

Material Safety Data Sheet
MSDS -ELISA Rev C 050515

Section 1-Product and Company Information

Product Name: ELISA tests
Product Description: Enzyme linked Immunoabsorbent assay for the qualitative or quantitative detection of substances in human specimen such as serum, plasma, or urine, saliva fluid.

Product Catalog:

E0100	E0410	E0720	E1010
E0105	E0420	E0721	E1020
E0121	E0510	E0810	E1030
E0170	E0511	E0811	
E0230	E0610	E0910	
E0231	E0710	E0911	
E0315	E0711	E0912	

Company: CTK Biotech, Inc
Street Address: 10110 Mesa Rim Road
City, State, Zip, Country: San Diego, CA 92121, USA
Technical Phone: 858-457-8698
Fax: 858-535-1739
Website: www.ctkbiotech.com
Emergency Phone: 858-344-2199

Section 3- Hazards Identification

Physical/Chemical Hazards (N/A: not available):

Substance Name	Amount	CAS#	EC Number	USOSHA	WHMIS	EU	R-phrases
Proclin-300	0.1%	(a) 55965-84-9 (b) 110-98-5	N/A	N/A	exempt	Irritant	43
Thimerosal	0.1%	54-64-8	200-210-4	Highly toxic	D2A	Xn	20/21/22-33
Sulfuric acid	5.5%	7664-93-9	231-639-5	Corrosive	Corrosive	Corrosive	35

Bio-hazards: The positive control, negative control, and calibrator may contain human originated ingredients. These ingredients are inactivated according to the standard procedure prior to be incorporated in the kit. However, they should be considered as potentially capable of transmitting infectious diseases.

1N H2SO4 [5.5% w/w Sulfuric acid], CAS# 7664-93-9, EC No 231-639-5 (pH52); Corrosive irritant to skin, corrosive to eyes.

GHS \ 2008/1272/EC Classification:



Label(s): GHS05
Signal Word: DANGER!
Label Hazard Statement: H314: Causes severe skin burns and eye damage. **Supplemental Hazard Statement:** None Specified
Precautionary Statement – Prevention: P260: Do not breathe dust/fume/ gas/mist/vapours/spray.
P264: Wash thoroughly after handling.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement – Response: P310: Immediately call a POISON CENTER or doctor/ physician.
P363: Wash contaminated clothing before reuse.
P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353: IF ON SKIN (or hair): Remove contaminated clothing. Rinse skin with water/shower.
P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Precautionary Statement – Storage: P405: Store locked up.
Precautionary Statement – Disposal: P501: This material and its container must be disposed of as hazardous waste.

0.1% thimerosal [C9H9HgNaO2S], CAS# 54-64-8, EC No 200-210-4 (dilution < 0.5% but ≥ 0.05 %).

GHS \ 2008/1272/EC Classification:



Label(s): GHS07, GHS08, GHS09
Signal Word: DANGER!
Label Hazard Statement: H302: Toxic if swallowed.
H312: Harmful in contact with skin. H317: May cause an allergic skin reaction. H332: Harmful if inhaled.
H361: Suspected of damaging fertility or the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.
Supplemental Hazard Statement: None Specified
Precautionary Statement – Prevention: P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust/fume/ gas/mist/vapours/spray.
P264: Wash thoroughly after handling.
P273: Do not eat, drink or smoke when using this product.
P280: Use of gloves, eye protection or face protection.
P281: Use of protective clothing.
P273: Avoid release to the environment.
P281: Use personal protective equipment as required.
Precautionary Statement – Response: P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P330: Rinse mouth
P363: Wash contaminated clothing before reuse.
P391: Collect spillage.
P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308 + P313: IF exposed or concerned: Get medical advice/attention.
P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention.
Precautionary Statement – Storage: None Specified
Precautionary Statement – Disposal: P501: This material and its container must be disposed of as hazardous waste.

Section 2- Composition/Information on Ingredients

Items	Description	Remarks
1	Antigen or antibody coated microwells*(solid)	Applicable to all the ELISA tests
2	Sample diluent* 12 ml	Applicable to some of the ELISA tests
3	HRP-conjugates*, 6-12 ml	Applicable to all the ELISA tests
4	Positive control*, 1ml	Applicable to all the qualitative ELISA test
5	Negative control*, 1ml	Applicable to all the qualitative ELISA test
6	Calibrator*, 1 ml	Applicable to all the quantitative ELISA tests
7	Concentrated wash buffer (30x), 20 ml	Applicable to all the qualitative ELISA test
8	TMB solution A, 6 ml	Applicable to all the ELISA tests
9	TMB solution B*, 6 ml	Applicable to all the ELISA tests

10	Stop solution (2N H ₂ SO ₄), 6 ml	Applicable to all the ELISA tests
11	ELISA working sheet	Applicable to all the ELISA tests
12	Package insert	Applicable to all the ELISA tests

*: Containing 0.1% Thimerosal and 0.1% Procline-300 as preservatives

Section 4- First –Aid Measures

Inhalation: Inhalation of any components in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

Ingestion: If a component of this kit is ingested, wash mouth out with water. If irritation or discomfort occurs, obtain medical attention.

Skin Contact: **Stop Solution** may cause irritation upon contact. If this component contacts the skin, remove any contaminated clothing and wash affected area with plenty of soap and water. If other components of this kit contact the skin and causes discomfort, remove any contaminated clothing. Wash affected area with plenty of soap and water. If pain or irritation occurs, obtain medical attention.

Eye Contact: **Stop Solution** may cause irritation upon contact. If this component enter the eyes, immediately wash eyes under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If other components of this kit enter the eyes and cause discomfort, gently wash eyes under potable running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Aggravating Condition: Repeated or prolonged exposure is not known to aggravate medical condition.

Section 5- Fire-fight measures

5.1 Extinguishing Media: For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam. No direct contact with water.

5.2 Special Fire Fighting Procedures: This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.3 Unusual Fire and Explosion Hazards: When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide, sulfur dioxide).

Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions.

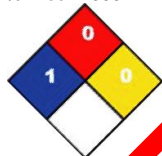
Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

5.4 Additional Considerations

5.4.1 Flash Point	Non Combustible
5.4.2 Auto-ignition Temperature	Not Applicable
5.4.3 Upper / Lower Explosion Limit	Not Applicable

5.5 NFPA Ratings

0.1% Procline-300



0.1% Thimerosal



2 M Sulfuric acid



Section 6- Accidental Release Measures

Personal Precaution: This kit contains materials of corrosive and biological hazards. Avoid personal contact. Use Universal Precautions during clean-up procedures.

Small Spill and Leak: Positive, negative, and Calibrator Use absorbent paper towel or cloth to absorb the spill solution and dispose or clean the contaminated surface in accordance with U.S. Federal, State, or local procedures or appropriate bio-hazardous standards

Other components: Use absorbent paper towel or cloth to absorb the spill solution and dispose Or clean the contaminated surface in accordance with U.S. Federal, State, or local procedures or appropriate standards.

Large Spill and Leak: Large spills in this kit are unlikely.

Section 7- Handling and Storage

Handling: As with all chemicals, avoid getting components within this kit **ON YOU** or **IN YOU**. Wash exposed areas thoroughly after using this kit. Do not eat, drink or apply cosmetic while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. This kit should be handled although capable of transmitting infectious diseases. Universal Precautions should be followed when using this kit. **Not for use by the general public.**

Storage: Keep container tightly closed. Keep product at 2-8°C. Do not freeze or expose to temperature higher than 30°C. Keep away from children.

Section 8- Exposure Control/Personal Protection

8.1 Exposure Limits:

	CAS#	Chemical Name	OSHA (PEL)	ACGIH (TLV) *	NIOSH
	SARA313	Proclin-300	N/A	0.1 mg/ m ³	N/A
	54-64-8	Thimerosal	0.01 mg(Hg)/ m ³	0.1 mg(Hg)/ m ³	0.1 mg(Hg)/ m ³
	7664-93-9	Sulfuric acid	1 mg/m ³	1 mg/m3	N/A

Biological Exposure Index (ACGIH).

Other exposure limits for potential decomposition products: None.

8.2 Occupational Exposure Controls:

Engineering Control: Eye bath. Use adequate ventilation to keep airborne concentrations low.

Hygiene Measures: Wash hands after handling compounds and before eating, smoking, using lavatory, and at the end of the day.

Personal Protective Equipment:

Respiratory Protection: None needed under normal conditions of use
Skin and Body: Lab coat as indicated by general lab practice guidelines.
Eyes: Safety glasses or face shield are recommended to prevent eye contact.
Hand: Impervious gloves (nitrile or equivalent) should be worn to prevent hand contact.

Environmental Controls: No special environmental controls are required.

Section 9- Physical/Chemical Properties

	Boiling Point	Melting point	Special gravity	Vapor pressure	Vapor density	Evapora-Tion rate	pH	Water solubility	Appearance and odor
Procline-300	233°C	N/A	1.03	0.06mmHg	N/A	<1	4.1 neutr al	Soluble	odorless
Thimerosal	N/A	N/A	N/A	N/A	N/A	N/A		Soluble	odorless
Sulfuric acid, 2M	100°C	0°C	1.0	water	0.7 water	< 1	< 1.0	Soluble	Clear, slight odor

Section 10- Stability and Reactivity

	Stability Conditions	Materials to avoid	Hazardous to avoid	Hazardous decomposition or Bio-products	Polymerization
Proclin-300 (0.1%)	Stable	Incompatible Materials	Strong oxidizers Perchloric Acid, > 25°C for prolonged periods	Hydrogen chloride, oxides of Nitrogen and sulfur	Not occur
Thimerosal (0.1%)	Stable	Incompatible Materials	Strong oxidizers strong acid	Thermal decomposition may release irritating fumes or toxic gases, (e.g., Mercury, CO, CO ₂) Sulfur trioxide and or dioxide fumes. Reacts with metals to form hydrogen gas	Not occur
Sulfuric acid (2M)	Stable	Incompatible Materials	Alkalies, amines, anhydrides, oxidizers, combustibles, organics, powdered metals		Not occur

Section 11- Toxicological Information

Proclin-300

LD₅₀ oral rat, female: 3723 mg/kg
LD₅₀ oral rat, male: 3600 mg/kg
LD₅₀ skin rabbit, female: >3600 mg/kg
LD₅₀ skin rabbit, male: 3500 mg/kg

To the best of our knowledge, the chemical, physical, and toxicological properties of this chemical have not been thoroughly investigated.

Thimerosal

Intraaural – Child LD₅₀ = 71 mg/kg Remarks: Behavioral: Ataxia. Gastrointestinal: Nausea or vomiting.
Nutritional and Gross Metabolic: Changes in metabolic acidosis.

Oral – Rat LD₅₀ = 75 mg/kg
Subcutaneous – Rat LD₅₀ = 98 mg/kg
Oral – Mouse LD₅₀ = 91 mg/kg
Intraperitoneal – Mouse LD₅₀ = 54 mg/kg
Subcutaneous – Mouse LD₅₀ = 66 mg/kg

Intravenous – Mouse LD₅₀ = 45 mg/kg Remarks: Kidney, Ureter, Bladder: Changes in tubules (including acute renal failure, acute tubular necrosis)

Irritation Data:

Eyes: Rabbit 0.008 mg Remarks: Mild irritation effect

Sulfuric acid

IMMEDIATE (ACUTE) EFFECTS:

LD50 (oral-rat): 140 mg/kg
LC50 (inhl-rat): 510 mg/m³/2 hr
LC50 (inhl-mouse): 320 mg/m³/2 hr

DELAYED (SUBCHRONIC AND CHRONIC) EFFECTS:

IARC and NTP have classified "strong inorganic acid mists containing sulfuric acid" as known human carcinogens. The state of California has also listed "strong inorganic acid mists containing sulfuric acid" on the Proposition 65 list as a cancer causing agent. No definitive causal relationship between sulfuric acid mist exposure and respiratory cancer has been shown.

OTHER DATA: None.

Section 12- Ecological Information

12.1 Ecotoxicity – Not Available

No adverse effects on the environment are expected from the components of this kit. There is no aquatic toxicity data for this kit at this time. Individual aquatic toxicology studies have been completed for the below listed chemicals.

Thimerosal

LC₅₀ (Lepomis macrochirus - Bluegill) = 87 mg/L Time: 24 hours
LC₅₀ (Lepomis macrochirus - Bluegill) = 58 mg/L Time: 48 hours

Sulfuric acid

Lethal (Lepomis macrochirus - Bluegill) = 24.5 ppm Time: 24 hours fresh water
LC₅₀ (Lepomis macrochirus - Prairie Perch) = 42.5 ppm Time: 48 hr/salt water

12.2 Mobility: Mobility data are not available for the components of this kit.

12.3 Persistence and Degradability: There is no persistence or degradation data for any component of this kit at this time.

12.4 Bioaccumulative Potential

There is limited potential for the components within this kit to accumulate in plant or animal systems.

Section 13- Disposal Consideration

Dispose of waste material, unused components and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Section 14- Transport Information

14.1 U.S. Transportation

This product is regulated per 49 CFR 172.101, the U.S. department of transportation:

PROPER SHIPPING NAME:	Chemical Kits
HAZARD CLASS NUMBER and DESCRIPTION:	Class 9, Miscellaneous
UN IDENTIFICATION NUMBER:	UN 3316
DOT LABEL(S) REQUIRED:	Class 9
PACKAGING GROUP:	N/A
NORTH AMERICAN RESPONSE GUIDEBOOK NUMBER (2000):	171
MARINE POLLUTANT:	No component is designated as a DOT Marine Pollutant.

Per 49 CFR 172.102, Chemical kits are exempted from specification packaging requirements when packaged in combination packaging. Chemical kits are also exempted from labeling and placarding requirements except when offered for transportation or transported by air. Chemical kits may be transported in accordance with the consumer commodity and ORM exceptions in 49 CFR 173.156 provided they meet all required conditions. Kits that are carried on board transport vehicles for first aid or operating purposes are not subject to these requirements.

14.2 Canadian Transportation

The above-listed DOT basic description applies to this product under the regulations of Transport Canada.

14.3 International Air Transportation

This product is regulated per International Air Transportation Association (IATA) Dangerous Goods Regulations:

PROPER SHIPPING NAME:	Chemical Kit
HAZARD CLASS NUMBER and DESCRIPTION:	Class 9, Miscellaneous
UN IDENTIFICATION NUMBER:	UN 3316
DOT LABEL(S) REQUIRED:	Class 9
PACKAGING GROUP:	III
Packing Instruction (Limited Quantity):	915 (Y915)

Small quantities of Class 9 materials may be shipped as "Chemical Kit", provided that the requirements of Section 2.7, "Dangerous Goods in Excepted Quantities" are met. The maximum quantity of material per inner

package must be less than 30 g or 30 mL; the total net quantity of Dangerous Goods in each outer package is limited to 1 kg or 1000 mL.

Section 15- Regulatory Information

15.1 U.S. Federal and State Regulations

	Proclin-300	Thimerosal 0.1%	2M sulfuric acid
40 CFR 355.30/355.40 - SECTION 302	Not listed	Not listed	N/A
40 CFR 302.4 – SECTION 304	Not listed	1 pound (as Hg)	N/A
40 CFR 372.65 – SECTION 313	Not listed	Listed (as Hg)	N/A

U.S. SARA SECTION 311/312 FOR KIT: Acute health effects; chronic health effects.

U.S. TSCA INVENTORY STATUS: The components of this kit are listed on the TSCA Inventory.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):

Components within this kit contain chemicals known to the state of California to cause developmental toxicity or cancer.

ANSI Z129.1	Labeling:	Label Precautions:
Proclin –300 (0.1%)	WARNING: Harmful if swallowed, inhaled or absorbed through skin. Eye and skin irritant.	Do not swallow or take internally. Do not breathe fumes, vapors or mists. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling.
Thimerosal (0.1%)	WARNING: Harmful if swallowed, inhaled or absorbed through skin. Eye and skin irritant. May be reproductive or nervous system toxin.	Do not swallow or take internally. Do not breathe fumes, vapors or mists. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling.
Sulfuric acid (2 M)	WARNING: Harmful if swallowed, inhaled or absorbed through skin. Eye and skin irritant. May be cause cancer.	Toxic. May cause cancer by inhalation. Causes burns on skin or eye. Reacts violently with water. Irritating to the respirator system
Kit Package	CAUTION: Kit components may be harmful if swallowed, inhaled, or absorbed through skin. Components may be eye and skin irritants.	Do not swallow or take internally. Do not get in eyes, on skin, or on clothing. This kit contains material of animal origin and should be considered as potential capable of transmitting infectious diseases. Follow package insert instructions for use.

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this kit into streams, ponds, estuaries, oceans or other waters, unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this kit to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

15.2 Canadian Regulations:

CANADIAN DSL/NDL INVENTORY STATUS:

The components of this kit are listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS:

0.1% Thimerosal



Class D2A

Toxic material

2M Sulfuric acid



Corrosive

Toxic material

15.3 Hazardous Material Information System Ratings

	0.1% Proclin –300	0.1% Thimerosal	2M sulfuric acid
Health	1	1	2
Fire Hazard	0	0	0
Reactivity	0	0	1
Personal Protection	B	B	B

15.4 EU Labeling Classification:

Classification:

0.1% Proclin-300



Irritant

Risk Phrases:

R43: May cause sensitization by skin contact

Safety Phrases:

S28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves

Classification:

0.1% Thimerosal (0.01% Hg)



Xn Harmful

Risk Phrases (for Thimerosal – Organic compounds of Hg):

R20 Harmful by inhalation
R21 Harmful in contact with skin
R22 Harmful if swallowed
R33 Danger of cumulative effects

Safety Phrases:

S13 Keep away from food, drink and animal feeding stuffs.
S28 After contact with skin, wash immediately with plenty of water
S36 Wear suitable protective clothing.

Classification:

2M Sulfuric acid



Corrosive

Risk Phrases (for sulfuric acid):

R35 Causes severe burns. Risk of serious damage to eyes.

Safety Phrases:

S1/2 Keep locked up and out of the reach of children.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell, seek medical advice immediately.

Section 16- Other Information

Risk Phrases:

R 20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R 22 Harmful if swallowed.
R 33 Danger of cumulative effects.
R 34 Causes burns.
R 36/38 Irritating to eyes and skin.
R 41 Risk of serious damage to eyes.
R 43 May cause sensitization by skin contact.
R 61 May cause harm to unborn child. (Designation is for concentrated thimerosal (mercury compounds), which is diluted to 0.1% -0.01% in kit components.)

Safety Phrases:

S13 Keep away from food, drink and animal feeding stuffs.
S 24 Avoid contact with skin.
S 24/25 Avoid contact with skin and eyes.

- S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S 28 After contact with skin, wash immediately with plenty of soap and water.
- S 35 This material and its container must be disposed of in a safe way.
- S 36 Wear suitable protective clothing.
- S 36/37 Wear suitable protective clothing and gloves.
- S 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
- S 37 Wear suitable protective gloves.

Notice to Reader

To the best of our knowledge, this information contained herein is accurate. However, neither the above named supplier nor may of its subsidiaries assume any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

ELISA Test Kit

Date of Issue: 2015-05-05

For Reference Only