

Material Safety Data Sheet (MSDS) QuikClot ACS+™ and QuikClot 1st Response™

1. CHEMICAL PRODUCT & COMPANY INFORMATION

- 1.1. Product Names: QuikClot ACS+™. QuikClot 1st Response™
- 1.2. Product Use: Temporary Traumatic Wound Treatment for Moderate-to-Severe Bleeding
- 1.3. Company Information: Z-Medica Corporation, 4 Fairfield Blvd., Wallingford, CT 06492 USA
Tel: +1-203-294-0000, Fax: +1-203-294-0688, www.z-medica.com

2. COMPOSITION/INFORMATION ON INGREDIENTS

- 2.1. Product Contents:
 - 2.1.1. ACS+ = One (1) Mesh Bag Containing 100-114g of Hemostatic Agent (Beads)
 - 2.1.2. 1st Response = One (1) Mesh Bag Containing 25-29g of Hemostatic Agent (Beads)
- 2.2. Composition of Mesh Bags: medical fabric (synthetic blend)
- 2.3. Composition of Hemostatic Beads

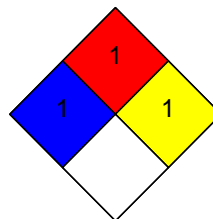
CAS #	Component	Percent (Dry Weight)
1344-01-0	Calcium sodium aluminosilicate	65-85%
1327-43-1	Magnesium aluminosilicate clay	15-35%
14808-60-7	Quartz	< Detectable Limit

Please note, the quartz (fibrous SiO₂) is only listed per OSHA requirements on USA Material Safety Data Sheets. The quartz may exist as a virtually undetectable impurity in the naturally occurring clay binder. In addition, the less than detectable quartz impurity is bound in the beads (not loose), preventing its respiratory exposure pathway to an individual. Furthermore, listing quartz at these less than detectable levels is not a requirement by European regulations and the Material Safety Data Sheets do not reflect its listing. No quartz has ever been detected by any method in QuikClot Brand Hemostatic Agents.

3. HAZARDS IDENTIFICATION

3.1. HMIS™ - Hazardous Material Information System

- 3.1.1. **Health Hazard:** Irritation possible if exposed to dust from broken beads.
- 3.1.2. **Flammability:** Mesh bags will burn when exposed to flame.
- 3.1.3. **Reactivity/Physical Hazard:** Materials adsorb water non-violently and generate small amount of heat.



HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	1

- 3.2. Potential Health Effects:**
- 3.2.1. **Primary Routes of Exposure:** Direct Contact.
 - 3.2.2. **Skin Contact:** May cause skin irritation.
 - 3.2.3. **Eye Contact:** May cause eye discomfort and/or irritation seen as tearing and reddening.
 - 3.2.4. **Ingestion:** None
 - 3.2.5. **Inhalation:** N/A
 - 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:** N/A
 - 4.4. **After Ingestion:** None
 - 4.5. **Notes to physician:** Carefully read instructions for use enclosed with this MSDS and printed on the primary packaging. Contact the company directly to report any adverse events. Product is capable of adsorbing other materials—such as hydrocarbons. If product has adsorbed other materials of a hazardous nature, identify the materials and treat symptomatically.
- 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:** Mesh bags 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:** See Section 8
 - 6.2. **Environmental precautions:** None
 - 6.3. **Clean-up:** Sweep, shovel or vacuum spilled beads and/or 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, open or loose.
 - 7.2. **Storage:** Store in original multi-layer foil 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:** 5"x10" Mesh bag containing 100-114g of tan beads (~2mm in diameter); 3.5"x3.5" Mesh bag contains 25-29g of tan beads (~2mm in diameter).
 - 9.2. **Odor:** None
 - 9.3. **pH:** 8-11 in Water
 - 9.4. **Boiling Point/Range:** N/A
 - 9.5. **Melting Point/Range:** Polyester Component of Mesh Material Will Melt @ 464-500°F (240-260°C).

10. STABILITY

10.1. Stability: Stable

10.2. Hazardous decomposition products: There are no decomposition products of the beads if used as directed. Hydrocarbons and other materials that accidentally contact the product can be retained in the beads. It is reasonable to expect that decomposition products will come from any accidentally retained materials. Smoke, carbon dioxide, and carbon monoxide are the hazardous combustion byproducts emitted from the mesh bag.

10.3. Conditions/Materials to avoid: Sudden contact with high concentration of chemicals having high heats of adsorption such as olefins, HCL, etc.

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, primary skin irritation, 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 (in its fresh unused state) is 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 – Class I, Product Code = FRO, Classification = Dressing, Prescription Only

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: 66035

16. CONTACT INFORMATION

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

QA Manager/Dir. of Regulatory Affairs

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