| Telephone | 01530 411000 0800 032 3399 |
| E-mail | customers@aspenmedicaleurope.com |
| 1.4. Emergency telephone number | +44 (0)1530 562216 |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

Physical hazards

| | | |
|-------------------|------------|--|
| Flammable liquids | Category 2 | H225 - Highly flammable liquid and vapour. |
|-------------------|------------|--|

Environmental hazards

| | | |
|--|------------|---|
| Hazardous to the aquatic environment, acute aquatic hazard | Category 1 | H400 - Very toxic to aquatic life. |
| Hazardous to the aquatic environment, long-term aquatic hazard | Category 2 | H411 - Toxic to aquatic life with long lasting effects. |

Hazard summary May be ignited by heat, sparks or flames. Dangerous for the environment if discharged into watercourses.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Hazard pictograms



Signal word Danger

Hazard statements

| | |
|------|--|
| H225 | Highly flammable liquid and vapour. |
| H400 | Very toxic to aquatic life. |
| H411 | Toxic to aquatic life with long lasting effects. |

Precautionary statements

Prevention

| | |
|------|--|
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P240 | Ground/bond container and receiving equipment. |

P241 Use explosion-proof electrical/ventilating/lighting equipment.
 P242 Use only non-sparking tools.
 P243 Take precautionary measures against static discharge.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/eye protection/face protection.

Response

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P370 + P378 In case of fire: Use water fog, foam, dry chemical powder, carbon dioxide to extinguish.

Storage

P403 + P235 Store in a well-ventilated place. Keep cool.

Disposal

Not assigned.

Supplemental label information None.

2.3. Other hazards Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

| Chemical name | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|------------------------|---|-----------------------|------------------------|-----------|-------|
| Hexamethyldisiloxane | 70-90 | 107-46-0 203-492-7 | - | - | |
| Classification: | Flam. Liq. 2;H225, Aquatic Acute 1;H400, Aquatic Chronic 2;H411 | | | | |
| Acrylate co-polymer | 10-30 | Trade secret | - | - | |
| Classification: | - | | | | |

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).
 M: M-factor
 PBT: persistent, bioaccumulative and toxic substance.
 vPvB: very persistent and very bioaccumulative substance.
 All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information Take off all contaminated clothing immediately. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact Flush eyes with water as a precaution. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.
Ingestion Rinse mouth. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both acute and delayed Exposure may cause temporary irritation, redness, or discomfort.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Thermal burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital.

SECTION 5: Firefighting measures

General fire hazards Highly flammable liquid and vapour.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture Vapours may form explosive mixtures with air. Vapours may travel considerable distance to a source of ignition and flash back. During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures

In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders

Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up.

6.2. Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil etc) away from spilled material. Take precautionary measures against static discharge. Use only non-sparking tools. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other sections

For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. When using do not smoke. Explosion-proof general and local exhaust ventilation. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use non-sparking tools and explosion-proof equipment. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat, sparks and open flame. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store in a well-ventilated place. Keep in an area equipped with sprinklers. Store away from incompatible materials (see section 10 of the SDS). Storage temperature: between 5 and 30°C.

7.3. Specific end use(s)

Medical device; skin barrier film foam applicator.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no effect levels (DNELs)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

General information

Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

| | |
|--|--|
| Eye/face protection | If contact is likely, safety glasses with side shields are recommended. |
| Skin protection | |
| - Hand protection | Wear appropriate chemical resistant gloves. The following glove materials are recommended: Latex, vinyl, nitrile rubber. |
| - Other | Wear suitable protective clothing. |
| Respiratory protection | In case of insufficient ventilation, wear suitable respiratory equipment. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |
| Hygiene measures | When using do not smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. |
| Environmental exposure controls | Inform appropriate managerial or supervisory personnel of all environmental releases. |

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

| | |
|--|---------------------------------------|
| Physical state | Liquid. |
| Form | Foam pad saturated with clear liquid. |
| Colour | Clear. |
| Odour | Slight. |
| Odour threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | -68 °C (-90.4 °F) |
| Initial boiling point and boiling range | -68 °C (-90.4 °F) |
| Flash point | -1.0 °C (30.2 °F) |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not applicable. |

Upper/lower flammability or explosive limits

| | |
|--|--|
| Explosive limit - lower (%) | 0.5 % |
| Explosive limit – upper (%) | 21.8 % |
| Vapour pressure | 20 hPa (20°C) (H ₂ O=1) |
| Vapour density | Not available. |
| Relative density | 0.76 (20°C) |
| Solubility(ies) | Insoluble in water. |
| Partition coefficient (n-octanol/water) | Log Pow: > 3.16. > 3.16 (25°C) (Hexamethyldisiloxane) |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Explosive properties | Not explosive. |
| Oxidising properties | Not oxidising. |

9.2. Other information No relevant additional information available.

SECTION 10: Stability and reactivity

| | |
|---|--|
| 10.1. Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| 10.2. Chemical stability | Material is stable under normal conditions. |
| 10.3. Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| 10.4. Conditions to avoid | Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials. |
| 10.5. Incompatible materials | Strong oxidising agents. Strong acids. Strong alkalis. |
| 10.6. Hazardous decomposition products | Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours. Silicon oxide fumes. |

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation No adverse effects due to inhalation are expected.
Skin contact No adverse effects due to skin contact are expected.
Eye contact Direct contact with eyes may cause temporary irritation.
Ingestion May cause discomfort if swallowed.

Symptoms Exposure may cause temporary irritation, redness, or discomfort.

11.1. Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

| Components | Species | Test results |
|---|---|--------------------|
| Hexamethyldisiloxane (CAS 107-46-0) | | |
| Acute | | |
| Dermal | | |
| LD50 | Rabbit | > 2000 mg/kg |
| Inhalation | | |
| LC50 | Rat | 15956 ppm, 4 Hours |
| Oral | | |
| LD50 | Rat | > 5000 mg/kg |
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. | |
| Serious eye damage/eye irritation | Based on available data, the classification criteria are not met. | |
| Respiratory sensitisation | Based on available data, the classification criteria are not met. | |
| 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. | |
| Specific target organ toxicity - single exposure | Based on available data, the classification criteria are not met. | |
| Specific target organ toxicity - repeated exposure | Based on available data, the classification criteria are not met. | |
| Aspiration hazard | Based on available data, the classification criteria are not met. | |
| Mixture versus substance information | No information available. | |
| Other information | This product has no known adverse effect on human health. | |

SECTION 12: Ecological information

12.1. Toxicity Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

| Components | Species | Test results |
|-------------------------------------|---------|--|
| Hexamethyldisiloxane (CAS 107-46-0) | | |
| Aquatic | | |
| <i>Acute</i> | | |
| Algae | EC50 | Selenastrum capricornutum (new name Pseudokirchnerella subca) > 0.93 mg/l, 96 hr |
| Crustacea | EC50 | Daphnia magna 0.79 mg/l, 72 hr |
| Fish | LC50 | Rainbow trout,donaldson trout (Oncorhynchus mykiss) 0.46 mg/l, 96 hr |

12.2. Persistence and degradability

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow) Log Pow: > 3.16.

Sorbaderm Barrier Film (Foam Applicator) > 3.16, (25°C) (Hexamethyldisiloxane)
Hexamethyldisiloxane (CAS 107-46-0) 4.2

Bioconcentration factor (BCF) Not available.

| | |
|---|---|
| 12.4. Mobility in soil | The product is immiscible with water and will spread on the water surface. |
| 12.5. Results of PBT and vPvB assessment | Not a PBT or vPvB substance or mixture. |
| 12.6. Other adverse effects | No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component. |

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------------------|--|
| Residual waste | Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| Contaminated packaging | Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal. |
| EU waste code | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Disposal methods/information | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Special precautions | Dispose in accordance with all applicable regulations. |

SECTION 14: Transport information

ADR

| | |
|---|---|
| 14.1. UN number | UN1993 |
| 14.2. UN proper shipping name | FLAMMABLE LIQUID, N.O.S. (Hexamethyldisiloxane) |
| 14.3. Transport hazard class(es) | |
| Class | 3 |
| Subsidiary risk | - |
| Label(s) | 3 |
| Hazard No. (ADR) | 33 |
| Tunnel restriction code | D/E |
| 14.4. Packing group | II |
| 14.5. Environmental hazards | Yes |
| 14.6. Special precautions for user | Read safety instructions, SDS and emergency procedures before handling. |

RID

| | |
|---|---|
| 14.1. UN number | UN1993 |
| 14.2. UN proper shipping name | FLAMMABLE LIQUID, N.O.S. (Hexamethyldisiloxane) |
| 14.3. Transport hazard class(es) | |
| Class | 3 |
| Subsidiary risk | - |
| Label(s) | 3 |
| 14.4. Packing group | II |
| 14.5. Environmental hazards | Yes |
| 14.6. Special precautions for user | Read safety instructions, SDS and emergency procedures before handling. |

ADN

| | |
|---|---|
| 14.1. UN number | UN1993 |
| 14.2. UN proper shipping name | FLAMMABLE LIQUID, N.O.S. (Hexamethyldisiloxane) |
| 14.3. Transport hazard class(es) | |
| Class | 3 |
| Subsidiary risk | - |
| Label(s) | 3 |
| 14.4. Packing group | II |
| 14.5. Environmental hazards | Yes |
| 14.6. Special precautions for user | Read safety instructions, SDS and emergency procedures before handling. |

IATA

| | |
|------------------------|--------|
| 14.1. UN number | UN1993 |
|------------------------|--------|

14.2. UN proper shipping name Flammable liquid, n.o.s. (Hexamethyldisiloxane)
14.3. Transport hazard class(es)
 Class 3
 Subsidiary risk -
 Label(s) 3
14.4. Packing group II
14.5. Environmental hazards Yes
ERG Code 3H
14.6. Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

14.1. UN number UN1993
14.2. UN proper shipping name FLAMMABLE LIQUID, N.O.S. (Hexamethyldisiloxane)
14.3. Transport hazard class(es)
 Class 3
 Subsidiary risk -
14.4. Packing group II
14.5. Environmental hazards
 Marine pollutant Yes
EmS F-E, S-E
14.6. Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code Not established.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorisation, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Not listed.

| | |
|---|---|
| Other regulations | The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended. |
| National regulations | Follow national regulation for work with chemical agents. |
| 15.2. Chemical safety assessment | No Chemical Safety Assessment has been carried out. |
| SECTION 16: Other information | |
| List of abbreviations | EC50: Effective Concentration, 50%. LD50: Lethal Dose, 50%. LC50: Lethal Concentration, 50%. |
| References | GESTIS Substance Database HSDB (2005) RTECS |
| Information on evaluation method leading to the classification of mixture | The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available. |
| Full text of any H-statements not written out in full under Sections 2 to 15 | H225 Highly flammable liquid and vapour. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects. |
| Training information | Follow training instructions when handling this material. |
| Disclaimer | Aspen Surgical Products, Inc cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available. |