Section 1: Product and Company Identification

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Product Name: *Cryptosporidium* ELISA Kit
Generic Name: NA
Synonyms: NA
Product Description: Diagnostic kit for *Cryptosporidium*
CAS # NA – mixture
Rev. # 3

Section 2: Hazard Identification

Emergency Overview: Appearance: Seven different liquids. **Warning!** Stop Solution is a corrosive liquid. All liquids may be irritating to eyes, skin, digestive tract or respiratory tract. For *in vitro* use only.

HMIS HEALTH	**1**
HMIS FLAMMABILITY	**0**
HMIS REACTIVITY	**0**
PERSONAL PROTECTION	**C**

Regulatory Status: Only the Positive Control, Negative Control and Stop Solution are considered hazardous under the OSHA standard or WHMIS.

Potential Health Effects:
Inhalation: Inhalation of liquid or mist may be irritating to the respiratory tract.
Ingestion: May cause irritation of the digestive tract. Stop Solution may cause burns to the digestive tract.
Skin Contact: May cause skin irritation. Stop Solution may cause burns. Formaldehyde in Positive and Negative controls may cause skin sensitization.
Eye Contact: May cause eye irritation. Stop Solution may cause burns.
Chronic Exposure: Repeated or prolonged exposure may cause allergic reactions in sensitive individuals.
Aggravation of Pre-existing Conditions: No information available.
Target Organs: No information available.

Section 3: Composition/Information On Ingredients

Kit Component	Contains	CAS #	EINECS #	Weight %
Reagent 1	Thimerosal	54-64-8	200-210-4	0.5%
Reagent 2	Thimerosal	54-64-8	200-210-4	0.5%
Positive Control	Formaldehyde	50-00-0	200-001-8	1%
Negative Control	Formaldehyde	50-00-0	200-001-8	10%
Chromogen	Tetramethylbenzidine	54827-17-7	259-364-6	<1%
Wash Concentrate	Thimerosal	54-64-8	200-210-4	0.4%
Stop Solution	Phosphoric Acid	7664-38-2	231-633-2	5%

Non-hazardous components may or may not be listed. Carcinogens are listed when present at 0.1% or more; components which are otherwise hazardous according to OSHA are listed when present at 1.0% or more. This is not intended to be complete compositional disclosure. See Section 15 for applicable states right to know and other regulatory information.

Section 4: First Aid Measures

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion: Drink several glasses of water or milk. Never give anything by mouth to an unconscious person. Get medical attention.
Skin: Immediately flush skin with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Eyes: Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.
Note to Physicians: N/A

Section 5: Fire Fighting Measures

Fire: Flash point: Not flammable.
Explosion: Not considered an explosion hazard.
Extinguishing Media: Use appropriate media for the surrounding fire.
Special Precautions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.
NFPA Rating: Health – 1 Flammability - 0 Reactivity - 0 Other – NA

Section 6: Accidental Release Measures

Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Collect liquid or solid in an appropriate container or absorb with an inert material (e. g., vermiculite, dry sand, earth), and place in a chemical waste container. Wash contaminated area with plenty of water.

Section 7: Handling and Storage

Keep all containers tightly closed. Store at 2-8°C. Protect material from long-term exposure to light. Short periods of exposure to light are acceptable.

Section 8: Exposure Control/Personal Protection

Compound	CAS#	OSHA PEL	ACGIH TLV	NIOSH TLV
Thimerosal	54-64-8	None Established	0.1mg/m^3 (TWA) (as Hg)	0.05 mg/m^3 (TWA) (vapor except organoalkyls, as Hg)
Tetramethylbenzidine	54827-17-7	None Established	None Established	None Established
Formaldehyde	50-00-0	0.75 ppm (TWA) 2 ppm (STEL)	0.3 ppm (Ceiling)	0.016 ppm (TWA) 20 ppm (IDLH)
Phosphoric acid	7664-38-2	1mg/m^3 (TWA)	1mg/m^3 (TWA) 3 mg/m^3 (STEL)	1mg/m^3 (TWA) 3 mg/m^3 (STEL)

Personal Protective Equipment:
Skin Contact: Wear impervious protective clothing, including boots, gloves, lab coat, apron or coveralls, as appropriate, to prevent skin contact. Latex and nitrile are suitable glove materials.
Eye Contact: Use chemical safety goggles and/or full face shield where misting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.
Inhalation: Use NIOSH-approved vapor respirator if exposure is unknown or exceeds permissible limits. A respiratory protection program that meets OSHA's 29 CFR 1910.134 or ANSI Z88.2 requirements must be followed whenever workplace conditions warrant respirator use. WARNING: Air-purifying respirators do not protect workers in oxygen deficient atmospheres.

Engineering Controls: A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, Industrial Ventilation, A Manual of Recommended Practices, most recent edition, for details.

Section 9: Physical and Chemical Properties

	Reagent 1	**Reagent 2**	**Positive Control**	**Negative Control**
Appearance	Clear blue liquid	Clear red liquid	Opaque brown liquid	Clear brown liquid
Melting Point	≈ 0ºC	≈ 0ºC	≈ 0ºC	≈ 0ºC
Boiling Point	≥ 100ºC	≥ 100ºC	≥ 100ºC	≥ 100ºC
Specific Gravity	About 1.0	About 1.0	About 1.0	About 1.0
pH	About 7.4	About 6.6	About 7.0	About 7.0
Solubility in water	Complete	Complete	Complete	Complete
	Chromogen	**Wash Concentrate**	**Stop Solution**	
Appearance	Clear colorless liquid	Clear colorless liquid	Clear colorless liquid	
Melting Point	≈ 0ºC	≈ 0ºC	≈ 0ºC	
Boiling Point	≥ 100ºC	≥ 100ºC	≥ 100ºC	
Specific Gravity	About 1.0	About 1.0	1.03	
pH	7.2	About 6.5	About 1.2	
Solubility in water	Complete	Complete	Complete	

Section 10: Stability and Reactivity

Chemical Stability: This product is stable in closed containers at room temperature.
Hazardous Decomposition Products: Carbon oxides (CO, CO_2), nitrogen oxides (NO, NO_2, N_2O), sulfur oxides (SO_2, SO_3), phosphorus oxides (P_2O_5), hydrogen chloride
Incompatibilities: Strong oxidizers, heat, strong acids or bases
Conditions to Avoid: Incompatible materials, combustible materials.

Section 11: Toxicological Information

Acute Dose Effects: Eye: Phosphoric acid: Draize Rabbit: 119 mg Severe; Formaldehyde: Draize Rabbit: 750 µg/24H Severe
Skin: Phosphoric acid: Rat LD50: 2740 mg/kg; Formaldehyde: Draize Rabbit: 2 mg/24H Severe; Rabbit LD50: 270 µL/kg
Ingestion: Phosphoric acid: Rat LD50: 1530 mg/kg; Formaldehyde: Rat LD50: 100 mg/kg
Inhalation: Rat LC50: >850 mg/m^3/1H Formaldehyde: Mouse LC50: 454 mg/m^3/4H; Rat LC50: 578 mg/m3/2H
Carcinogenicity: OSHA-regulated carcinogen; ACGIH: A2 - Suspected Human Carcinogen; NTP: Suspect carcinogen; IARC: Group 1 carcinogen

Section 12: Ecological Information

Environmental Fate: This product is not expected to bioaccumulate. When released into water or air its expected halflife is 1- 10 days.
Ecotoxicity: Dilute nature and small volumes of products makes any ecological effect highly unlikely.

Section 13: Disposal Considerations

As a waste, this material in its raw form IS NOT considered a HAZARDOUS WASTE under RCRA (29 CFR 261).
Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State

and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

Section 14: Transport Information

All the solutions are unregulated by DOT and IATA except for the Stop Solution.
The quantity of Stop Solution qualifies for excepted quantity rules and dangerous goods declarations are not necessary.
With proper packaging and labeling this kit can be transported by passenger and cargo aircraft.
This kit cannot be sent through the mail.
Full disclosure and labeling would be as follows:

Domestic or Int. Air **Proper Shipping Name**: Phosphoric acid solution
Hazard Class: 8
UN Number: UN 1805
Packing Group: III

This data provided for information only. The description shown may not apply to all shipping situations. Consult 49 CFR, or appropriate regulations to properly classify your shipment for transportation.

Section 15: Regulatory Information

TSCA Chemical Inventory: All of the chemicals in this product are listed on the TSCA Inventory.
TSCA Sec 4 Chemical Test Rule: None of the chemicals in this product are under a Chemical Test Rule.
TSCA Sec 8(d): None of the chemicals in this product are on the Health and Safety Reporting List.
TSCA Sec 12(b) Notices of Export: None of the chemicals in this product are on this list.
TSCA Significant New Use Rule (SNUR): None of the chemicals in this product are on this list.
SARA Sec 302 (EHS) TPQ: Formaldehyde, 500 lbs.
SARA Sec 302 (EHS) RQ: Formaldehyde, 100 lbs.
SARA Sec 311/312: Acute – Phosphoric acid and formaldehyde; Chronic –Formaldehyde; Fire – NO; Release of Pressure – NO; Reactivity – NO
SARA 313 List: Formaldehyde in this product is reportable under Section 313 Title III and 40 CFR Part 372.
CERCLA Hazardous Substances and corresponding RQs: Phosphoric acid, 5000 lbs; Formaldehyde, 100 lbs
RCRA: Formaldehyde has a Hazardous waste code of U122
Clean Air Act: **Hazardous Air Pollutants?** 50-00-0 **Class 1 Ozone Depletors?** NO **Class 2 Ozone Depletors?** NO
Clean Water Act: **Hazardous Substance?** Phosphoric acid, formaldehyde **Priority Pollutant?** NO **Toxic Pollutant?** NO
Chemical Weapons Convention: None of the chemicals in this product are on this list.
Drug Enforcement Agency (DEA) CDTA: None of the chemicals in this product are on this list.
OSHA: Formaldehyde in this product is considered Highly Hazardous by OSHA.
State Right-to-Know Lists: Phosphoric acid is found on the Right-to-Know lists of California, Florida, New Jersey, Pennsylvania, Massachusetts or Minnesota. Formaldehyde is found on the Right-to-Know lists of California, New Jersey, Pennsylvania, Massachusetts and Minnesota.
California Proposition 65: This product contains Formaldehyde, a chemical known to the state to cause cancer or reproductive toxicity. This product contains Thimerosal, a chemical known to the state to cause cancer or reproductive toxicity. A person in the course of doing business must warn others who may consume, come into contact with, or otherwise be exposed to this chemical.
Canadian DSL/NDSL Status: As an *in vitro* diagnostic product, this product is regulated by Health Canada (Medical Devices Regulations, SOR/98-282).
European Union
Hazard Symbols: C
Risk Phrases: R20/21/22 – Harmful by inhalation, in contact with skin and if swallowed
R36/38- Irritating to eyes and skin.
R25- Toxic if swallowed.

R26- Very toxic by inhalation.
R34- Causes burns.
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.
S28- After contact with skin, wash immediately with plenty of water.
S36/37- Wear suitable protective clothing and gloves.
S39- Wear eye/face protection.
S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Section 16: Other Information

Abbreviations and acronyms used:

ACGIH	American Conference of Governmental Industrial Hygienists	NA	not applicable, not available
ANSI	American National Standards Institute	NIOSH	National Institute for Occupational Safety and Health
atm	Atmosphere (pressure unit)	ND	not determined
BOD	biological oxygen demand	NFPA	National Fire Prevention Association
CAS	Chemical Abstracts Service	NTP	National Toxicology Program
CC	closed cup	OC	open cup
CDTA	Chemical Drug and Trafficking Act	OSHA	Occupational Safety and Health Administration
COC	Cleveland Open Cup	Part	partition
COD	chemical oxygen demand	PEL	permissible exposure limits
coeff.	coefficient	ppb	parts per billion
CFR	Code of Federal Regulations	PPE	personal protection equipment
CPR	cardio-pulmonary resuscitation	ppm	parts per million
DEA	Drug Enforcement Agency	psi	pounds per square inch
DOT	Department of Transportation	RCRA	Resource Conservation and Recovery Act
FDA	Food and Drug Administration	RQ	Reportable quantity
IARC	Internat'l Agency for Research on Cancer	RTK	Right to Know
IDLH	immediate danger to life and health	SARA	Superfund Amendments and Reauthorization Act
kg	kilogram	STEL	short-term exposure limit
L	liter	TCC	Tagliabue Closed Cup
LC50	median lethal concentration	TPQ	threshold planning quantity
LD50	median lethal dose	TQ	threshold quantity
LEL	lower explosive limit	TSCA	Toxic Substances Control Act
mg	milligram	TWA	time-weighted average
mL	milliliter	WHMIS	Workplace Hazardous Materials Information System

This document was prepared in accordance with 29 CFR 1910.1200 and ANSI Z400.1-2004.

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