1. Information on the Substance/Preparation and Company

1.1 Catalog # Product name
   03-05000 Clostridium difficile Toxin, Reagents for Cytotoxicity Assay

   Kit components
   03-05130 Toxin Control
   03-05300 Antitoxin Reagent
   03-05050 Specimen Diluent

1.2 Company
   Diagnostic HYBRIDS, Inc.
   1055 East State Street, Suite 100
   Athens, OH 45701, USA
   (740) 589-3300 or (866) 344-3477

1.3 In emergencies
   Call your local emergency center

2. Components and Hazardous Ingredients

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>Hazardous Ingredients</th>
<th>Classification Substance*</th>
<th>EINECS Nr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxin Control</td>
<td>2% FBS (Fetal Bovine Serum)</td>
<td>(none listed)</td>
<td>(unlisted)</td>
</tr>
<tr>
<td>Antitoxin Reagent</td>
<td>Clostridium difficile toxin</td>
<td>T+, R:26/27/28, 36/37/38</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gentamicin Sulfate</td>
<td>Xn, R:42/43, 36, 61, S:23, 36/37, 45</td>
<td>215-778-9</td>
</tr>
<tr>
<td></td>
<td>Streptomycin Sulfate</td>
<td>Xi, R:20/21/22, 52, 63, S:22, 36/37/39, 45</td>
<td>223-286-0</td>
</tr>
<tr>
<td></td>
<td>HEPES</td>
<td>Xi, R:36/37/38, S:26, 36</td>
<td>230-907-9</td>
</tr>
<tr>
<td></td>
<td>[Proprietary ingredients]</td>
<td>[Not applicable]</td>
<td>[Not applicable]</td>
</tr>
<tr>
<td>Specimen Diluent</td>
<td>Amphotericin B</td>
<td>Xi, R:38, 41 S:2, 22, 26, 36</td>
<td>215-742-2</td>
</tr>
<tr>
<td></td>
<td>Gentamicin Sulfate</td>
<td>Xn, R:42/43, 36, 61, S:23, 36/37, 45</td>
<td>215-778-9</td>
</tr>
<tr>
<td></td>
<td>[Proprietary ingredients]</td>
<td>[Not applicable]</td>
<td>[Not applicable]</td>
</tr>
</tbody>
</table>

Classification key: Toxic (T); Very toxic (T+); Harmful (Xn); Irritant (Xi); Dangerous for the environment (N); Oxidizing agent (O); Explosive (E); Flammable (F)
Proprietary ingredients: Contains non-hazardous quantities of proprietary ingredients [OSHA Regulations (Standards-29CFR) Hazard Communication-1910.1200(i)(1)]

3. Hazards Identification

- L-Glutamine may cause allergic skin and/or respiratory reaction. Irritating to eyes, respiratory system, and skin.
- Gentamicin may cause harm to the unborn child. May cause sensitization by inhalation and skin contact. Irritating to eyes.
- Streptomycin is very hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.
- Amphotericin B is hazardous with severe and potentially lethal side effects. May cause sensitization by inhalation and skin contact. Irritating to eyes.
- FBS may cause eye and skin irritation. May be harmful if inhaled and may be irritating to mucous membranes and upper respiratory tract. May be harmful if swallowed.
- Contains non-hazardous quantities of proprietary ingredients [OSHA Regulations (Standards-29CFR) Hazard Communication-1910.1200(i)(1)].

3. First Aid Measures

   **Eye contact:**
   - Rinse immediately with water for 15 minutes, occasionally lifting the upper and lower eyelids
   - Consult a doctor/medical service

   **Skin contact:**
   - Rinse with plenty of water
   - Remove clothing before washing
Consult a doctor/medical service

After inhalation:
- Remove the victim into fresh air
- Consult a doctor/medical service

After ingestion:
- Consult a doctor/medical service

5. Fire Fighting Measures

**Suitable extinguishing media:**
- All non combustible extinguishing media allowed

**Unsuitable extinguishing media:**
- No data available

**Special exposure hazards:**
- No data available

**Instructions:**
- Take account of contaminated fire fighting water
- Use fire fighting water moderately and contain it

**Special protective equipment for firefighters:**
- No data available

6. Accidental Release Measures

**Personal protection:**
- See 8.2, below

**Environmental precautions:**
- Discharge according to local regulations

**Clean-up:**
- Take up liquid spill into absorbent material
- Discharge absorbed material according to local regulations
- Wash clothing and equipment after handling

7. Handling and Storage

**Handling:**
- If solution is spilled: take up with an absorbent material; if contact is possible, wear gloves as protection.
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

**Storage:**
- Keep away from: heat sources
- 2°C to 8°C

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

<table>
<thead>
<tr>
<th>Chemical/Component</th>
<th>TLV/NIOSH REL</th>
<th>OSHA PEL</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutamine</td>
<td>Not determined</td>
<td>Not listed</td>
<td>56-85-9</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>Not determined</td>
<td>Not listed</td>
<td>1405-41-0</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>Not determined</td>
<td>Not listed</td>
<td>57-92-1</td>
</tr>
<tr>
<td>Amphotericin B</td>
<td>Not determined</td>
<td>Not listed</td>
<td>1397-89-3</td>
</tr>
<tr>
<td>HEPES</td>
<td>Not determined</td>
<td>Not listed</td>
<td>7365-45-9</td>
</tr>
<tr>
<td>Fetal Bovine Serum</td>
<td>Not determined</td>
<td>Not listed</td>
<td>Not available</td>
</tr>
</tbody>
</table>

*Note: Information in above table from NIOSH Pocket Guide to Chemical Hazards, 2005.*

8.2 Control of Exposure

**Eye protection:**
- Safety glasses or Face shield

**Hand protection:**
- Gloves should be waterproof
- Suitable materials: Butyl rubber, natural rubber, neoprene, nitrile rubber, polyethylene, PVC
- Hands should be washed after working with this product

**Skin protection:**
- Protective clothing

**Respiratory protection:**
- Area ventilation is generally adequate; avoid generation of dusts, mists or other airborne forms when working with the product
- Insufficient ventilation: wear respiratory protection
9. Physical and Chemical Properties

| Product Name: Clostridium difficile Toxin, Reagents for Cytotoxicity Assay |

- **Clear, aqueous liquid; cherry-peach to light red in color; odorless.**
- **Note:** Boiling and Freezing Points for all aqueous components are near those of pure water.

10. Stability and Reactivity

- **Stability:** Hazardous polymerization will not occur. Stable if stored in specified conditions (see label).
- **Reactivity/Hazardous decomposition products:** No hazardous decomposition products are formed in high quantities.
- **Conditions/Materials to avoid:** Strong oxidizing agents.

11. Toxicological Information

**Acute toxicity:**

<table>
<thead>
<tr>
<th>Product/Compound</th>
<th>Route</th>
<th>LD₅₀ (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clostridium difficile Toxin</strong></td>
<td>IV, mouse</td>
<td>&gt;200 mg/kg</td>
</tr>
<tr>
<td>L-Glutamine</td>
<td>Oral, rat</td>
<td>7500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral, mouse</td>
<td>21,700 mg/kg</td>
</tr>
<tr>
<td><strong>Streptomycin</strong></td>
<td>Oral, rat</td>
<td>430 mg/kg</td>
</tr>
<tr>
<td></td>
<td>IP, rat</td>
<td>1,219 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral, mouse</td>
<td>430 mg/kg</td>
</tr>
<tr>
<td><strong>Amphotericin B</strong></td>
<td>Oral, rat</td>
<td>&gt;5000 mg/kg</td>
</tr>
<tr>
<td><strong>Gentamicin</strong></td>
<td>Oral, rat</td>
<td>&gt;5000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>IV, rat</td>
<td>96 mg/kg</td>
</tr>
<tr>
<td></td>
<td>IP, rat</td>
<td>630 mg/kg</td>
</tr>
</tbody>
</table>

**Chronic toxicity:**

<table>
<thead>
<tr>
<th>Product/Compound</th>
<th>Target Organ(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clostridium difficile Toxin</strong></td>
<td>gastrointestinal tract</td>
</tr>
<tr>
<td>L-Glutamine</td>
<td>None identified</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>Skin, eyes, kidneys, ears</td>
</tr>
<tr>
<td>Amphotericin B</td>
<td>Kidneys</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>Kidney, central nervous system, ears</td>
</tr>
</tbody>
</table>

**Routes of exposure:**

- Ingestion, inhalation, eyes and skin
- Caution! Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals. Causes photosensitivity. Exposure to light can result in allergic reactions resulting in dermatologic lesions, which can vary from sunburn-like response to edematous, vesiculated lesions or bullae.

**Acute effects/symptoms:**

- **Streptomycin:** May cause skin, eye, and mucous membranes and upper respiratory tract irritation. May be harmful if swallowed.
- **Amphotericin B:** Well to have severe and potentially lethal side effects consisting of high fever, shaking chills, hypotension, anorexia, nausea, vomiting, headache, dyspnea, and tachypnea.
- **Gentamicin:** May cause skin, eye, and mucous membranes and upper respiratory tract irritation. May be harmful if swallowed.

**Chronic effects:**

- **Streptomycin:** Aminoglycosides are associated with significant nephrotoxicity and/or ototoxicity. The chemical, physical, and toxicological properties have not been thoroughly investigated.
- **Amphotericin B:** Multiple organ damage associated therapeutic doses with significant nephrotoxicity and/or hepatotoxicity. Several forms of anemia and other blood dyscrasias have been reported.
- **Gentamicin:** Aminoglycosides are associated with significant nephrotoxicity and/or ototoxicity. The chemical, physical, and toxicological properties have not been thoroughly investigated.
12. Ecological Information

Aquatic toxicity:

Streptomycin:
- LC₅₀ (96 h): >180 mg/L (Oncorhynchus mykiss; rainbow trout)
- LD₅₀ (48 h): 650 mg/L (Daphnia magna; water flea)
  Toxic to daphnia ad other aquatic invertebrates

Other Information:
- Effect on the ozone layer: Not dangerous for the ozone layer (1999/45/EC)
- Greenhouse effect: No data available
- Effect on waste water purification: No data available

13. Waste Disposal Considerations

Provisions relating to waste: Hazardous waste (91/689/EEC)

Packaging/container:

Disposal methods:
- All the kit components must be considered as hazardous waste; dispose following local regulations.

14. Transport Information

USA: No restrictions.
Canada: No restrictions
EU: No restrictions

15. Regulatory Information

Classification according to directives 67/548/EEC and 1999/45/EC

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Toxin Control, Antitoxin Reagent, Specimen Diluent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xn – harmful</td>
<td>Very toxic by inhalation, in contact with skin and if swallowed.</td>
</tr>
<tr>
<td>Xi – irritant</td>
<td>Irritating to eyes, respiratory system and skin.</td>
</tr>
<tr>
<td>R41:</td>
<td>Risk of serious damage to eyes</td>
</tr>
<tr>
<td>R42/43:</td>
<td>May cause sensitization by inhalation and skin contact</td>
</tr>
<tr>
<td>R52:</td>
<td>Harmful to aquatic organisms</td>
</tr>
<tr>
<td>R61/63:</td>
<td>May cause harm to the unborn child</td>
</tr>
<tr>
<td>S22/23:</td>
<td>Do not breathe dust or aerosols</td>
</tr>
<tr>
<td>S26:</td>
<td>In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.</td>
</tr>
<tr>
<td>S36/37/39:</td>
<td>Wear suitable protective clothing, gloves and eye/face protection.</td>
</tr>
<tr>
<td>S45:</td>
<td>In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</td>
</tr>
</tbody>
</table>

16. Other Information

- This product is designed for use by professionals.
- Based on: US 29 CFR 1910:1200(g); Canadian Hazardous Product Act, Part II; Directive 911155/EEC et seq.
- The above information is believed to be accurate and represents the information available to date, but Diagnostic Hybrids does not purport it to be all-inclusive; this should be used only as a guide.
- Refer to the Product Insert for this Product for additional details on the proper storage, handling, use, and disposal of the reagents included in this Product.
- Contact Diagnostic Hybrids, Inc. if additional information is required.

[End of Document]