IDENTIFICATION OF PRODUCT (SUBSTANCE) AND SUPPLIER (1):

Product Name: Pathfinder™ Rotavirus ELISA Kit

Product Number: Catalog 79673 (50 tests)

Catlog number(s) for replacement, optional and separately purchased components that can be obtained for use with this kit and which are covered by this MSDS include: 79481 (refer to Section 2).

Intended Use: The PATHFINDER™ Direct Antigen Detection System for Rotavirus is a qualitative enzyme immunoassay (ELISA) for the direct detection of human rotavirus antigen in stool specimens.

Supplier's Name: Bio-Rad Laboratories, Inc.

Address: 6565 185th Avenue NE
Redmond, WA 98052-5039

Phone Number: 1-800-2-BIORAD (1-800-224-6723); or (425) 881-8300 (daytime PST)

Emergency Phone Number: This MSDS is listed with CHEMTREC (800) 424-9300. Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

COMPOSITION / INFORMATION ON INGREDIENTS -- HAZARDOUS COMPONENTS (2):

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

<table>
<thead>
<tr>
<th>Component *</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 Rotavirus Antibody Tubes (1X50 tubes)</td>
<td>- Rabbit anti-rotavirus IgG coated polystyrene tubes. Clear, colorless solid tubes.</td>
</tr>
<tr>
<td>R2 Rotavirus Conjugate (1X5 mL)</td>
<td>- Horseradish peroxidase conjugated murine monoclonal anti-rotavirus antibodies in buffered saline, pH 7.4, with protein stabilizer, containing &lt; 5% animal serum (bovine, murine, rabbit and avian), &lt; 2% boric acid (H3BO3, CAS# 11113-50-1), &lt; 2% Tris hydroxymethyl aminomethane (acid/base) (CAS# 1185-53-1, 77-86-1). - Preserved with 0.01% thimerosal [C9H9HgNaO2S], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution &lt; 0.05%).</td>
</tr>
<tr>
<td>R3 Rotavirus Sample Diluent (1X25 mL)</td>
<td>- Buffered saline, pH 7.5, with &lt; 1% Tween 20 surfactant. - &lt; 1% EDTA acid / EDTA (chelating agent) [C10H16N2O8], CAS# 60-00-4 [&lt; 20% dilution not subject to EU labeling according to EU Directives]. - Preserved with 0.01% thimerosal [C9H9HgNaO2S], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution &lt; 0.05%). Clear, colorless liquid.</td>
</tr>
</tbody>
</table>
| R4 Rotavirus Positive Control, 3 mL (1X3 mL) Catalog # 79481 | - Inactivated simian rotavirus (SA-11) in buffered saline, pH 7.5, with < 1% Tween 20 surfactant. - < 1% EDTA acid / EDTA (chelating agent) [C10H16N2O8], CAS# 60-00-4 [< 20% dilution not subject to EU labeling according to EU Directives]. - < 5% animal serum (bovine, murine, rabbit and avian). - Preserved with 0.01% thimerosal [C9H9HgNaO2S], EINECS/ELINCS No: 200-210-4, CAS# 54-64-8; R43-61; S24/25-28-36-53-60-61 (1999/45/EC – dilution < 0.05%). Clear to slightly yellow liquid. Note: Rotavirus SA-11 Positive Control contains inactivated simian rotavirus that has been inactivated via standard accepted methods. However, Universal Precautions and general biosafety procedures should be employed.
**Pathfinder™ Rotavirus ELISA Kit**

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R5</strong></td>
<td><strong>Rotavirus Substrate</strong></td>
</tr>
</tbody>
</table>
| **Buffer**  | - Citrate buffer, pH 4.2, containing < 2% boric acid (H<sub>3</sub>BO<sub>3</sub>, CAS# 11113-50-1).  
- 0.012% hydrogen peroxide [H<sub>2</sub>O<sub>2</sub>], EINECS/ELINCS No: 231-765-0, CAS# 7722-84-1 [(S25-36) ≥ 1% but < 5% dilution not subject to EU labeling according to EU Directives].  
Clear, colorless liquid.                                                                                                        |
| **R6**      | **Rotavirus Chromogen**                                                                                                                                                                                                                                                                                                           |
| **(1X2.5 mL)** | - 0.3% 3,3',5,5’ tetramethylbenzidine (TMB) dissolved in:  
- 0.1N hydrochloric acid [HCl] CAS# 7647-01-0, pH < 2.  
Clear, colorless liquid.                                                                                                        |

*Replacement separately purchased component catalog numbers are provided in this column where available.*

### HAZARDS IDENTIFICATION -- HAZARDOUS COMPONENTS (3):

The following information is furnished for those kit hazardous constituents that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data from the chemical raw material (LD50, exposure limits, etc.). The kit contains a significantly diluted concentration in an aqueous solution; thus, the assessment below has taken hazard reduction processing into consideration when possible. The EU classification was made according to the latest editions of the EU lists and expanded upon from company and literature data.

<table>
<thead>
<tr>
<th>Chemical Ingredient</th>
<th>Chemical Data / Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thimerosal [0.01% Merthiolate Sodium, C&lt;sub&gt;6&lt;/sub&gt;H&lt;sub&gt;4&lt;/sub&gt;HgNaO&lt;sub&gt;2&lt;/sub&gt;S in R2, R3, R4]</td>
<td>CAS# 54-64-8 (thimerosal powder, 100%) + EINECS/ELINCS No: 200-210-4 (100%) + RTECS# OV8400000 (100%) + IATA/DOT ID: UN2025 (100%) + LD50 (oral-rat): 75 mg/kg (100%) + LC50: NE PEL/TLV: 0.01 mg Hg/m&lt;sup&gt;3&lt;/sup&gt; TWA (skin) (100%) + CA Proposition 65: Chemical known to the State of California to cause reproductive toxicity ++ HMIS Codes: H=2, F=0, R=0 ++ IATA/DOT ID: UN2025 (100%) + EU Classification: Dilution below 1999/45/EC labeling requirement (&lt; 0.05%); R43-61; S24/25-36-53-60-61 ++</td>
</tr>
<tr>
<td>0.1N Hydrochloric Acid [-0.8% v/v HCl in R6]</td>
<td>CAS#: 7647-01-0 (100%) + RTECS#: MW4025000 (100%) + LD50 (oral-rat): NE TLV and PEL: 5 ppm (ceiling) (100%) + RCRA Code: D002 (if not neutralized) ++ IATA/DOT ID: UN1789 (100%) + HMIS Codes: H=1, F=0, R=1 ++ EINECS/ELINCS No: 231-595-7 (100%) + EU Classification: None (due to dilution, &lt; 1%); S 24/25-35-36 ++</td>
</tr>
</tbody>
</table>

Thimerosal (merthiolate sodium) is an organo-mercury biocidal preservative which may be detrimental if enough is ingested, targets the central nervous system (CNS) and is a significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals. There are ample cases of sensitization resulting from exposure to dilute thimerosal solutions. The chemical, physical and toxicological properties have not been thoroughly investigated. Thimerosal, classified under the generic class of mercury compounds, is known to the State of California to cause developmental toxicity. Avoid exposure. After contact with skin, wash immediately with plenty of water. Mercury compounds are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects. Avoid release to the environment. Spent mercury-containing solutions with a concentration greater than 0.2 ppm are considered RCRA hazardous waste (D009). This material and its container must be disposed of as hazardous waste and in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. (Note: Mercury (Hg) makes up 49.55% of the thimerosal molecule; thus, a component with 0.01% thimerosal contains ~0.005% (50 ppm) mercury w/v).

Dilute ≤ 0.1N hydrochloric acid solutions may be detrimental if swallowed and by contact, particularly to eyes. Keep away from strong bases and reducing agents. Wastes can typically be neutralized to pH 6-8 for disposal; however, always dispose of dilute acidic solutions in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices.
<table>
<thead>
<tr>
<th>Chemical Ingredient</th>
<th>Chemical Data / Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,3',5,5'-Tetramethyl-benzidine [0.3% TMB, C_{16}H_{20}N_{2} in R6]</td>
<td>CAS#: 64285-73-0 (TMB dihydrochloride, 100%) + CAS#: 54827-17-7 (TMB Free Base, 100%) + RTECS#: DV2300000 (100%) + Flash Point: NE LD50 (ipr-mouse): 135 mg/kg (100%) + LC50: NE TLY and PEL: NE RCRA Code: NE HMIS Codes: H=1, F=0, R=0 ++ IATA/DOT ID: NE EINECS/ELINCS No: 264-769-6 (TMB dihydrochloride, 100%), 259-364-6 (TMB Base, 100%) + EU Classification: None (due to dilution, &lt; 20%); S36 ++ The chemical, physical and toxicological properties have not been thoroughly investigated. TMB is considered a non-carcinogenic and non-mutagenic analog of benzidine suitable as an EIA chromogen for peroxidase. The raw material supplier indicates that it may cause slight irritation by all routes of entry, but this potential is unlikely if handled with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.</td>
</tr>
<tr>
<td>Animal Sera [&lt; 5% in R2, R4]</td>
<td>This material is of animal origin (bovine, murine, rabbit and avian) and may be a potential contact irritant. Hazard Unknown. Handle as potentially infectious. The chemical, physical and toxicological properties have not been thoroughly investigated. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions. Dispose of this material in accordance with local, regional and national regulations.</td>
</tr>
<tr>
<td>Rotavirus Positive Control [R4]</td>
<td>The rotavirus SA-11; the Positive Control contains inactivated simian rotavirus that has been inactivated via standard accepted methods. However, Universal Precautions should be followed when handling this biological. Handle as if capable of transmitting infectious disease, in a Biosafety Level 2 lab, applying the guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories. Employ aseptic technique for personal protection and to avoid product contamination; use of a Biosafety Cabinet (BSC) may be warranted or desired in certain situations. Avoid splashing, spills and the generation of aerosols. Secure in secondary containment with proper biohazard labeling. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ decontamination procedures with appropriate decon agent or disinfectant (typically a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor like 0.5% Wescodyne Plus (EPA Reg. #4959-16), an o-phenylphenol/amyphenol such as 0.8% Vesphene (EPA Reg. #1043-87) or equiv.) before discarding any materials utilized or returning equipment used to general use. Dispose of this material in accordance with local, regional and national regulations. Handle appropriately with the requisite Good Laboratory Practices and Universal Precautions.</td>
</tr>
</tbody>
</table>

+ The Kit Concentration was not tested; the values refer to the solution concentration as tested, designated by percentage within parentheses.  
++ The Kit Concentration was tested or the values given were estimated for the general diagnostic laboratory usage of the kit reagent dilution.  
NE: Not Established or Unknown (unable to locate data).  
Abbreviations for component HMIS hazard ratings are as follows: H=Health, F=Flammability, R=Reactivity

**General Kit Composite Health Hazards:**

- No significant adverse health effects are expected by any route for the following chemical constituents in the kit volumes and concentrations present [dilution not subject to EU Directive labeling]:

<table>
<thead>
<tr>
<th>Chemical Constituent Details</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2% <strong>Tris</strong> hydroxymethyl aminomethane buffer solution (acid/base): 2-amino-2-(hydroxy-methyl)-1, 3-propanediol [C₆H₁₁NO₃ • HCl], EINECS/ELINCS No 214-684-5, CAS# 1185-53-1, and/or TRIZMA Base 2-Amino-2-(hydroxymethyl)-3,1-propanediol, [C₆H₁₁NO₃], EINECS/ELINCS No: 201-064-4, CAS# 77-86-1, 25149-07-9; 108195-86-4. [&lt; 20% dilution not subject to EU labeling according to EU Directives].</td>
<td>R2</td>
</tr>
<tr>
<td>&lt; 2% boric acid [H₃BO₃], CAS# 11113-50-1</td>
<td>R2, R5</td>
</tr>
<tr>
<td>&lt; 1% <strong>EDTA</strong> acid / EDTA (chelating agent) [C₆H₁₂N₂O₄], CAS# 60-00-4 [&lt; 20% dilution not subject to EU labeling according to EU Directives].</td>
<td>R3, R4</td>
</tr>
<tr>
<td>&lt; 1% <strong>TWEEN® 20</strong> [C₁₅H₂₁₁O₂₅], EINECS/ELINCS No: 585-580-06-X, CAS #9005-64-5</td>
<td>R3, R4</td>
</tr>
<tr>
<td>0.012% hydrogen peroxide [H₂O₂], EINECS/ELINCS No: 231-765-0, CAS# 7722-84-1 [{(S₂5-36) ≥ 1% but &lt; 5% dilution not subject to EU labeling according to EU Directives].</td>
<td>R5</td>
</tr>
</tbody>
</table>
No significant adverse health effects are expected by any route for the miscellaneous salts, buffers, protein-stabilizers, antibodies, conjugates, water, catalytic or other non-reactive ingredients, in the kit volumes and/or concentrations present.

According to the concept of Universal Precautions (29 CFR 1910.1030), all human blood and certain human body fluids must be treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. No known test method can offer complete assurance that products derived from human blood will not transmit infection; thus, they should be handled as though they contain infectious agents. Furthermore, individual patient samples being tested represent a heightened, unknown hazard. Aerosolization/inhalation, contact and mucous membrane exposure should be avoided during sample and kit handling. Consider equipment that potentially comes in contact with human source material as contaminated until appropriately decontaminated.

<table>
<thead>
<tr>
<th>EMERGENCY FIRST AID MEASURES (4):</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health Effects:</strong> Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis. May cause allergic skin reaction upon repeated exposure. May be toxic to developing fetus, generally at concentrations and volumes that greatly exceed that of this kit.</td>
</tr>
<tr>
<td><strong>Eye Contact:</strong> Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.</td>
</tr>
<tr>
<td><strong>Skin Contact:</strong> Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.</td>
</tr>
<tr>
<td><strong>Inhalation:</strong> Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.</td>
</tr>
<tr>
<td><strong>If Swallowed:</strong> If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.</td>
</tr>
<tr>
<td><strong>Notes to Physician</strong></td>
</tr>
<tr>
<td>According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), Universal Precautions apply. Persons handling human blood source samples should be offered hepatitis B vaccination prior to working with human source material.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FIREFIGHTING MEASURES (5):</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Extinguishing Media:</strong> Use extinguishing media appropriate for the surrounding fire.</td>
</tr>
<tr>
<td><strong>Special Firefighting Procedures:</strong> Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ACCIDENTAL RELEASE MEASURES (6):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.</td>
</tr>
<tr>
<td>In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.</td>
</tr>
<tr>
<td>Follow established laboratory policy and applicable CDC/NIH biosafety and/or OSHA/WISHA hazardous material spill guidelines for appropriate hazardous chemical and/or biological material spill response and cleanup.</td>
</tr>
</tbody>
</table>
Wear appropriate PPE. Immediately, and on-site if possible:

- Decontaminate **biohazardous** material spills, which should always be treated as potentially infectious, including the area, spill materials and any contaminated surfaces or equipment. Utilize an appropriate chemical decon agent or disinfectant that is effective for the known or potential pathogens relative to the samples involved (commonly a 1:10 dilution of bleach, 70-80% ethanol or isopropanol, an iodophor (such as Wescodyne Plus) or a phenolic, etc.).
- Neutralize **acidic** spills with the appropriate Acid adsorbent product.
- Absorb **thimerosal**-containing reagents; handle and dispose of as RCRA hazardous waste.

Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, acid absorbent pads, etc.), which are secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all local, regional and national regulations.

### HANDLING AND STORAGE INFORMATION (7):

**Handling:** This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Follow proper good laboratory practices and safety guidelines for handling chemical, biological and laboratory hazards. Wear appropriate personal protective equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per Universal Precautions. Refer to Section 8 for more specifics. Consult with your Environmental Health and Safety Office for assistance.

**Storage:** Store according to product and label instructions (generally at 2-8°C).

Read and follow all the precautions and warnings in the kit product instructions.

### EXPOSURE CONTROL / PERSONAL PROTECTION MEASURES (8):

The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes, and to prevent hazard inhalation, under normal conditions of use and for the time during which the protective equipment is utilized.

**Ventilation:** Adequate lab ventilation is required. It is recommended that users handle potentially infectious human source material/patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.

**Eye Protection:** Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.

**Protective Gloves:** Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves such as nitrile, neoprene and vinyl are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.

**Protective Clothing:** Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.

**Other:** All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. Protective coverings such as plastic wrap, aluminum foil or imperviously backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.

**Note:** Exposure limit values and health hazard data were given in Section 3. Environmental controls are included in the following sections.
PHYSICAL AND CHEMICAL PROPERTIES (9):

Appearance: Variable, refer to Section 2.

Fire Hazard: Although the components have not been tested for fire hazard and explosion data, being water-based, they are not expected to be fire hazards, but some of the kit packaging materials may burn under fire conditions.

Flash Point: Not applicable.

Auto Igniting: Product is not known to be self-igniting.

Danger of Explosion: Product is not known to present an explosion hazard.

Boiling Point: Not established.

Melting Point: Not established.

Solubility: The liquid chemical components are soluble in water. The acidic solutions may release heat.

pH: Most of the liquid chemical components are between pH 6 and 8; exceptions are the following solutions:

- **Substrate Buffer** at pH~4.
- **Chromogen** at pH ~1.5.

Specific Gravity: Approximately 1

No other standard characteristics applicable to the identification or hazards of the kit are known.

STABILITY AND REACTIVITY INFORMATION (10):

Stability: Stable under ordinary conditions of use and storage.

Conditions and/or Materials to Avoid: Do not allow the acidic solutions to come in contact with strong bases.

Hazardous Decomposition Products: May release toxic oxides of carbon, nitrogen or mercury.

Hazardous Polymerization: Has not been reported to occur.

TOXICOLOGICAL INFORMATION -- GENERAL COMPOSITE (11):

Refer to Section 3 for the kit component concentrations. The composite toxicological information for this product is:

**Acute Health Effects**

Toxicity: May be harmful in contact with skin and if enough is swallowed (generally quantities above those found in the kit).

Primary Irritant Effect: May slightly irritate eyes or skin, depending on amount and contact time.

Other Acute Health Effects: Targets the Central Nervous System (CNS).

**Biohazard Potential:**

**Rotavirus** SA-11 Positive Control contains inactivated simian rotavirus that has been inactivated via standard accepted methods and is not considered infectious. Patient blood samples tested with this kit represent an unknown, heightened hazard. Employ Universal Precautions; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease, in a Biosafety Level 2 laboratory, applying the guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories or equivalent. Persons handling blood samples should have the option of receiving hepatitis B vaccination.
Chronic Toxicity

Sensitization: **Thimerosal** is a significant sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals.

Carcinogenicity: No carcinogenic effect known. No component, mixture or constituent has been classified as a carcinogen by NTP, IARC or OSHA.

Reproductive Hazard: **Thimerosal** (merthiolate sodium), an organo-mercury biocidal preservative mercury compound, is known to the State of California to cause developmental toxicity.

Additional Toxicological Information:

Mercury compounds, such as **thimerosal** (merthiolate sodium), an organo-mercury biocidal preservative, are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities. Danger of cumulative effects; avoid release to the environment.

To the best of our knowledge the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

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**ECOLOGICAL INFORMATION (12):**

The ecological information for the dilute organo-mercury preservative, **thimerosal** has not been thoroughly investigated; however, mercury and its compounds are expected to significantly bioaccumulate. United States regulation considers mercury hazardous to the environment to 0.2 ppm mercury (0.01% thimerosal contains ~50 ppm mercury, which makes up ~50% of the molecule); at or above this level, any waste must be handled as dangerous waste.

Components R5 (pH 4) and R6 (pH < 2) are hazardous for drinking water and toxic to aquatic organisms by pH modification if not neutralized.

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**DISPOSAL CONSIDERATIONS (13):**

Disposal of hazardous and/or laboratory wastes, product or packaging must be conducted in accordance with all applicable local, regional and national regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact your Environmental Health and Safety Office for your specific disposal procedures.

**Recommended Product Disposal:**

Waste containing **thimerosal**, an organo-mercury compound, is a regulated hazardous waste if the final concentration is $\geq 0.2$ mg/L (0.2 ppm). The components in this kit that contain 0.01% thimerosal equates to 0.005% = 50 mg/L (50 ppm) mercury w/v. If the thimerosal-containing waste has a final concentration that is $\geq 0.2$ mg/L (0.2 ppm) mercury, it requires disposal as a toxic environmental pollutant material in an RCRA approved waste facility (or equivalent); the US RCRA Waste Disposal Code for this waste is D009; check your national, regional and local ordinances accordingly.

All human source and other potentially infectious material must be appropriately decontaminated or disposed of as infectious material; check your national, regional and local ordinances accordingly. Note that the thimerosal preserved Negative and Positive Controls must be decontaminated prior to hazardous chemical waste disposal.

Dilute acidic waste **substrate buffer** pH ~4 may need to be neutralized to pH 6-8 for safe sewer disposal in many areas; check your local and regional ordinances accordingly.

Acidic waste **chromogen** pH $< 2$ should be neutralized to pH 6-9 for safe sewer disposal; check your local and regional ordinances accordingly. In addition, if the final pH measures $\leq 2$, it requires disposal as a corrosive material in an RCRA approved waste facility (or equivalent). The US RCRA Waste disposal Code for this waste, if not neutralized, is D002; check your national and regional ordinances accordingly.

**Recommended Unclean Packaging Disposal:** Dispose of in accordance with all applicable local, regional and national regulations.
TRANSPORT INFORMATION (14):

Shipping and disposal of product and packaging waste must be conducted in accordance with all applicable local, regional and national regulations. Processing, use or contamination of the kit components may change shipping requirements and options. Contact your Environmental Health and Safety Office for your specific shipping procedures.

**Recommended Unused Product Multi-Modal Transportation:** No known transport restrictions. Hazardous substance, non-dangerous goods.

**Recommended Used Product Hazardous Waste Disposal Transportation:** Potential air and land transportation information for discarded kit components and waste from this product when used as intended is:

Components **R2, R3, R4** in this kit contains approximately 0.005 % = 50 mg/L = 50 ppm mercury (w/v) from the 0.01% thimerosal preservative. Therefore, any discarded kit components and waste generated from their use which result in a final concentration that is greater than or equal to 0.2 mg/L (0.2 ppm) must be transported as follows:

- **Proper Shipping Name:** Hazardous Waste Liquid n.o.s.
- **DOT Class:** 9
- **Packing group:** III
- **DOT ID Number:** UN 3082

Acidic component **R6** in this kit contains 0.1N hydrochloric acid [HCl], pH < 2; thus, any unneutralized discarded kit component or waste generated from its use resulting in a corrosive liquid (pH ≤ 2 per Method 9040 (USEPA Publication SW-846) or Corrodes Steel (NACE Standard TM-01-69)) must be transported as follows:

- **Proper Shipping Name:** Corrosive Liquid n.o.s.
- **DOT Class:** 8
- **Packing group:** III
- **DOT ID Number:** UN 1760

REGULATORY INFORMATION (15):

<table>
<thead>
<tr>
<th>Composite HMIS Rating:</th>
<th>Health: 2</th>
<th>Flammability: 0</th>
<th>Reactivity: 1</th>
</tr>
</thead>
</table>

California Proposition 65: **WARNING:** THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE REPRODUCTIVE TOXICITY.

Chemicals known to cause reproductive toxicity: Thimerosal (merthiolate sodium), CAS# 54-64-8; classified under the generic class of mercury compounds.

Carcinogenicity Categories: No component, mixture or constituent has been classified as a carcinogen by NTP (National Toxicity Program), IARC (International Agency for Research on Cancer), TLV-CAR (Threshold Limit Value established by ACGIH) or OSHA.

WHMIS Classification: This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.

Markings according to European guidelines: The dilution of chemicals in this product is not subject to EU hazard designation according to EU lists, directives and other sources of literature known to us. However, mercury compounds are considered reproductive toxicants and environmental pollutants by many government agencies at certain concentrations/quantities, so the following hazard precautions and guidelines should be applied.

**Hazard of Concern:** 0.01% Thimerosal (< 0.05%), EINECS/ELINCS No: 200-210-4, CAS# 54-64-8 [R43-61; S24/25-28-36-53-60-61]
Pathfinder™ Rotavirus ELISA Kit

Risk Phrases:
R 43 May cause sensitisation by skin contact.
R 61 May cause harm to unborn child. (Designation is for concentrated thimerosal (mercury compounds), which is diluted to 0.01% in kit components.

Caution Contains inactivated pathogen. Handle as if capable of transmitting potentially infectious agents (Universal Precautions).

Safety Phrases:
S 24/25 Avoid contact with skin and eyes.
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 53 Avoid exposure – obtain special instructions before use.
S 60 This material and its container must be disposed of as hazardous waste.
S 61 Avoid release to the environment. Refer to special instructions/safety data sheet.

OTHER INFORMATION (16):

This test kit should be handled only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

This revision: Reformatted and updated existing information.

Contact for general information: Bio-Rad Laboratories, Redmond Operations
Environmental Health & Safety
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