Section 1 - IDENTITY OF THE MANUFACTURER AND PRODUCT

PRODUCT GROUP:  Celiac Disease Kits

PRODUCT IDENTITY: Transglutaminase ELISA Kit  PRODUCT CODE #: 7044
Antigliadin IgG ELISA Kit  7040
Antigliadin IgA ELISA Kit  7042

MANUFACTURER ADDRESS:  Biomerica, Inc.
17571 Von Karman Avenue
Irvine, CA 92614, USA
Telephone: 949-645-2111
Fax: 949-553-1231
E-mail: bmra@biomerica.com

Telephone Number in Case of Emergency: 800 535-5053 - InfoTrac 24 hours

Section 2 - COMPOSITION AND INGREDIENT INFORMATION

Chemical Nature of the Preparation:  Stable

Dangerous Substances in the Preparation:  Sulfuric Acid, Blood Components, Sodium Azide, Bromo-nitro-dioxane

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS#</th>
<th>EC #</th>
<th>Designation</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric Acid</td>
<td>7664-93-9</td>
<td>231-639-5</td>
<td>Corrosive</td>
<td>3.0%</td>
</tr>
<tr>
<td>Blood Components</td>
<td>N/A</td>
<td>N/A</td>
<td>Potential Biohazard</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Sodium Azide (in 1X)</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>Highly Toxic</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td>Bromo-nitro-dioxane</td>
<td>30007-47-7</td>
<td>250-001-7</td>
<td>Harmful</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

Section 3 - HAZARDS IDENTIFICATION

Potential Biohazard:

Calibrators are formulated with a buffer base, animal or human serum. The kit components that are made with human serum are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at the Biosafety Level 2, as recommended for any potentially infectious human blood product, in the United States Center for Disease Control (USCDC) and National Institute of Health (USNIH) manual "Biosafety in Microbiological Laboratories", 1988. All bovine serum products used are derived from animals of US origin, processed in USDA licensed facilities

Chemical Hazard:

Wash Buffer, Serum Diluent and Calibrators in kits are formulated with Sodium Azide as a preservative. Concentrated Sodium Azide may react with copper and lead plumbing to form explosive metal azides. It may also react with acids to form explosive hydrazoic acid. If drain disposed, flush with large amounts of water to prevent azide build-up. Components also contain bromo-nitro-dioxane which is harmful by
inhalation, in contact with skin and if swallowed. Avoid contact with Stop Solution containing 1N H$_2$SO$_4$ (Sulfuric Acid), an irritant to the skin and mucous membranes.

**Section 4 - FIRST AID MEASURES**

**Skin Contact:** Remove contaminated clothing and wash the exposed skin area thoroughly with soap and water.

**Eye Contact:** Flush with copious amounts of water for at least 15 minutes. Seek medical attention.

**Inhalation:** Remove to fresh air, give oxygen if breathing becomes difficult and seek medical attention.

**Ingestion:** Flush mouth with copious amounts of water, provided that the person is conscious and seek medical attention.

**Section 5 - FIRE AND EXPLOSION DATA**

**Suitable Extinguishing Media:** Chemical or water fire extinguisher.

**Extinguishing Media Not to be Used:** None known.

**Special Fire Fighting Procedures:** None Known.

**Unusual Fire and Explosion Hazards:** None known.

**NFPA Rating:** Health: 3, Flammability: 0, Reactivity: 2 (for concentrated Sulfuric Acid)

**Section 6 - MEASURES IN CASE OF ACCIDENTAL SPILL**

**Body Precautions:** Wear gloves, impermeable shoe covers and laboratory coat. Ensure adequate ventilation.

**Environmental Precautions:** Contain the spill to the smallest area possible.

**Cleaning Measures:** Take care not to contaminate body. Neutralize a Stop Solution spill with dilute base, then absorb the material with disposable towels. Soak a calibrator or control spill area with a 10% bleach solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations.

**Section 7 - HANDLING AND STORAGE**

**Handling:** Wear suitable personal protective equipment. Take care not to splash, spill or splatter standards, stop solution or controls. Avoid contact with skin or eyes.

**Storage:** Store kit reagents in 2 - 8°C in refrigerators designated and labeled to contain human blood products.
Section 8 - EXPOSURE CONTROL AND PERSONAL PROTECTION

Body Protection: Wear laboratory coat.
Respiratory protection: In case of fire, wear self-contained breathing apparatus.
Hand Protection: Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated.
Eyes Protection: Wear safety glasses or goggles when a splash hazard exists.
Others: None known.

Section 9 - PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical State: Liquid except for Calibrators B to Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin coated microwell.
Color:
- Antigliadin IgA: Red for Serum Diluent, Red for Calibrators
- Antigliadin IgG: Blue for Serum Diluent, Blue for Calibrators
- Transglutaminase: Red for Serum Diluent, Red for Calibrators and clear for all other liquid reagents.
Odor: None detectable.
pH: 5.56 – 7.4 for all components except Stop Solution at <2 (highly acidic)
Boiling Point: Not applicable.
Melting Point: Not applicable.
Flash Point: Not applicable.
Flammability: Not Flammable.
Auto flammability: Will not occur.
Vapor Pressure: Not applicable.
Relative Density: 1-3 mg/ml
Water Solubility: 100% soluble.

Section 10 - STABILITY AND REACTIVITY DATA

Stability: Stable in Normal Conditions.
Conditions to Avoid: None known.
Materials to Avoid: None known.
### Section 11 - TOXICOLOGY INFORMATION

**Hazardous Decomposition Products:** None Known.

**Effects of Dangerous Substances at the Concentrations Present in the Preparation:**

- **Toxic Effects:** Potential Biohazard.
- **Harmful Effects:** Potential Biohazard.
- **Sensitizing Effects:** None known.
- **Carcinogenic/Mutagenic/Teratogen Effects:** None known.

### Section 12 - ECOLOGICAL INFORMATION

None Known.

### Section 13 - DISPOSAL CONSIDERATIONS

- **Disposal of Preparation Left:** Dispose according to current regional and national rules.
- **Contaminated Containers:** Dispose of following current regulations.

### Section 14 - TRANSPORTATION INFORMATION

- **Road / Railway Haulage ADR/RID:** Not restricted.
- **Sea Freight IMO (IMDG):** Not restricted.
- **Air Freight IATA (ICAO):** Not restricted.
- **UN Number:** Not applicable.

### Section 15 - OTHER REGULATORY INFORMATION

- **Classification:** This preparation is classified and labeled according to EEC Directive n. 88/379.
- **Symbols of Danger:** None.
- **"R" Phrases Indicating Specific Risks:** R 35 – (for concentrated Sulfuric Acid) Causes severe burns.
- **"S" Phrases Indicating Caution:** S 26 – (for concentrated Sulfuric Acid) In case of contact with eyes, rinse immediately with plenty of water and seek medical advise.

### Section 16 - OTHER INFORMATION

- **Recommended Use:** For research or in vitro diagnostic use only. Not for use on or in humans and animals.

The information contained herein is believed to be correct as of the date of issue but is provided without warranty of any kind. Biomerica shall not be held liable for any damage resulting from handling or from contact with the above product. The recipient is responsible for observing any applicable laws and guidelines. Use the product according to the package insert.