Material Safety Data Sheet

Section 1: Product and Company Identification

IVD Research, Inc.
5909 Sea Lion Place Suite D
Carlsbad, California 92010
USA
Telephone: (760) 929-7744

Product Name: C. difficile Toxins A+B ELISA Kit
Generic Name: NA
Synonyms: NA
Product Description: Diagnostic kit for C. difficile toxins A+B
CAS #: NA – mixture
Rev. #: 3

Section 2: Hazard Identification

Emergency Overview: Appearance: Eight 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 Stop Solution is 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.
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

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>Contains</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent 1</td>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>0.5%</td>
</tr>
<tr>
<td>Reagent 2</td>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>0.5%</td>
</tr>
<tr>
<td>Positive Control</td>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>0.05%</td>
</tr>
<tr>
<td>Negative Control</td>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>247-852-1</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td>Chromogen</td>
<td>Tetramethylbenzidine</td>
<td>54827-17-7</td>
<td>259-364-6</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Dilution Buffer</td>
<td>Sodium Azide</td>
<td>22628-22-8</td>
<td>247-852-1</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td>Wash Concentrate</td>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>200-210-4</td>
<td>0.4%</td>
</tr>
<tr>
<td>Stop Solution</td>
<td>Phosphoric Acid</td>
<td>7664-38-2</td>
<td>231-633-2</td>
<td>5%</td>
</tr>
</tbody>
</table>

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

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**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 facemask operated in the pressure demand or other positive pressure mode.

**NFPA Rating:** Health – 1 Flammability - 0 Reactivity - 0 Other – NA

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**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.

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**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.

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**Section 8: Exposure Control/Personal Protection**

<table>
<thead>
<tr>
<th>Compound</th>
<th>CAS#</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
<th>NIOSH TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thimerosal</td>
<td>54-64-8</td>
<td>None Established</td>
<td>0.1mg/m³ (TWA) (as Hg)</td>
<td>0.05 mg/m³ (TWA) (vapor except organoalkyls, as Hg)</td>
</tr>
<tr>
<td>Sodium Azide</td>
<td>26628-22-8</td>
<td>None Established</td>
<td>0.11 ppm as HN₃</td>
<td>0.1 ppm skin as HN₃ (Ceilings)</td>
</tr>
<tr>
<td>Tetramethylbenzidine</td>
<td>54827-17-7</td>
<td>None Established</td>
<td>None Established</td>
<td>None Established</td>
</tr>
<tr>
<td>Phosphoric acid</td>
<td>7664-38-2</td>
<td>1mg/m³ (TWA)</td>
<td>1mg/m³ (TWA) 3mg/m³ (STEL)</td>
<td>1mg/m³ (TWA) 3mg/m³ (STEL)</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th></th>
<th>Reagent 1</th>
<th>Reagent 2</th>
<th>Positive Control</th>
<th>Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear blue liquid</td>
<td>Clear red liquid</td>
<td>Clear liquid</td>
<td>Clear colorless liquid</td>
</tr>
<tr>
<td>Melting Point</td>
<td>≈ 0°C</td>
<td>≈ 0°C</td>
<td>≈ 0°C</td>
<td>≈ 0°C</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>≥ 100°C</td>
<td>≥ 100°C</td>
<td>≥ 100°C</td>
<td>≥ 100°C</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>About 1.0</td>
<td>About 1.0</td>
<td>About 1.0</td>
<td>About 1.0</td>
</tr>
<tr>
<td>pH</td>
<td>About 7.4</td>
<td>About 6.6</td>
<td>About 6.4</td>
<td>About 7.4</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Chromogen</th>
<th>Dilution Buffer</th>
<th>Wash Concentrate</th>
<th>Stop Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear colorless liquid</td>
<td>Clear colorless liquid</td>
<td>Clear colorless liquid</td>
<td>Clear colorless liquid</td>
</tr>
<tr>
<td>Melting Point</td>
<td>≈ 0°C</td>
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<td>Boiling Point</td>
<td>≥ 100°C</td>
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<td>≥ 100°C</td>
<td>≥ 100°C</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>About 1.0</td>
<td>About 1.0</td>
<td>About 1.0</td>
<td>1.03</td>
</tr>
<tr>
<td>pH</td>
<td>7.2</td>
<td>About 7.4</td>
<td>About 6.5</td>
<td>About 1.2</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
</tr>
</tbody>
</table>

### Section 10: Stability and Reactivity

**Chemical Stability:** This product is stable in closed containers at room temperature.

**Hazardous Decomposition Products:** Carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂, N₂O), sulfur oxides (SO₂, SO₃), phosphorus oxides (P₂O₅), 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
Skin: Phosphoric acid: Rat LD₅₀: 2740 mg/kg
Ingestion: Phosphoric acid: Rat LD₅₀: 1530 mg/kg
Inhalation: Rat LC₅₀: >850 mg/m³/1H

**Carcinogenicity:** Not listed by OSHA, NTP or IARC.

### Section 12: Ecological Information

**Environmental Fate:** This product is not expected to bioaccumulate. When released into water or air its expected half-life 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:** Sodium azide, 500 lbs.
**SARA Sec 302 (EHS) RQ:** Sodium azide, 1000 lbs.
**SARA Sec 311/312:** Acute – Phosphoric acid and Sodium azide; Chronic – Sodium azide; Fire – NO; Release of Pressure – NO; Reactivity – NO
**SARA 313 List:** Sodium azide 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; Sodium azide, 1000 lbs.
**RCRA:** Sodium azide has a Hazardous waste code of P105.

**Clean Air Act:** Hazardous Air Pollutants? NO Class 1 Ozone Depletors? NO Class 2 Ozone Depletors? NO Clean Water Act: Hazardous Substance? Phosphoric acid Priority Pollutant? NO Toxic Pollutant? NO Chemical Weapons Convention: None of the chemicals in this product are considered Highly Hazardous by OSHA.
**Drug Enforcement Agency (DEA) CDTA:** None of the chemicals in this product are on this list.

California Proposition 65: 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:** 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
- ANSI: American National Standards Institute
- atm: Atmosphere (pressure unit)
- BOD: biological oxygen demand
- CAS: Chemical Abstracts Service
- CC: closed cup
- CDTA: Chemical Drug and Trafficking Act
- COC: Cleveland Open Cup
- COD: chemical oxygen demand
- coeff.: coefficient
- CFR: Code of Federal Regulations
- CPR: cardio-pulmonary resuscitation
- DEA: Drug Enforcement Agency
- DOT: Department of Transportation
- FDA: Food and Drug Administration
- IARC: Internat’l Agency for Research on Cancer
- IDLH: immediate danger to life and health
- kg: kilogram
- L: liter
- LC50: median lethal concentration
- LD50: median lethal dose
- LEL: lower explosive limit
- mg: milligram
- mL: milliliter
- NA: not applicable, not available
- NIOSH: National Institute for Occupational Safety and Health
- ND: not determined
- NFPA: National Fire Prevention Association
- NTP: National Toxicology Program
- OC: open cup
- OSHA: Occupational Safety and Health Administration
- Part: partition
- PEL: permissible exposure limits
- PPE: personal protection equipment
- ppm: parts per million
- psi: pounds per square inch
- PEL: permissible exposure limits
- RQ: Reportable quantity
- RTK: Right to Know
- RCRA: Resource Conservation and Recovery Act
- SARA: Superfund Amendments and Reauthorization Act
- STEL: short-term exposure limit
- TCC: Tagliabue Closed Cup
- TQ: threshold quantity
- TSCA: Toxic Substances Control Act
- TPQ: threshold planning quantity
- TWA: time-weighted average
- 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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