

Safety Data Sheet

Issue Date: 06-Apr-2011 Revision Date: 29-Mar-2018 Version 3

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

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 pointBiomerica (949) 645-2111Email Addressbmra@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) 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

Product Identifier

Contains Sulfuric acid

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

BIO-006-EU - ACTH ELISA Kit

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 HCI. 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

3.1. 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 >=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.

Self Protection of the First Aider No specific precautions necessary.

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.

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

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. 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-UpNeutralize 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 mist. 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.

BIO-006-EU - ACTH ELISA Kit

Revision Date: 21-Mar-2018

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	-	STEL: 0.15 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.1 mg/m ³
7664-93-9		TWA: 0.05 mg/m ³	STEL: 3 mg/m ³		Ceiling / Peak: 0.1
		_			mg/m³
					Skin
Component	Italy	Portugal	Netherlands	Finland	Denmark
Sulfuric Acid	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³	TWA: 0.05 mg/m ³
7664-93-9 (3)				STEL: 0.1 mg/m ³	
Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Sulfuric Acid	STEL 0.2 mg/m ³	STEL: 0.1 mg/m ³	STEL: 3 mg/m ³	TWA: 0.1 mg/m ³	TWA: 0.05 ppm
7664-93-9	TWA: 0.1 mg/m ³	TWA: 0.1 mg/m ³	TWA: 1 mg/m ³	STEL: 0.3 mg/m ³	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

Appearance Liquid except for Calibrators B to Odour None detectable

Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin

coated microwell

Colour Blue for Reagent 1 (ACTH Biotinylated Odour Threshold Not determined

> Ab Solution), Red for Reagent 2 (Enzyme labeled Ab Solution) and clear for all other liquid reagents

Property Values Remarks • Method pН 5.56-7.4 Stop Solution pH <2

Melting Point/Freezing Point Not applicable **Boiling Point/Boiling Range** Not applicable Flash Point Not applicable Not determined **Evaporation Rate** 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 = 1)

Water Solubility Completely soluble Solubility(ies) Not determined **Partition Coefficient** Not determined

Revision Date: 21-Mar-2018

Values Remarks • Method **Property**

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

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 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 ma/L 17,000.00 Vapor Units mg/L

Revision Date: 21-Mar-2018

Component Information

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

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye damage

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

Harmful to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Crustacea	
Sulfuric Acid		500: 96 h Brachydanio rerio mg/L	29: 24 h Daphnia magna mg/L	
		LC50 static	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 Not applicable

Annex II of MARPOL73/78 and

the IBC Code

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/ELIN CS	PICCS	ENCS	IECSC	AICS	KECL
Sulfuric acid 7664-93-9 (3)	Х	X	Х	Х	Present	Х	Х	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 sections 3

H314 - Causes severe skin burns and eye damage

Legend

SVHC: Substances of Very High Concern for Authorization

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Legend

TWA TWA (time-weighted average) STEL STEL \(Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Classification Procedure

Calculation method

 Issue Date:
 06-Apr-2011

 Revision Date:
 29-Mar-2018

Revision Note: Update SDS to include each section per Commission Regulation (EU) No. 2015/830 Annex

II Part B.

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