

**Date:** January 2013

**Material Safety Data Sheet (MSDS):**

Reference: This MSDS is prepared to comply with Directive 93/42/EEC amended to 2007/47/EC. CE Conformance Declaration according to annex II (Full Quality Assurance system).

**Section 1 - Identification of Product and Company**

**Product Name:** *Eclipse Adherent Sacral*  
**Product Code:** CR3985, CR3986  
**Product Information:** Super absorbent sacral dressing with silicone contact layer  
**Classification:** IIb Medical Device Directive 93/42/EEC amended by Directive 2007/47/EC, Rule 4 (Secondary Intent)

**Manufacturer:**

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This product does not contain any medicinal substances and any tissues of animal origin and meets the provisions of the European Medical Devices Directive 93/42/EEC.

This product does not contain substances classified as hazardous under EC nor US OSHA regulations. Main ingredients and packaging materials are listed below.

**Section 2 - Composition/ Information on Ingredients**

| Chemical Name                     | CAS-No. | EC-No. |
|-----------------------------------|---------|--------|
| Polyurethane film/ paper liner    | N/A     |        |
| Polyurethane Film                 | N/A     |        |
| Polyurethane Foam                 | N/A     |        |
| Cardboard Containers (Retail Box) | N/A     |        |
| Paper Pouch (Primary Pack)        | N/A     |        |

**Section 3 - Hazards Identification**

**None Identified**

This product is intended to be used in contact with skin and used in accordance with the Instructions For Use (IFU).

#### Section 4 - First Aid Measures

|                                |  |
|--------------------------------|--|
| <b>In case of eye contact</b>  | Should irritation occur, flush the entire eyeball with copious amounts of water. If irritation persists seek medical advice.       |
| <b>In case of skin contact</b> | This product is not a skin irritant. Intended to be in contact with skin when used as directed on the IFU.                         |
| <b>If inhaled</b>              | This product is not respirable   |
| <b>If ingested/ swallowed</b>  | No specific intervention is indicated as the compound is not hazardous by ingestion but if symptoms occur, consult medical advice. |
| <b>Other</b>                   | Show this MSDS to a treating physician or treating doctor at an Emergency ward.  |

#### Section 5 - Fire Fighting Measures

|   |  |
|---|--|
| <b>Extinguishing media</b>              | Co2  |
| <b>Special fire fighting procedures</b> | Wear respiratory apparatus. Use water, spray, dry chemical, carbon dioxide and foam. |
| <b>Exposure hazard</b>                  | Avoid inhalation of fumes.   |

#### Section 6 - Accidental Release Measures

None

#### Section 7 - Handling and Storage

|                       |  |
|-----------------------|--|
| <b>Handling</b>       | See Instructions for Use   |
| <b>Storage</b>        | Store away from direct heat and damp conditions. Store at room temperature (23°C +/- 5°C) and use straight away when opened. |
| <b>Waste Disposal</b> | If unused dispose as non-hazardous waste in accordance with local regulations. If used, dispose of as clinical waste.        |

#### Section 8 - Exposure Controls/ Personal Protection

|                                     |  |
|-------------------------------------|--|
| <b>Engineering Measures</b>         | None identified.   |
| <b>Personal Protective Measures</b> | Good clinical practice (gloves to prevent contamination to treating physician) |
| <b>Exposure Limit Values</b>        | None   |

#### Section 9 - Physical and Chemical Properties

|                                      |  |
|--------------------------------------|--|
| <b>Appearance</b>                    | Layered absorbent dressing with beige backing and silicone contact layer |
| <b>Odor</b>                          | None   |
| <b>Physical State</b>                | Dry dressing with adhesive layer   |
| <b>pH</b>                            | N/A  |
| <b>Vapor Pressure</b>                | Not determined   |
| <b>Vapor Density</b>                 | Not determined   |
| <b>Boiling Point</b>                 | Not determined   |
| <b>Melting Point/ Freezing Point</b> | Not determined   |
| <b>Solubility</b>                    | Not determined   |
| <b>Density</b>                       | Not determined   |
| <b>Flash Point</b>                   | N/A  |

### Section 10 - Stability and Reactivity

|                                 |                                     |
|---------------------------------|-------------------------------------|
| <b>Stability</b>                | Stable under normal user conditions |
| <b>Conditions to Avoid</b>      | See IFU                             |
| <b>Materials to Avoid</b>       | N/A                                 |
| <b>Hazardous Decomposition</b>  | N/A                                 |
| <b>Hazardous Polymerization</b> | N/A                                 |

### Section 11 - Toxicological Information

|                              |                |
|------------------------------|----------------|
| <b>Acute Effects</b>         | Not determined |
| <b>Chronic Effects</b>       | Not determined |
| <b>Carcinogenicity</b>       | Not determined |
| <b>Mutagenicity</b>          | Not determined |
| <b>Reproductive Effects</b>  | No data        |
| <b>Developmental Effects</b> | No data        |

### Section 12 - Ecological/ Environmental Information

Ecotoxicological data has not been determined specifically for this product. Based on toxicity data on the materials no effects are expected to the environment. However, the product is not biodegradable and discharge to the environment should be avoided.

### Section 13 - Disposal Considerations

The recommended disposal technology is incineration at any approved facility. The disposal should always be in compliance with National, Federal, State and Local Regulations. This product should not be discharged to the environment.

USA: if this product as supplied becomes waste, it does not meet the criteria of a hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261.

EU: as per the European Waste Catalogue (EWC), in accordance with EC Directive 75/44EEC, the following Waste Code can be used: 18 01 04 00 wastes whose collection and disposal is not subject to special requirements in view of prevention (e.g dressings). However, if the waste in view of prevention of infection needs special requirements, other waste codes shall be used. It is the responsibility of the holder of the waste to determine the actual classification. Waste from private households may be disposed of together with other household waste.

If unused dispose of as non hazardous waste in accordance with local regulations in the UK. If used, dispose of as clinical waste.

### Section 14 - Transport Information

**Not dangerous goods (ADR, 2003, RID, DOT).**

## Section 15 - Regulatory Information

United States: This product is regulated under the Federal Food Drug and Cosmetic Act and do not require an MSDS for hazard communication as stated in 29 CFR 1910.1200.

This MSDS is supplied as an additional service.

European Union: This product is a medical device and is regulated under the Council Directive 93/42/EEC (commonly known as the Medical Device Directive). Medical devices do not require a safety data sheet for hazard communication.

This safety data sheet is supplied as an additional service.

| <b>Hazardous chemicals according to Directive 67/548/EEC and later amendments</b> | <b>Risk Phrase</b> | <b>Safety Phrase</b> |
|---|--------------------|----------------------|
| None  | None               | None                 |

## Section 16 - Other Information

The above information has been compiled from sources believed to be reliable and is accurate to the best of our knowledge. However, Brighwake/ Advancis Medical cannot give any guarantees regarding information from other sources and expressly does not make any warranties, nor assumes any liability, for its use.