

ZeniFoam-AG Gentle Border Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: ZeniFoam-AG Gentle Border
Use/Size: Silver Foam dressing with Silicone adhesive and border. Sizes: 4" x 4" and "6" x 6"
Manufacturer/Supplier: ZeniMedical, LLC dba Fidalis
Address: 1410 East Weisgarber Road, Knoxville, TN 37909
Phone: 1-888-945-1493
Issue Date: January, 10, 2018

Section 2. COMPOSITION / INFORMATION ON THE COMPONENTS

Non-Border version:

| Component Name | CAS#/Codes | Concentration | R Phrases | Classification |
|--------------------------|------------|---------------|-----------|----------------|
| Polyurethane film | 51852-81-4 | 3~5% | None list | None list |
| Silver Polyurethane foam | - | 40~60% | None list | None list |
| Polysiloxane | 9016-00-6 | 25~40% | None list | None list |
| PE(Polyethylene) | 9002-88-4 | 10~17% | None list | None list |

Border version:

| Component Name | CAS#/Codes | Concentration | R Phrases | Classification |
|--------------------------|------------|---------------|-----------|----------------|
| Polyurethane film | 51852-81-4 | 8~12% | None list | None list |
| Non-Woven fibres | - | 5~15% | None list | None list |
| Silver Polyurethane foam | - | 20~30% | None list | None list |
| Polysiloxane | 9016-00-6 | 35~45% | None list | None list |
| PE(Polyethylene) | 9002-88-4 | 15~20% | None list | None list |

Section 3. HAZARD IDENTIFICATION

Routes of Entry

Eyes, skin, oral

Carcinogenic Status

Not considered carcinogenic by NTP, IARC, and OSHA.

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Target Organs

None

Health Effects - Eyes

Contact may cause redness or discomfort due to mechanical abrasion.

Health Effects - Skin

Intradermal irritation and skin sensitisation testing indicated non-irritant and non-sensitising.

Health Effects - Ingestion

Ingestion of the dressing may cause a choking hazard or internal blockage.

Health Effects - Inhalation

Not relevant.

Section 4. FIRST AID MEASURES

Eyes

If in contact with eyes, hold the eye open and immediately flood the eyes with plenty of water for at least 15 minutes. Obtain medical attention if soreness or redness persists.

Skin

If skin irritation develops, or other symptoms occur, discontinue use. Wash skin thoroughly with soap and water. Seek medical attention if symptoms persist.

Ingestion

Obtain medical attention immediately.

Inhalation

Not relevant.

Advice to Physicians

Treat symptomatically.

Section 5. FIRE FIGHTING MEASURES

Extinguishing Media

On large fires use dry chemical, foam or water spray. On small fires use carbon dioxide(CO₂), dry chemical or water spray. Water can be used to cool fire exposed containers.

Unusual Fire and Explosion Hazards

None

Protective Equipment for Fire-Fighting

Wear full protective clothing and self-contained breathing apparatus.

Section 6. ACCIDENTAL RELEASE MEASURES

No specific measures necessary.

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Section 7. HANDLING AND STORAGE

Use reasonable care and store away from oxidizing materials.

Storage area should be: - cool - dry .

Use with adequate ventilation.

Avoid eye contact.

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Standards

There are no components with workplace exposure limits.

Engineering Control Measures

Local Ventilation: None should be needed.

General Ventilation: Recommended.

Respiratory Protection

None required for normal use.

Hand Protection

Not required during normal use.

Eye Protection

Wear eye protection whenever there is the possibility of contact with eyes.

Body Protection

Normal work wear.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|----------------------------|---|
| Physical State | Solid and gel |
| Color | Skin-color backing film, yellow or light brown PU silver foam(white Non-Woven fibres in border version), transparent perforated silicone wound contact layer. |
| Odor | Slight |
| Specific Gravity(25°C) | Not applicable |
| pH | Not applicable |
| Boiling Range/Point (°C/F) | Not applicable |
| Flash Point (PMCC) (°C/F) | Not determined |
| Explosion Limits (%) | Not applicable |
| Vapor Pressure | Not applicable |
| Solubility in Water | Undissolved |
| Vapor Density (Air = 1) | Not applicable |
| Viscosity (cSt) | Not applicable |

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Section 10. STABILITY AND REACTIVITY

Stability

Stable under normal store conditions.

Conditions to Avoid

Keep away from sunlight.

Materials to Avoid

Oxidising agents such as hypochlorite solutions or hydrogen peroxide.

Hazardous Polymerization

Will not occur.

Hazardous Decomposition Products

None

Section 11. TOXICOLOGICAL INFORMATION

Cytotoxicity

This product saline extract did not cause cytotoxicity.

Acute Toxicity

This product saline extract did not cause acute toxicity by Intraperitoneal injections at 4, 24, 48 and 72 hours.

Chronic Toxicity/Carcinogenicity

This product is not expected to cause long term adverse health effects.

Genotoxicity

This product is not expected to cause any mutagenic effects.

Reproductive/Developmental Toxicity

This product is not expected to cause adverse reproductive effects.

Section 12. ECOLOGICAL INFORMATION

Mobility Not available.

Persistence/Degradability Not available.

Bio-accumulation Not available.

Ecotoxicity Not available.

Section 13. DISPOSAL

Dispose of in accordance with all applicable local and national regulations.

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Section 14. TRANSPORT INFORMATION

The data provided in this section is for information only. Please apply the appropriate regulations to properly classify your shipment.

U.S. DOT Hazard Class: Not regulated as hazardous

UN Number: Not regulated as hazardous

Section 15. REGULATORY INFORMATION

Not Available.

Section 16. OTHER INFORMATION

Not Available.

These data are offered in good faith as typical values and not as product specifications. No warranty, either expressed or implied, is hereby made. The recommended industrial hygiene and safe handling procedures are believed to be generally applicable. However, each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.
