



Safety Data Sheet

Issue Date: 15-Jan-2003

Revision Date: 29Mar18

Version 5

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

1.1. Product Identifier

SDS # BIO-003-EU
Product Code 7024
Product Name Calcitonin ELISA Kits
Synonyms None

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

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS
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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)

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 medical attention if necessary.
Skin Contact	Wash with soap and water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention
Inhalation	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.
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.
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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: 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 ³ 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
Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
Sulfuric acid 7664-93-9	TWA: 0.05 mg/m ³	TWA: 0.05 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: 0.1 mg/m ³ STEL: 0.3 mg/m ³	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		
Appearance	Liquid except for Calibrators A to Calibrator F and Control 1/Control 2 which are lyophilized and Streptavidin coated microwell	Odour	No detectable odor
Colour	Blue for Reagent 1 (Calcitonin 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 available	
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 an explosive	
Oxidising Properties	Not an oxidizer	

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 ³ (Rat) 2 h

Skin corrosion/irritation	Causes skin irritation.
Serious eye damage/eye	Causes serious eye damage.
Sensitization	Not classified.
Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
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 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, ADN, 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/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 Authorisation:

Legend

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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

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

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