

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

1.1. Product Identifier

SDS #	BIO-006-EU
Product Code	7023
Product Name	ACTH ELISA Kit
Synonyms	Pituitary 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
1-800-854-3002

For further information, please contact

Email Address	bmra@biomerica.com
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1.4. Emergency telephone number

Emergency Telephone (24 hr)	INFOTRAC 1-352-323-3500 (International) 1-800-535-5053 (North America)
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Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Regulation (EC) No 1272/2008

Not classified as dangerous according to Regulation (EC) No. 1272/2008.

Classification according to 67/548/EEC

Full text of R-phrases: see section 16

Hazard Symbols

Not dangerous

2.2. Label Elements

Not classified as dangerous according to Regulation (EC) No. 1272/2008.

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. 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

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	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

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	May cause irritation to the mucous membranes and upper respiratory tract. May include redness, drying and cracking of skin.
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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: 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.

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.

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.

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 ³	TWA: 0.05 mg/m ³ STEL: 3 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.1 mg/m ³ Ceiling / Peak: 0.1 mg/m ³ Skin
Component	Italy	Portugal	Netherlands	Finland	Denmark
Sulfuric Acid 7664-93-9 (3)		TWA: 0.2 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
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	STEL: 3 mg/m ³ TWA: 1 mg/m ³ TWA: 0.05 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 1 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	Liquid except for Calibrators B to Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin coated microwell	Odour	None detectable
Colour	Blue for Reagent 1 (ACTH Biotinylated Ab Solution), Red 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 mg/mL	
Water Solubility	Completely soluble	
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

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.

Eye Contact

Avoid contact with eyes.

Skin Contact

Avoid contact with skin.

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	71,333.00
Units	mg/kg
Inhalation	
Mist	8.50
Units	mg/L
Vapor	17,000.00
Units	mg/L

Component Information

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

Skin corrosion/irritation	Not classified.
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
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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

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 sections 2 and 3

H314 - Causes severe skin burns and eye damage

Classification Procedure

Calculation method

Issue Date: 06-Apr-2011
Revision Date: 24-Feb-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

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