



# Safety Data Sheet

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Version 5

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

### 1.1. Product Identifier

SDS # BIO-002-EU  
Product Code 7022  
Product Name PTH ELISA Kit  
Synonyms Thyroid ELISA 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  
1-800-854-3002

### For further information, please contact

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

#### **Classification according to 67/548/EEC**

*Full text of R-phrases: see section 16*

#### Hazard Symbols

Not dangerous

### 2.2. Label Elements

#### **Product Identifier**

Contains Sulfuric acid

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

**Signal Word**

None

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. ELISA Wash Concentrate contains Ciprofloxacin HCl. Keep from personnel who have demonstrated a sensitivity to Quinoline based drug products. Females who are, or may be pregnant, should avoid contact with Ciprofloxacin

<b>Section 3: COMPOSITION/INFORMATION ON INGREDIENTS</b>
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**3.1 Substances** \_\_\_\_\_ Not applicable.

**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	231-639-5	7664-93-9	3	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**

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)

<b>Section 4: FIRST AID MEASURES</b>
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**4.1. Description of First Aid Measures**

<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediately call a poison center or doctor/physician.
<b>Skin Contact</b>	Wash with soap and water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, give oxygen. Call a physician if you feel unwell.
<b>Ingestion</b>	Flush mouth with copious amounts of water, provided that the person is conscious, and seek medical attention.
<b>Self-Protection of the First Aider</b>	No specific precautions necessary.

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

<b>Symptoms</b>	May cause irritation to the mucous membranes and upper respiratory tract. May include redness, drying and cracking of skin. Causes serious eye damage.
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**4.3. Indication of any Immediate Medical Attention and Special Treatment Needed**

<b>Notes to Physician</b>	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.

### 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 protective clothing as described in Section 8 of this safety data sheet. Take care not to contaminate body.

#### **For Emergency Responders**

Use personal protection recommended in Section 8.

### 6.2. Environmental Precautions

Contain the spill to the smallest area possible. Avoid release to the environment. 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**

Avoid breathing vapours or mists. Use only in well-ventilated areas. Use personal protection recommended in Section 8. Take care not to splash, spill, or splatter standards, stop solution, or controls. Wash face, hands and any exposed skin thoroughly after handling.

#### **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 <sup>3</sup> 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
Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
Sulfuric acid 7664-93-9	TWA: 0.05 mg/m <sup>3</sup>	TWA: 0.05 mg/m <sup>3</sup>	TWA: 0.05 mg/m <sup>3</sup>	TWA: 0.05 mg/m <sup>3</sup> STEL: 0.1 mg/m <sup>3</sup>	TWA: 0.05 mg/m <sup>3</sup>
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Sulfuric acid 7664-93-9	STEL 0.2 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup>	STEL: 0.1 mg/m <sup>3</sup> TWA: 0.1 mg/m <sup>3</sup>	STEL: 3 mg/m <sup>3</sup> TWA: 1 mg/m <sup>3</sup>	TWA: 0.1 mg/m <sup>3</sup> STEL: 0.3 mg/m <sup>3</sup>	TWA: 0.05 ppm STEL: 0.15 ppm

### 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	Odour	None detectable
Appearance	Liquid except for Calibrators A to Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin coated microwell		
Colour	Yellow for Reagent 1 (PTH Biotinylated Ab Solution), Blue for Reagent 2 (Enzyme labeled Ab Solution) 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	
Lower Flammability Limit	Not applicable	
Vapour Pressure	Not applicable	
Vapour Density	Not determined	
Relative Density	1-3	(Water = 1)
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	

**9.2 Other information** \_\_\_\_\_ No further relevant information available.

## 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**

Avoid breathing vapors or mists.

##### **Eye Contact**

Avoid contact with eyes.

##### **Skin Contact**

Avoid contact with skin.

##### **Ingestion**

Do not ingest.

##### **Unknown Acute Toxicity**

0.18% 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
Inhalation	
Mist	8.50
Units	mg/L
Vapor	17,000.00
Units	mg/L

#### Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sulfuric acid	= 2140 mg/kg (Rat)		= 510 mg/m <sup>3</sup> (Rat) 2 h

<b>Skin corrosion/irritation</b>	Causes skin irritation
<b>Serious eye damage/eye irritation</b>	Causes serious eye damage.
<b>Sensitization</b>	Not classified.
<b>Germ cell mutagenicity</b>	Not classified.
<b>Carcinogenicity</b>	Not classified.
<b>Reproductive toxicity</b>	Not classified.
<b>STOT - single exposure</b>	Not classified.
<b>STOT - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not classified.
<b>Symptoms</b>	Please see section 4 of this SDS for symptoms.

## Section 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Harmful to aquatic life with long lasting effects.

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

Not determined.

#### **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, ADN, IMDG, ICAO, IATA- Void

14.2 Proper Shipping Name ADR, ADN, IMDG, ICAO, IATA- Void

14.3 Transport Hazard Class(es) ADR, ADN, IMDG, ICAO, IATA- Void

14.4 Packing Group ADR, AND, IMDG, ICAO, 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 (3)	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 R-phrases referred to under sections 2 and 3**

R35 - Causes severe burns

**Full text of H-Statements referred to under section 3**

H314 - Causes severe skin burns and eye damage

**Legend**

SVHC: Substances of Very High Concern for Authorization:

**Legend**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

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

**Classification Procedure**

Calculation method

**Issue Date:** 15-Jan-2003

**Revision Date:** 29 Mar 18

**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**

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End of Safety Data Sheet