

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.

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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

EC#	Designation	% w/w
-9 231-639-5	Corrosive	3.0%
N/A	Potential Biohazard	<1%
2-8 247-852-1	Highly Toxic	< 0.1%
7-7 250-001-7	Harmful	<1%
	-9 231-639-5 N/A 2-8 247-852-1	-9 231-639-5 Corrosive N/A Potential Biohazard 2-8 247-852-1 Highly Toxic

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

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inhalation, in contact with skin and if swallowed. Avoid contact with Stop Solution containing 1N H₂SO₄ (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.

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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.

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Hazardous Decomposition Products: None Known.

Section 11 - TOXICOLOGY INFORMATION

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.

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