

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

### 1.1. Product Identifier

**SDS #** BIO-008-EU  
**Product Code** Myoglobin ELISA Product Code #: 7030  
Troponin I ELISA Product Code #: 7031  
hs-CRP ELISA Product Code #: 7033  
**Product Name** Cardiac Marker ELISA Kits

Contains Hydrochloric 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](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]

### 2.2. Label Elements

#### **Product Identifier**

Contains Hydrochloric 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**

Reference standards in Troponin I kits are formulated with a human serum base and with BSA in the Myoglobin and hs-CRP kits. 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. Reference standards, enzyme conjugate and sample diluent (except Troponin I) in kits are formulated with ProClin-300 as a preservative. TMB Reagent contains tetramethylbenzidine and hydrogen peroxide. In case of contact with any of these reagents, wash thoroughly with water.

**Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**

**3.2 MIXTURES**

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Hydrochloric acid	Present	7647-01-0	<5	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	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. If eye irritation persists: Get medical advice/attention.
- Skin Contact**                                      Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If irritation occurs: Get medical advice/attention.
- Inhalation**    Remove to fresh air. If breathing is difficult, give oxygen. Seek medical attention.
- 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. Causes serious eye irritation.

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

**Notes to Physician**                                      Treat symptomatically.

**Section 5: FIREFIGHTING MEASURES**

**5.1. Extinguishing Media**

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

**Unsuitable Extinguishing Media**  
Not determined.

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

Calibrators and Conjugate in kits are formulated with Proclin-300 as a preservative. Stop solution is a caustic solution of dilute HCl.

**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.

**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 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.

**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
Hydrochloric acid 7647-01-0	TWA 5 ppm TWA 8 mg/m <sup>3</sup> STEL 10 ppm STEL 15 mg/m <sup>3</sup>	STEL: 5 ppm STEL: 8 mg/m <sup>3</sup> TWA: 1 ppm TWA: 2 mg/m <sup>3</sup>	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> TWA: 5 ppm TWA: 7.6 mg/m <sup>3</sup>	TWA: 2 ppm TWA: 3 mg/m <sup>3</sup>
Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
Hydrochloric acid 7647-01-0	TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>	STEL: 10 ppm STEL: 15 mg/m <sup>3</sup> Ceiling: 2 ppm TWA: 5 ppm TWA: 8 mg/m <sup>3</sup>	STEL: 15 mg/m <sup>3</sup> TWA: 8 mg/m <sup>3</sup>	STEL: 5 ppm STEL: 7.6 mg/m <sup>3</sup>	Ceiling: 5 ppm Ceiling: 8 mg/m <sup>3</sup>
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Hydrochloric acid 7647-01-0	STEL 10 ppm STEL 15 mg/m <sup>3</sup> TWA: 5 ppm TWA: 8 mg/m <sup>3</sup>	STEL: 4 ppm STEL: 6 mg/m <sup>3</sup> TWA: 2 ppm TWA: 3.0 mg/m <sup>3</sup>	STEL: 10 mg/m <sup>3</sup> TWA: 5 mg/m <sup>3</sup>	Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup>	TWA: 5 ppm TWA: 8 mg/m <sup>3</sup> STEL: 10 ppm STEL: 15 mg/m <sup>3</sup>

**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** Coloured liquids (See: Colour) **Odour** None  
**Colour** Conjugate – Red; Sample Diluent and Reference Standards – yellow to orange; all other reagents clear **Odour Threshold** Not determined

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	5.5-7.4	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)	Liquid-not applicable	
Flammability Limits in Air		
Upper Flammability Limits	Not applicable	
Lower Flammability Limit	Not applicable	
Vapour Pressure	Not determined	
Vapour Density	Not determined	
Relative Density	Not determined	
Water Solubility	Not determined	
Solubility(ies)	Not determined	
Partition Coefficient	Not determined	
Auto-ignition Temperature	Will not occur	
Decomposition Temperature	Not determined	

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
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**

Keep out of reach of children.

**10.5.Incompatible Materials**

None known based on information supplied.

**10.6.Hazardous Decomposition Products**

None known.

**Section 11: TOXICOLOGICAL INFORMATION**

**11.1. Information on Toxicological Effects**

**Acute Toxicity**

**Product Information**

Potential biohazard.

<b>Inhalation</b>	Do not inhale.
<b>Eye Contact</b>	Avoid contact with eyes.
<b>Skin Contact</b>	Avoid contact with skin.
<b>Ingestion</b>	Do not ingest.

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

<b>ATEmix (oral)</b>	14,000.00 mg/kg
<b>ATEmix (inhalation-gas)</b>	33,135.42 ppm
<b>ATEmix (inhalation-dust/mist)</b>	5.1 mg/L

**Unknown Acute Toxicity**

- 1.7 % of the mixture consists of ingredient(s) of unknown toxicity.
- 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.
- 0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).
- 1.7 % 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**

<b>Chemical Name</b>	<b>Oral LD50</b>	<b>Dermal LD50</b>	<b>Inhalation LC50</b>
Hydrochloric acid	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h

<b>Skin corrosion/irritation</b>	Not classified.
<b>Serious eye damage/eye irritation</b>	Not classified.
<b>Sensitisation</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.

**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
Hydrochloric acid		282: 96 h Gambusia affinis mg/L LC50 static	

**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

**Named dangerous substances per Seveso Directive (2012/18/EU)**

Chemical Name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
Hydrochloric acid - 7647-01-0	25	250

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

Not applicable

**International Inventories**

Component	TSCA	DSL/NDSL	EINECS/ELINCS	PICCS	ENCS	IECSC	AICS	KECL
Hydrochloric acid 7647-01-0 (<5)	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**

H331 - Toxic if inhaled  
 H314 - Causes severe skin burns and eye damage

**Legend**

SVHC: Substances of Very High Concern for Authorisation:

**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:** 20-Dec-2012

**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