

**Material Safety Data Sheet (MSDS) for
QuikClot® Combat Gauze™ brand hemostatic agent**

1. CHEMICAL PRODUCT & COMPANY INFORMATION

- 1.1. Product Name: QuikClot® Combat Gauze™
 1.2. Product Use: For temporary external use to control traumatic bleeding.
 1.3. Company Information: Z-Medica Corporation, 4 Fairfield Blvd., Wallingford, CT 06492 USA
 Tel: +1-203-294-0000 x262, Fax: +1-203-294-0688, www.z-medica.com

2. COMPOSITION/INFORMATION ON INGREDIENTS

- 2.1. Product Contents:
 2.1.1. QuikClot® Combat Gauze™ = One (1) Sterile Strip 3 in. wide x 4 yds. long coated with Hemostatic Agent
 2.2. Composition of Strip: medical fabric (synthetic blend)
 2.3. Composition of Hemostatic Agent:

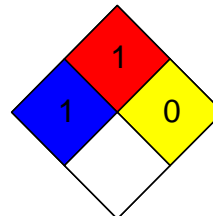
CAS #	Component	Percent (Dry Weight)
56-81-5	Glycerin	Proprietary %
1332-58-7	Kaolin	Proprietary %
14808-6-7	Silica	< 0.05 %

NOTE: The Silica is bound to the medical fabric with the Kaolin under normal conditions, preventing its respiratory exposure pathway to an individual, therefore QuikClot® Combat Gauze™ is not considered to produce airborne particles of a respirable size.

3. HAZARDS IDENTIFICATION

3.1. HMIS™ - Hazardous Material Information System

- 3.1.1. **Health Hazard:** Irritation possible if exposed to dust from heated and dried medical fabric.
 3.1.2. **Flammability:** Medical fabric will burn when exposed to flame.
 3.1.3. **Reactivity/Physical Hazard:** Components are stable and produce no hazardous decomposition products.



HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0

3.2. Potential Health Effects:

- 3.2.1. **Primary Routes of Exposure:** Dust may be generated if medical fabric is heated and dried—resulting in possible contact of dust with eyes and lungs.
 3.2.2. **Skin Contact:** None
 3.2.3. **Eye Contact:** Dust from heated and dried medical fabric may cause eye discomfort and/or irritation.
 3.2.4. **Ingestion:** May cause irritation to gastrointestinal tract.
 3.2.5. **Inhalation:** Dust from heated and dried medical fabric may cause lung discomfort and/or irritation.
 3.2.6. **Chronic Effects:** None

4. FIRST-AID MEASURES

- 4.1. **Eye Contact:** Flush immediately with plenty of water for at least 15 minutes. If eye irritation persists, consult a physician.
 4.2. **Skin Contact:** None
 4.3. **After Inhalation:** Remove to fresh air; artificial respiration if necessary.

- 4.4. **After Ingestion:** Drink two or three glasses of water to dilute stomach contents. DO NOT induce vomiting. Call a physician immediately.
- 4.5. **Notes to physician:** Carefully read instructions for use printed on the primary packaging. Contact the company directly to report any adverse events.
5. **FIRE FIGHTING MEASURES**
- 5.1. **Suitable extinguishing media:** Water spray, dry chemical, and carbon dioxide.
- 5.2. **Unsuitable extinguishing media:** None.
- 5.3. **Fire and explosion hazards:** Medical fabric will burn when exposed to flame.
- 5.4. **Special protective equipment:** In the case of smoke, use self-contained breathing apparatus.
- 5.5. **Flash Point:** N/A
6. **ACCIDENTAL RELEASE MEASURES**
- 6.1. **Personal protection:** None
- 6.2. **Environmental precautions:** None
- 6.3. **Clean-up:** Sweep, shovel or vacuum product into appropriate containers (do not use vacuum if materials has contacted a hydrocarbon material). Dispose of spilled product in accordance with all applicable government regulations.
7. **HANDLING & STORAGE**
- 7.1. **Handling:** No special handling required. Discard packages that are damaged or open.
- 7.2. **Storage:** Store in original package. Discard unused portion. Do not reuse. No special storage conditions required.
8. **EXPOSURE CONTROLS/PERSONAL PROTECTION**
- 8.1. **Engineering Controls:** N/A
- 8.2. **Personal protection equipment:** N/A
9. **PHYSICAL & CHEMICAL PROPERTIES**
- 9.1. **Form:** QuikClot® Combat Gauze™ = One (1) Sterile Strip 3 in. wide x 4 yds. long
- 9.2. **Odor:** Slightly Sweet
- 9.3. **pH:** 5.5-6.5 in Water
- 9.4. **Boiling Point/Range:** N/A
- 9.5. **Melting Point/Range:** Polyester component of medical fabric will melt @ 464-500°F (240-260°C).
10. **STABILITY**
- 10.1. **Stability:** Stable
- 10.2. **Hazardous decomposition products:** There are no decomposition products if product is used as directed. Smoke, carbon dioxide, and carbon monoxide are the hazardous combustion byproducts emitted from the medical fabric.
- 10.3. **Conditions/Materials to avoid:** None
11. **TOXICOLOGICAL INFORMATION**
- Product has passed the appropriate biocompatibility/toxicology testing for a medical device intended for use on breached or compromised surfaces (traumatic wounds) in accordance with ISO 10993-1:2003(E). This testing includes: cytotoxicity, skin sensitization, and intracutaneous reactivity.
12. **ECOLOGICAL INFORMATION**
- 12.1. **Mobility:** No data available
- 12.2. **Biodegradation:** No data available
- 12.3. **Bioaccumulation:** No data available
- 12.4. **Aquatic Toxicity:** No data available
13. **DISPOSAL CONSIDERATIONS**
- 13.1. **Provisions relating to waste:** EPA – Resource Conservation and Recovery Act (RCRA) Hazardous and Solid Waste Management Regulations.
- 13.2. **Disposal Information:** This product or any of its components are not listed by generic name or trademark name in the U.S. EPA’s RCRA regulations and does not possess any of the identifying characteristics of hazardous waste (ignitability, corrosivity, reactivity or toxicity). Materials of a

hazardous nature that contact the product may be retained on the product. The user of the product must identify the hazards associated with the retained material in order to assess the waste disposal options.

14. TRANSPORT INFORMATION

14.1. UN-No.: N/A

14.2. Proper Shipping Name: Medical Goods, Blood Clotting Agent (Harmonized Tariff (Export) Schedule B Code 3005900000 (Non-Adhesive Wound Dressing). No Export License Required.

14.3. Packing Group: N/A

14.4. Transport Mode:

14.4.1. U.S. DOT – Not Regulated

14.4.2. ADR/RID – Not Regulated

14.4.3. IMDG – Not Regulated

14.4.4. IATA – Not Regulated

15. REGULATORY INFORMATION

15.1. US FDA/CDRH – Unclassified, Product Code = FRO, K072474

15.2. EU – Class IIb, NB=BSI, AR=Emergo Europe, Molenstraat 15, 2513 BH, The Hague, The Netherlands

15.3. Canada – Class II, Canadian License 77763

16. CONTACT INFORMATION

For technical, health, safety and environmental information, please contact:

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