

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product Identifier

**SDS #** BIO-009-EU  
**Product Code** Transglutaminase ELISA Kit Product Code #: 7044  
Antigliadin IgG ELISA Kit Product Code #: 7040  
**Product Name** Antigliadin IgA ELISA Kit Product Code #: 7042  
Celiac Disease Kits

### 1.2. Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Recommended Use** For research or in vitro diagnostic use only  
**Uses Advised Against** Not for use on or in humans

### 1.3. Details of the Supplier of the Safety Data Sheet

**Supplier**  
Biomerica  
17571 Von Karman Avenue  
Irvine, CA 92614, USA

### For further information, please contact

**Contact Point** Biomerica: (949) 645-2111  
**Email Address** bmra@biomerica.com

### 1.4. Emergency telephone number

Emergency Telephone (24 hr) INFOTRAC 1-352-323-3500 (International)  
1-800-535-5053 (North America)

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

Regulation (EC) No 1272/2008

Skin corrosion/irritation

Category 2

**Classification according to 67/548/EEC**  
*Full text of R-phrases: see section 16*

**Hazard Symbols**  
Not dangerous

### 2.2. Label Elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP].

**Signal Word**

Warning

**Hazard Statements**

H315 - Causes skin irritation

**Precautionary Statements - EU (§28, 1272/2008)**

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P332 + P313 - If skin irritation occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

**2.3. Other Hazards****General Hazards**

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. Wash Buffer, Serum Diluent and Calibrators in kits are formulated with bromo-nitro-dioxane as a preservative. Bromo-nitro-dioxane is harmful if swallowed or inhaled. It can also cause skin and eye irritation if in contact. Avoid contact with Stop Solution containing 1N H<sub>2</sub>SO<sub>4</sub> (Sulfuric Acid), an irritant to the skin and mucous membranes

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.2. Mixtures**

Chemical Name	EC No	CAS No	Weight-%	Classification according to 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Sulfuric Acid	Present	7664-93-9	<5	C; R35	Skin Corr. 1A (H314)	Not determined

**Full text of R-phrases: see section 16****Full text of H- and EUH-phrases: see section 16****Additional Information**

Substances without a classification are included, because they have established occupational exposure limits

## Section 4: FIRST AID MEASURES

**4.1. Description of First Aid Measures****Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get immediate medical advice/attention.

<b>Skin Contact</b>	Take off contaminated clothing. Wash with soap and water.
<b>Inhalation</b>	Remove to fresh air. If person is having difficulty breathing, give oxygen and call a physician immediately.
<b>Ingestion</b>	Flush mouth with copious amounts of water, provided that the person is conscious, and seek medical attention.

**4.2. Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms** Causes skin irritation.

**4.3. Indication of any Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician** Treat symptomatically.

**Section 5: FIRE-FIGHTING MEASURES**

**5.1. Extinguishing Media**

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

**Unsuitable Extinguishing Media**  
None known.

**5.2. Special Hazards Arising from the Substance or Mixture**

None known.

<b>Hazardous Combustion Products</b>	None known.
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**5.3. Advice for Firefighters**

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment as required.

**Section 6: ACCIDENTAL RELEASE MEASURES**

**6.1. Personal Precautions, Protective Equipment and Emergency Procedures**

**Personal Precautions**  
Wear gloves, impermeable shoe covers, and laboratory coat. Take care not to contaminate body. Ensure adequate ventilation.

**For Emergency Responders**  
Use personal protection recommended in Section 8.

**6.2. Environmental Precautions**

Contain the spill to the smallest area possible.

**6.3. Methods and Material for Containment and Cleaning Up**

**Methods for Containment** Prevent further leakage or spillage if safe to do so.

**Methods for Clean-Up** 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.

**6.4. Reference to Other Sections**

See Section 13: DISPOSAL CONSIDERATIONS.

**Section 7: HANDLING AND STORAGE**

**7.1. Precautions for Safe Handling**

**Advice on Safe Handling**

Use personal protection recommended in Section 8. Take care not to splash, spill, or splatter standards, stop solution, or controls. Avoid contact with skin and eyes.

**General Hygiene Considerations**

Handle in accordance with good industrial hygiene and safety practice.

**7.2. Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions**

Store kit reagents in 2-8°C in refrigerators designated and labeled to contain human blood products.

**7.3. Specific End Use(s)**

**Specific Use(s)**

For research or in vitro diagnostic use only.

**Risk Management Methods (RMM)**

The information required is contained in this Safety Data Sheet.

**Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1. Control Parameters**

**Exposure Limits**

Chemical Name	European Union	United Kingdom	France	Spain	Germany
Sulfuric Acid 7664-93-9		TWA: 0.05 mg/m <sup>3</sup>	TWA: 0.05 mg/m <sup>3</sup> STEL: 3 mg/m <sup>3</sup>	TWA: 0.05 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> Ceiling / Peak: 0.1 mg/m <sup>3</sup> Skin

**8.2. Exposure Controls**

**Engineering Controls**

Apply technical measures to comply with the occupational exposure limits.

**Personal Protective Equipment**

**Eye/Face Protection**

Wear approved safety goggles where a splash hazard exists.

**Hand Protection**

Wear non-permeable rubber, neoprene, latex, or nitrile disposable gloves. Change gloves when they become contaminated.

**Skin and Body Protection**

Wear laboratory coat.

**Respiratory Protection**

In case of fire, wear self-contained breathing apparatus.

**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1. Information on Basic Physical and Chemical Properties**

<b>Physical State</b>	Liquid		
<b>Appearance</b>	Liquid except for Calibrators B to Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin coated microwell	<b>Odour</b>	None
<b>Colour</b>	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	<b>Odour Threshold</b>	Not determined

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	5.56-7.4	Stop Solution pH <2
Melting Point/Freezing Point	Not applicable	
Boiling Point/Boiling Range	Not applicable	
Flash Point	Not applicable	
Evaporation Rate	Not determined	
Flammability (Solid, Gas)	Not flammable	
Flammability Limits in Air		
Upper Flammability Limits	Not applicable	
Lower Flammability Limit	Not applicable	
Vapour Pressure	Not determined	
Vapour Density	Not determined	
Relative Density	1-3 mg/mL	
Water Solubility	100% soluble	
Solubility(ies)	Not determined	
Partition Coefficient	Not determined	
Auto-ignition Temperature	Will not occur	
Decomposition Temperature	Not determined	
Kinematic Viscosity	Not determined	
Dynamic Viscosity	Not determined	
Explosive Properties	Not determined	
Oxidising Properties	Not determined	

**Section 10: STABILITY AND REACTIVITY**

**10.1. Reactivity**

Not reactive under normal conditions.

**10.2. Chemical stability**

Stable under normal conditions.

**10.3. Possibility of Hazardous Reactions**

**Possibility of Hazardous Reactions**

None under normal processing.

**10.4. Conditions to Avoid**

None known.

**10.5. Incompatible Materials**

None known.

**10.6. Hazardous Decomposition Products**

None known.

<b>Section 11: TOXICOLOGICAL INFORMATION</b>
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**11.1. Information on Toxicological Effects****Acute Toxicity****Product Information**

Potential biohazard.

**Eye Contact** Avoid contact with eyes.**Skin Contact** Causes skin irritation.**Inhalation** Avoid breathing vapors or mists.**Ingestion** Do not taste or swallow.**Unknown Acute Toxicity** 0% of the mixture consists of ingredient(s) of unknown toxicity.**The following values are calculated based on chapter 3.1 of the GHS document:**

Oral LD50	71,333.00
Units	mg/kg
Dermal LD50	99,999.00
Units	mg/kg
Inhalation	
Gas	99,999.00
Units	mg/L
Mist	99,999.00
Units	mg/L
Vapor	99,999.00
Units	mg/L

**Component Information**

<b>Chemical Name</b>	<b>Oral LD50</b>	<b>Dermal LD50</b>	<b>Inhalation LC50</b>
Sulfuric Acid	= 2140 mg/kg ( Rat )		= 510 mg/m <sup>3</sup> ( Rat ) 2 h
Bromo-nitro-dioxane	= 455 mg/kg ( Rat )		

**Skin corrosion/irritation** Causes skin irritation.**Serious eye damage/eye irritation** Not classified.**Sensitization** Not classified.**Germ cell mutagenicity** Not classified.**Carcinogenicity** None known based on information supplied.**Reproductive toxicity** Not classified.

**STOT - single exposure** Not classified.

**STOT - repeated exposure** Not classified.

**Aspiration hazard** Not classified.

**Symptoms** Please see section 4 of this SDS for symptoms.

**Section 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity**

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Sulfuric Acid		500: 96 h Brachydanio rerio mg/L LC50 static	29: 24 h Daphnia magna mg/L EC50

**12.2. Persistence and Degradability**

Not determined.

**12.3. Bioaccumulative Potential**

Not determined.

**12.4. Mobility in Soil**

**Mobility**

Not determined.

**12.5. Results of PBT and vPvB Assessment**

Not determined.

**12.6. Other Adverse Effects**

Not determined.

**Section 13: DISPOSAL CONSIDERATIONS**

**13.1. Waste Treatment Methods**

**Waste from Residues / Unused Products** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated Packaging** Improper disposal or reuse of this container may be dangerous and illegal.

**Section 14: TRANSPORT INFORMATION**

**IMDG**

14.1 UN/ID No Not regulated

**RID**

14.1 UN/ID No Not regulated

**ADR**

14.1 UN/ID No Not regulated

ICAO (air)

14.1 UN/ID No Not regulated

IATA

14.1 UN/ID No Not regulated

**Section 15: REGULATORY INFORMATION****15.1. Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture****European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

**International Inventories**

Not determined.

TSCA	-
EINECS/ELINCS	-
DSL/NDSL	-
PICCS	-
ENCS	-
IECSC	-
AICS	-
KECL	-

**Legend**

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

**15.2. Chemical Safety Assessment**

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

**Section 16: OTHER INFORMATION****Full text of R-phrases referred to under sections 2 and 3**

R35 - Causes severe burns

R28 - Very toxic if swallowed

R32 - Contact with acids liberates very toxic gas

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

**Full text of H-Statements referred to under sections 2 and 3**

H314 - Causes severe skin burns and eye damage

H300 - Fatal if swallowed

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

EUH032 - Contact with acids liberates very toxic gas



**Classification Procedure**

Calculation method

**Issue Date:** 17-Oct-2014

**Revision Date:** 17-Oct-2014

**Revision Note:** New format.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006, as amended by Regulation (EU) No. 453/2010**

**Disclaimer**

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**End of Safety Data Sheet**