

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

Product Name Celiac Disease Kits

Contains Sulfuric Acid

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

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

2.2. Label Elements

Product Identifier

Contains Sulfuric Acid

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

EUH210 - Safety data sheet available on request

2.3. Other 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 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 H₂SO₄ (Sulfuric Acid), an irritant to the skin and mucous membranes

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS
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3.2 MIXTURES

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Sulfuric Acid	Present	7664-93-9	<5	Skin Corr. 1A (H314)	Not determined
Sodium azide	Present	26628-22-8	<0.1	(EUH032) Acute Tox. 2 (H300) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not determined

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

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.
Skin Contact	Take off contaminated clothing. Wash with soap and water.
Inhalation	Remove to fresh air. If person is having difficulty breathing, give oxygen and call a physician immediately.
Ingestion	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.
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4.3. Indication of any Immediate Medical Attention and Special Treatment Needed

Notes to Physician	Treat symptomatically.
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Section 5: FIREFIGHTING 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.

Hazardous Combustion Products

None known.

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. See Section 12 for additional Ecological Information.

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	-	STEL: 0.15 mg/m ³ TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³ STEL: 3 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.1 mg/m ³
Sodium azide 26628-22-8	S* TWA 0.1 mg/m ³ STEL 0.3 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	S* STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.2 mg/m ³
Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
Sulfuric Acid 7664-93-9	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³ STEL: 0.1 mg/m ³	TWA: 0.05 mg/m ³
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	STEL: 0.3 mg/m ³ Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm TWA: 0.1 mg/m ³	Skin STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ Skin
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Sulfuric Acid 7664-93-9	STEL 0.2 mg/m ³ TWA: 0.1 mg/m ³	STEL: 0.1 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.05 ppm STEL: 0.15 ppm
Sodium azide 26628-22-8	Skin STEL 0.3 mg/m ³ TWA: 0.1 mg/m ³	STEL: 0.4 mg/m ³ TWA: 0.2 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ 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

Physical state	Liquid		
Appearance	Liquid except for Calibrators B to Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin coated microwell	Odour	None
Colour	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	Odour Threshold	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	

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Lower Flammability Limit	Not applicable	
Vapour Pressure	Not determined	
Vapour Density	Not determined	
Relative Density	Not determined	
Water Solubility	Completely 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.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity

Product Information

Potential biohazard.

Inhalation	Do not inhale.
Eye Contact	Avoid contact with eyes.
Skin Contact	Avoid contact with skin.
Ingestion	Do not ingest.

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	71,333.00 mg/kg
ATEmix (inhalation-dust/mist)	8.50 mg/L

Unknown Acute Toxicity

- 3 % of the mixture consists of ingredient(s) of unknown toxicity.
- 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
- 3 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
- 3 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
- 3 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapour).
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sulfuric Acid	= 2140 mg/kg (Rat)		= 510 mg/m ³ (Rat) 2 h
Bromo-nitro-dioxane	= 455 mg/kg (Rat)		
Sodium azide	= 27 mg/kg (Rat)	= 50 mg/kg (Rat) = 20 mg/kg (Rabbit)	

Skin corrosion/irritation Not classified.

Serious eye damage/eye irritation Not classified.

Sensitisation Not classified.

Germ cell mutagenicity Not classified.

Carcinogenicity Not classified.

Reproductive toxicity Not classified.

STOT - single exposure Not classified.

STOT - repeated exposure Not classified.

Aspiration hazard Not classified.

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
Sodium azide		0.7: 96 h Lepomis macrochirus mg/L LC50 5.46: 96 h Pimephales promelas mg/L LC50 flow-through 0.8: 96 h Oncorhynchus mykiss mg/L LC50	

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

14.1 UN No.	ADR, AND, IMDG, IATA- Void
14.2 Proper Shipping Name	ADR, AND, IMDG, IATA- Void
14.3 Transport Hazard Class(es)	ADR, AND, IMDG, IATA- Void
14.4 Packing Group	ADR, AND, IMDG, IATA- Void
14.5 Environmental Hazards	Not applicable
14.6 Special precautions for user	Not applicable
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

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 .

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

Component	TSCA	DSL/NDSL	EINECS/ELINCS	PICCS	ENCS	IECSC	AICS	KECL
Sulfuric Acid 7664-93-9 (<5)	X	X	X	X	Present	X	X	Present
Sodium azide 26628-22-8 (<0.1)	X	X	X	X	Present	X	X	Present

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 H-Statements referred to under section 3

H300 - Fatal if swallowed H400

- Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

H314 - Causes severe skin burns and eye damage

EUH032 - Contact with acids liberates very toxic gas

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend

TWA

Ceiling

TWA (time-weighted average)

Maximum limit value

STEL

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STEL (Short Term Exposure Limit)

Skin designation

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Classification Procedure

Calculation method

Issue Date: 06-Apr-2011

Revision Date: 21-Dec-2017

Revision Note: Regulatory update.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) No. 2015/830

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet