

1. Identification of the product and the company
Product Name: Mepitel®
Type: Sterile Non-Adherent Silicone Dressing
Company: Mölnlycke Health Care
Address: 826 Newtown-Yardley Road, Suite 300 Newtown, PA 18940
Information Telephone Number: 1-800-882-4582
2. HMIS
Health: 0
Fire: 0
Reactivity: 0
Personal Protective Equipment: None required
3. Composition/information on ingredients
Composition: Silicone gel (medical grade), polyamide net.
4. Latex
None of the materials used in the manufacture of the above product contain dry crumb rubber or natural rubber latex materials. The unit package contains a sealing adhesive made from natural rubber latex.
5. Health Hazard/First aid measures
Eyes: Possible eye irritation. Immediately flush eyes with water for at least 15 minutes. Get medical attention.
Skin: None expected. If irritation develops, get medical attention.
Inhalation: None expected, not an expected route of exposure.
Ingestion: None expected, not an expected route of exposure. Get medical attention.
6. Safety Testing
Cytotoxicity (In Vitro) Passed
Guinea Pig Skin Irritation & Sensitization Passed
Ethylene Oxide Residue Passed
ASTM 90-Day Implant Passed
ASTM Hemolysis Passed

7. Fire and Explosion Hazard Data

Flash Point:	Not applicable
Extinguishing Media:	Whatever is appropriate for surrounding fire.
Personal Protective Equipment:	Whatever is appropriate for surrounding fire.
Special Instructions:	None known.

8. Reactivity Data

Stability:	Stable
Incompatibility (materials to avoid):	None known
Hazardous Decomposition or By-products:	Thermal decomposition may produce carbon dioxide, carbon monoxide, nitrogen Oxides, and formaldehydes.
Hazardous Polymerization:	Will not occur

9. Precautions for Safe Handling and Use

Handling:	Single use.
Sterility:	The sterility of contents is guaranteed unless individual package is damaged or opened.
Warnings:	Mepitel used on burns treated with meshed grafts or after facial resurfacing can leave imprints.
Precautions:	The wound should be inspected for signs of infection and managed according to clinical judgement. Mepitel used on burns treated with mesh grafts: avoid placing unnecessary pressure upon the dressing. Mepitel used after facial resurfacing: avoid placing pressure upon the dressing; lift and reposition the dressing at least every second day.
Contraindications:	None known

10. Ecological information

No known ecological hazards associated with this product.

11. Disposal considerations

Dispose in accordance to federal, state, and local regulations.