

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product Identifiers

Product Name : TSH ELISA
Catalog No : IB19109

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses : For In Vitro Use Only. For research use only. Not for use in diagnostic procedures.
Restrictions : Not for human or animal consumption.

1.3. Details of the supplier of the Safety Data Sheet

Company : Manufactured for:
IBL-America
8201 Central Ave NE, Suite P
Minneapolis, MN 55434 USA
Telephone : (888) 523-1246
Fax : (763) 780-2988

1.4. Emergency telephone number

Emergency Phone Number : In the event of a medical emergency, please dial 911.

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

- GHS Classification in accordance with REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures.
- This SDS describes the hazards associated with the specific components, as follows:
 - Sample Diluent, IgG Calibrator, IgG Positive Control, IgM Negative Control, Wash Concentrate:** Skin sensitization (Category 1A)
 - ProClin Solution:** Not classified as hazardous.
 - Stop Solution:** Eye irritation (Category 2A); Skin irritation (Category 2)

2.2. GHS Label elements, including precautionary statement

- Sample Diluent, IgG Calibrator, IgG Positive Control, IgG Negative Control, Wash Concentrate**

- Contains:** 2-Methyl-2H-isothiazol-3-one

- Pictogram:** To the right

- Signal Word:** Warning

- Hazard Statement(s)**

H317



May cause an allergic skin reaction

- Precautionary statement(s)**

P280

Wear protective gloves

P302 + P352

IF ON SKIN: Wash with plenty of soap and water

P333 + P313

If skin irritation or rash occurs: Get medical advice/attention.

- ProClin Solution**

Contains: Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Pictogram: To the right

Signal Word: Warning

Hazard Statement(s):

H317



May cause an allergic skin reaction

Precautionary statement(s):

P280

Wear protective gloves

P302 + P352

IF ON SKIN: Wash with plenty of soap and water

P333 + P313

If skin irritation or rash occurs: Get medical advice/attention.

Stop Solution**Pictogram:** To the right.**Signal Word:** Warning.**Hazard Statement(s)**

H315



Causes skin irritation

H319

Causes serious eye irritation

Precautionary statement(s):

P264

Wash exposed skin thoroughly after handling.

P280

Wear eye protection/face protection. Wear protective gloves.

P302 + P352

IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P332 + P313

If skin irritation occurs: Get medical advice/attention.

P337 + P313

If eye irritation persists: Get medical advice/attention.

P362 + P364

Take off contaminated clothing and wash before reuse.

2.3. Hazards not otherwise classified

Not applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS**3.1. Mixtures**

Product	Ingredient	Concentration	CAS #	EC-No.
Sample Diluent	2-Methyl-2H-isothiazol-3-one	< 1.0%	2682-20-4	613-167-00-5
IgG Calibrator	2-Methyl-2H-isothiazol-3-one	< 1.0%	2682-20-4	613-167-00-5
IgG Positive Control	2-Methyl-2H-isothiazol-3-one	< 1.0%	2682-20-4	613-167-00-5
IgG Negative Control	2-Methyl-2H-isothiazol-3-one	< 1.0%	2682-20-4	613-167-00-5
Wash Concentrate	2-Methyl-2H-isothiazol-3-one	< 1.0%	2682-20-4	613-167-00-5
ProClin Solution	ProClin	0.05%	55965-84-9	613-167-00-5
Stop Solution	Sulfuric Acid	0.028%	7664-93-9	231-639-5

Note: Unless otherwise specified, the information in the remainder of this document is applicable to both product components.**4. FIRST AID MEASURES****4.1. Descriptions of first aid measures****General Advice**

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If irritation or other health effects arise or continue after first aid treatment, seek medical attention.

In case of skin contact

Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. If irritation or other health effects arise or continue after first aid treatment, seek medical attention. Wash contaminated clothing before reuse.

In case of eye contact

Rinse thoroughly with water for at least 15 minutes and consult a physician. If irritation or other symptoms arise or persist after first aid treatment, seek medical attention.

If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (section 2.2) and/or in section 11.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIREFIGHTING MEASURES**5.1. Suitable extinguishing media**

Fire-fighting media should be selected depending on the surrounding materials and equipment.

5.2. Specific hazards arising from product

The components of this product are non-combustible. Ambient fire may liberate hazardous gases (e.g., oxides of carbon and sulfur).

5.3. Specific protective equipment and precautions for fire-fighter

It is recommended that fire-fighters wear protective gear and self-contained breathing apparatus to limit their exposure. Rinse all equipment thoroughly before returning to service.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedure

Use personal protective equipment (nitrile gloves, safety glasses with side shield, lab coat). Avoid breathing vapors, mist or spray. Ensure adequate ventilation. Clear the area immediately surrounding the spill.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3. Methods and materials for containment and cleaning up

Soak up with absorbent material (e.g., polypads). Wipe-down the area with a damp sponge or polypad to remove all residue. Keep spill debris generated in suitable, closed containers for disposal according to local regulations.

6.4. References to other section

See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

This kit should be handled and used by a qualified, trained professional, maintaining general good laboratory practice. Do not smoke, drink, or apply cosmetics in chemical use areas. Handle calibrators and unknown samples as potentially infectious.

7.2. Conditions for safe storage

This kit should be stored as recommended on the product label. Refer to the storage section of the package insert for further information. Store away from any incompatible material (see Section 10).

7.3. Specific End Uses

Research and development.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limits

This product contains the following substances that have specific airborne occupational exposure limits:

Sulfuric Acid

EU OEL: TWA = 0.05 mg/m³ 8 hour(s). Form: (mist); the mist is defined as the thoracic fraction.

ACGIH TLV: TWA = 0.2 mg/m³ (thoracic fraction)

OSHA PEL: TWA = 1 mg/m³

NIOSH REL: TWA = 1 mg/m³; IDLH = 15 mg/m³

National Airborne Occupational Exposure Limits (OEL) for European Union Members:

SULFURIC ACID

Austria: STEL= 0.2 mg/m ³ ; TWA= 0.1 mg/m ³	Estonia: TWA= 1 mg/m ³ (fume)	Italy: Not established	Portugal: TWA= 0.05 mg/m ³
Belgium: TWA= 0.2 mg/m ³	Finland: STEL= 0.1 mg/m ³ ; TWA= 0.05 mg/m ³	Latvia: TWA= 0.05 mg/m ³	Romania: TWA= 0.05 mg/m ³
Bulgaria: TWA= 0.05 mg/m ³	France: STEL= 3 mg/m ³ ; TWA= 0.05 mg/m ³	Lithuania: STEL= 3 mg/m ³ ; TWA= 0.05 mg/m ³	Slovakia: TWA= 0.1 mg/m ³
Croatia: TWA= 0.05 mg/m ³	Germany: C = 0.2 mg/m ³ ; TWA= 0.1 mg/m ³	Luxemburg: TWA= 0.05 mg/m ³	Slovenia: TWA= 0.05 mg/m ³ (inhalable fraction)
Republic of Cyprus: TWA= 0.05 mg/m ³	Greece: TWA= 0.05 mg/m ³	Malta: TWA= 0.05 mg/m ³	Spain: TWA= 0.05 mg/m ³
Czech Republic: TWA= 1 mg/m ³ ; TWA= 0.05 mg/m ³ (concentrated mist); C = 2 mg/m ³	Hungary: TWA= 0.05 mg/m ³	Netherlands: TWA= 0.05 mg/m ³	Sweden: STEL= 0.2 mg/m ³ inhalable fraction; TWA= 0.1 mg/m ³ (inhalable fraction)
Denmark: TWA= 0.05 mg/m ³	Ireland: STEL= 0.15 mg/m ³ ; TWA= 0.05 mg/m ³	Poland: TWA= 0.05 mg/m ³	United Kingdom: STEL = 0.15 mg/m ³ ; TWA=0.05 mg/m ³ 8

8.2. Engineering controls

Use with adequate ventilation. Ensure that eyewash stations and safety showers are close to the workstation location.

8.3. Individual protection measures

Wear protective clothing and appropriate footwear as protection against splashing or contamination. Also wear approved safety goggles and protective gloves. After finishing the work or before going on break, wash hands thoroughly.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

ProClin Solution, Sample Diluent, IgG Calibrator, IgG Positive Control, IgG Negative Control, Wash Concentrate

Physical characteristics

Description: Colorless liquid

Odor: Not detectable

Odor threshold: Not applicable

Chemical properties

pH: 6-8

Boiling point: Approximately 100°C at 760mmHg

Melting point: Less than 0°C (32°F)

Flash point: Not applicable

Evaporation rate (water = 1): Approximately 1.0

Flammability (solid, gas): Not applicable

Upper/lower flammability or explosive limits: Not applicable

Vapor pressure: Not applicable

Vapor density: Not applicable

Relative density: Not applicable

Partition coefficient n-octanol/water: Not applicable

Auto-ignition temperature: Not applicable

Decomposition temperature: Not applicable

Viscosity, kinematic: Not applicable

Explosive properties: Not applicable

Oxidizing properties: Not applicable

Solubility in water: Soluble

% Volatile Organic Content: Not applicable

Stop Solution

Physical characteristics

Description: Colorless liquid

Odor: Not detectable

Odor threshold: Not applicable

Chemical properties

pH: 2.2

Boiling point: Approximately 100°C at 760mmHg

Melting point: Less than 0°C (32°F)

Flash point: Not applicable

Evaporation rate (water = 1): Approximately 1.0

Flammability (solid, gas): Not applicable

Upper/lower flammability or explosive limits: Not applicable

Vapor pressure: Not applicable

Vapor density: Not applicable

Relative density: Not applicable

Partition coefficient n-octanol/water: Not applicable

Auto-ignition temperature: Not applicable

Decomposition temperature: Not applicable

Viscosity, kinematic: Not applicable

Explosive properties: Not applicable

Oxidizing properties: Not applicable

Solubility in water: Soluble

% Volatile Organic Content: Not applicable

10. STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical Stability

Stable under recommended storage conditions.

10.3. Conditions to avoid

Exposure to extreme temperatures and incompatible materials.

10.4. Materials to avoid

Use only clean glass and plastic suitable for laboratory use when handling the kit components. The components of this kit are Individual solutions that are not compatible with the following chemicals:

- **ProClin Solution, Sample Diluent, IgG Calibrator, IgG Positive Control, IgG Negative Control, Wash Concentrate:** Water-reactive compounds and strong oxidizers.
- **Stop Solution:** Strong oxidizing agents, metals and strong bases.

10.5. Hazardous decomposition products

Under the conditions of a fire, the components of this kit will thermally decompose and release the following products: Individual ingredients are not compatible with the following chemicals:

- **Sample Diluent, IgG Calibrator, IgG Positive Control, IgG Negative Control, Wash Concentrate:** Water vapor and oxides of carbon, sulfur, and nitrogen.
- **ProClin Solution:** Water vapor and oxides of carbon, sulfur, and chlorine
- **Stop Solution:** Water vapor and oxides of sulfur.

11. TOXICOLOGICAL INFORMATION

11.1. Information on likely routes of exposure

Occupational exposures to the components of this product are most apt to occur via skin and eye contact. The components of product could be inhaled via splashes, sprays and mists. Ingestion of the components of this product are unlikely, except under unusual circumstances or procedures involving poor chemical hygiene (e.g., eating in product use areas).

11.2. Symptoms related to physical, chemical and toxicological characteristics

The following symptoms may arise after exposures occur:

Sample Diluent, IgG Calibrator, IgG Positive Control

IgG Negative Control, Wash Concentrate, ProClin Solution

Inhalation: May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin: May cause skin irritation and allergic skin reactions.

Eyes: May cause eye irritation.

Stop Solution

Inhalation: May respiratory tract irritation.

Ingestion: May be harmful if swallowed and cause serious irritation of the tissues of the digestive tract.

Skin: Causes skin irritation, which can result in redness, itching, and pain.

Eyes: Causes serious eye irritation, which can result in redness, tearing, and pain.

11.3. Delayed and immediate effects

No other delayed or immediate effects, as defined by 29 CFR 1910 (OSHA Hazard Communication Standard), Appendix A (Health Hazard Criteria), are associated with the solutions comprising this product.

11.4. Numerical measures of toxicity

Acute Toxicity Estimate: The following values have been calculated for the components of this kit:

Sample Diluent, IgG Calibrator, IgG Positive Control

IgG Negative Control, Wash Concentrate, ProClin Solution

ATE (oral) > 5000 mg/kg ATE

(dermal) > 5000 mg/kg ATE

(inhalation) > 30 mg/L

Stop Solution

ATE (oral) > 5000 mg/kg ATE

(dermal) > 5000 mg/kg ATE

(inhalation) > 30 mg/L

Component Toxicity Values: The following data are available for the chemicals in the kit's solutions.

Sample Diluent, IgG Calibrator, IgG Positive Control

IgG Negative Control, Wash Concentrate,

2-METHYL-3-ISOTHIAZOLONE

LD50 (oral, rat) = 120 mg/kg

LD50 (dermal, rabbit) = 200 mg/kg

LDC50 (inhalation, rat) = 0.11mg/m³/4 hours

Stop Solution

SULFURIC ACID

LD50 (oral, rat) = 2140 mg/kg

LDC50 (inhalation, rat) = 510 mg/m³/2 hours

TCLo (inhalation, human) = 1 mg/m³/3 hours
(thorax, lungs, respiration, other changes)

TCLo (inhalation, human) = 3 mg/m³/24 weeks

(changes in teeth and supporting structures)

LDLo (unreported, man) = 135 mg/kg

ProClin Solution

PROCLIN

ATE (oral) = 100 mg/kg

ATE (dermal) = 3000 mg/kg

11.5. Listing as a carcinogen

No component of this product (based on its form and its intended nature of use), or present greater than 0.1% is identified as probable, possible or confirmed human carcinogen by the International Agency for Research on Carcinogens (IARC), the National Toxicology Program (NTP) or OSHA.

12. ECOLOGICAL INFORMATION

12.1. Ecotoxicity

This product is not classified as an Aquatic Toxicity hazard (per United Nations Globally Harmonized System of Classification and Labelling of Chemicals). The following aquatic toxicity data is available for the components of this product:

Sample Diluent, IgM Calibrator, IgM Positive Control,

IgM Negative Control, Wash Concentrate

2-METHYL-3-ISOTHIAZOLONE

LC50 – 96 hours: 0.07 mg/L (Oncorhynchus mykiss)

EC50 – 48 hours: 0.18 mg/L (Water flea)

Stop Solution

SULFURIC ACID

LC50 - 96 hours: 16 - 28 mg/L - Lepomis macrochirus

(Bluegill sunfish), static test

EC50 - 48 hours: > 100 mg/L - Daphnia magna (Water flea), static test

NOEC: 0.13 mg/L – Algae

NOEC: 0.13 mg/L - 10 Months - Salvelinus fontinalis

(brown trout) flow-through test

ProClin Solution

PROCLIN

Known to be very toxic to aquatic life

12.2. **Persistence and degradability**

Persistence is unlikely, based on the available data.

12.3. **Bioaccumulative potential**

Based on the available data, the components of this product are not anticipated to bioaccumulate.

12.4. **Mobility in soil**

Based on the available data, the components of this product are expected to have some mobility in soil.

12.5. **Other adverse effects**

This product does not contain components that are known to cause ozone depletion, cause endocrine disruption, or contribute to global warming.

13. **DISPOSAL CONSIDERATIONS**

Dispose of each component according to federal, state and local environment control regulations. Contaminated packaging should be handled with care, and also discarded according to appropriate regulations.

14. **TRANSPORT INFORMATION**

The components of this product are not regulated as hazardous material by the Department of Transportation, International Air Transportation Association, or International Maritime Organization.

14.1. **Basic description information**

All Solutions

UN Number: Not applicable.

Class: Not applicable.

Packing Group: Not applicable.

Proper Shipping Name: Not applicable.

14.2. **Environmental hazards**

Not applicable.

14.3. **Special precautions for users**

Not applicable.

14.4. **Special precautions for users**

Not applicable.

15. **REGULATORY INFORMATION**

15.1. **European Regulations**

- **EU Regulation (EC) No. 1907/2006 (REACH) – REACH Status:** All components are exempted or listed.
- **German Water Hazard Classification:** Low hazard to waters.
- **France: Tableaux de Maladies Professionnelles (Table of Occupational Illnesses):** No listing.
- **The Netherlands: List of Carcinogens, Mutagens, and Reproductive Toxins:** Sulfuric Acid mist is listed; this entry is not pertinent to the product, in either its form or usage.
- **Denmark: List of compounds and processes considered to be carcinogenic.:** No listing.

15.2. **Chemical Safety Assessment**

No applicable

16. OTHER INFORMATION

16.1. Statement from company

The above information is believed to be correct but does not purport to be an all-inclusive document. Calbiotech, Inc. shall not be liable or responsible in any way for use of either this information or the material supplied. Final determination of suitability and safe use of these materials is the sole responsibility of the user. Disposal of hazardous materials may be subject to federal, state or local laws or regulations.

16.2. Definitions

ACGIH: American Conference of Government Industrial Hygienists

ATE: Acute Toxicity Estimated, calculated based on available data

CAS #: Chemical Abstract Service Number, used by the American Chemical Society to uniquely identify a chemical.

EC50: The Effect Concentration of a substance which will be fatal to 50% of exposed test aquatic species

IARC: International Agency for Research on Cancer

LD50 or LC50: The Lethal Dose or Lethal Concentration of a substance which will be fatal to 50% of exposed test animals by the designated route of administration.

mg/m³: Milligrams per cubic meter

NOEC: No observable effect concentration

NIOSH: National Institute of Occupational Safety and Health

NTP: National Toxicology Program

OEL: Occupational Exposure Limit

OSHA: U.S. Occupational Safety and Health Administration

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

ppm: Parts per Million

TCLo: The lowest concentration of exposure to create an adverse health effect

16.3. Documentation

Changes: review and update of regulatory information based on ECHA Harmonized Classification