Safety Data Sheet

Issue Date: 17-Oct-2014 **Revision Date:** 17-Oct-2014 **Version** 1

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

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
Serious eye damage/eye 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
H319 - Causes serious eye irritation

Precautionary Statements - EU (§28, 1272/2008)
P280 - Wear eye protection/ face protection
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
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention

2.3. Other Hazards

General 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 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Hydrochloric acid	Present	7647-01-0	<5	T; R23 C; R35 C; R34 Xi; R37	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Not determined

Full text of R-phrases: see section 16

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

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: FIRE-FIGHTING 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.

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

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; hs-CRP Sample Diluent is red, Myoglobin Sample Diluent is yellow, Reference Standards caps are yellow to orange; all other reagents clear	**Odour Threshold**	Not determined

Property	**Values**	**Remarks • Method**
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	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

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.

Eye Contact Causes serious eye irritation.

Skin Contact Causes skin irritation.

Inhalation Avoid breathing vapors or mists.

Ingestion Do not taste or swallow.

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	41,176.00
Units	mg/kg
Dermal LD50	294,706.00
Units	mg/kg
Inhalation	
Gas	91,882.00
Units	mg/L
Mist	29.47
Units	mg/L
Vapor	183,765.00
Units	mg/L

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Hydrochloric acid	= 700 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 3124 ppm (Rat) 1 h

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

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
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

IMDG
14.2 Proper Shipping Name Not regulated

RID
14.2 Proper Shipping Name Not regulated

ADR
14.2 Proper Shipping Name Not regulated

ICAO (air)
14.2 Proper Shipping Name Not regulated

IATA
14.2 Proper Shipping Name 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
R34 - Causes burns
R35 - Causes severe burns
R23 - Toxic by inhalation
R37 - Irritating to respiratory system

Full text of H-Statements referred to under sections 2 and 3
H314 - Causes severe skin burns and eye damage
H331 - Toxic if inhaled

Classification Procedure
Calculation method

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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