



## I. Identification

<b>Trade Name (as labelled)</b>	BD GeneOhm™ Cdiff
<b>Product use</b>	BD GeneOhm™ Cdiff assay is a rapid <i>in vitro</i> diagnostic test for the direct, qualitative detection of <i>Clostridium difficile</i> Toxin B gene ( <i>tcdB</i> )
<b>Supplier/manufacturer's name</b>	BD Diagnostics
<b>ADDRESS:</b>	2050 boul. René-Lévesque O., 4 <sup>e</sup> étage, Ste-Foy, Québec, Canada G1V 2K8
<b>Customer Service:</b>	(888) GeneOhm (888-436-3646)
<b>Web Site:</b>	<a href="http://www.bd.com/geneohm/english/">http://www.bd.com/geneohm/english/</a>

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## II. Composition and information on ingredients

This Material Safety Data Sheet (MSDS) describes the composition of the BD GeneOhm™ Cdiff assay. This assay is designed for rapid amplification and detection of *C. difficile* Toxin B gene (*tcdB*) in human faecal specimens from patients suspected of having *C. difficile*-associated disease (CDAD). It consists of the 5 following tubes:

TUBE NAME	IDENTIFICATION IN THIS DOCUMENT
Sample buffer	tube A
Lysis Tube	tube B
Master Mix	tube C
Diluent	tube D
Control DNA	tube H

This MSDS provides complete information on all the components described in the following tables. Unless otherwise specified, the information in each of the following sections (sections III to XVI) of this document is pertinent to each reagent.

Tube ID	Chemical name	CAS #	% v/v or w/w	Exposure limits in air					
				ACGIH		OSHA			Other
				TLV mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	PEL mg/m <sup>3</sup>	STEL mg/m <sup>3</sup>	IDLH mg/m <sup>3</sup>	mg/m <sup>3</sup>
A, D, H	Tris(hydroxymethyl) amino-methane (Tris)	77-86-1	0.1	NE	NE	NE	NE	NE	NE
A, H	Ethylenediamine-tetraacetic acid (EDTA)	60-00-4	0.005	NE	NE	NE	NE	NE	10 mg/m <sup>3</sup> (TWA)
B	glass beads acid washed	N/Ap	84.6	NE	NE	*15mg/m <sup>3</sup> **5mg/m <sup>3</sup>	NE	NE	NE
C	DNA polymerase complex	9012-90-2	< 0.01	10mg/m <sup>3</sup>	NE	NE	NE	NE	NE
C	Bovine serum albumin (BSA)	None	< 0.04	NE	NE	NE	NE	NE	NE
C, H	D-Trehalose Dihydrate	18835-2	9.3	NE	NE	no	no	no	NE
C, D	Magnesium Chloride Hexahydrate (MgCl <sub>2</sub> •6H <sub>2</sub> O)	7791-18-6	0.05	NE	NE	NE	NE	NE	NE
C	Internal control Non infectious DNA	None	< 0.01	NE	NE	NE	NE	NE	NE
D	Ammonium Sulfate	7783-20-2	0.07	NE	NE	NE	NE	NE	NE
D	Potassium Chloride (KCl)	7447-40-7	0.09	NE	NE	NE	NE	NE	NE
H	<i>Clostridium difficile</i> ATCC 43255 genomic DNA	None	< 0.001	NE	NE	NE	NE	NE	NE
C	<i>Escherichia coli</i> ATCC 25922 genomic DNA	None	< 0.001	NE	NE	NE	NE	NE	NE
Water and other constituents: each of the other constituents found is present in concentrations of less than 0.1%			Balance	None of the other constituent in this mixture contributes significantly to the hazards associated with this component. All hazard information pertinent to this product has been provided in this Material Safety Data Sheet, per the Requirements of the U.S. Federal Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent standards, and Canadian Workplace Hazardous Materials Identification System Standard (CPR 4)					

\*Total dust.

\*\* Breathable fraction.

NE = Not established.

N/Ap = Not applicable

See Section XVI for definitions of terms used.

### III. Hazard Identification

#### Symptoms of overexposure by route of exposure

**No adverse health effects** should occur from routine, occupational use of this assay's components in the manner specified by the instructions. Due to the small product size and dilute concentration of the constituents, this product is not anticipated to breed any hazard.

The potential health effects of the **non diluted** components are as followed:

- 1. Injection** - Accidental injection of any of these components, via laceration or puncture by a contaminated object, may cause local reddening, tissue swelling, and discomfort in addition to the wound.

**2. Health effect or risks from exposure****a. Acute effects****Tubes A and H:***EDTA:*

INGESTION: Substance has low toxicity by ingestion. Large amounts may cause gastro-intestinal upset due to osmotic imbalance caused by its ability to sequester metal ions. It may cause gastrointestinal irritation with nausea, vomiting and diarrhea.

INHALATION: Mild irritant. Can cause sore throat and coughing. Dust may cause irritation of the respiratory tract. Can produce delayed pulmonary edema.

EYE CONTACT: Can cause redness, pain, eye irritation. May cause chemical conjunctivitis.

SKIN CONTACT: May cause skin irritation.

**Tubes A, D and H:***Tris:*

INGESTION: Mild alkali. Causes irritation and reddening to the mucous membranes of the mouth, esophagus, and gastrointestinal tract when ingested. Symptoms may include nausea, vomiting and diarrhea. Large oral doses may cause weakness, collapse and coma. Estimated lethal dose: 50 grams.

INHALATION / SKIN & EYE CONTACT: May be harmful by inhalation or absorption through the skin. May cause irritation to eyes, mucous membranes and upper respiratory tract. Symptoms may include irritation, redness, pain, coughing and shortness of breath.

**Tube B:***Glass Beads*

INHALATION: May cause irritation to upper respiratory tract.

**Tube C:***Internal control:*

This product is not known to be hazardous.

*Escherichia coli* ATCC 25922 genomic DNA:

This product is not known to be hazardous.

**Tubes C and H:***D-Trehalose Dihydrate:*

May be harmful by inhalation, ingestion, or skin absorption; may cause irritation.

**Tubes C and D:***MgCl<sub>2</sub>:*

INGESTION/ INHALATION: May cause kidney damage, gastrointestinal irritation (with nausea, vomiting and diarrhea) and respiratory tract irritation. Inhalation of fumes may cause metal-fume fever, which is characterized by flu-like symptoms with metallic taste, fever, chills, cough, weakness, chest pain, muscle pain and increased white blood cell count.

EYE/ SKIN CONTACT: May cause mild eye irritation and skin irritation.

*All other components:* Beyond mild irritation of the skin or eyes, contact with these components does not usually cause acute health effects.

**Tube D:***Ammonium sulfate*

INGESTION/ INHALATION: Not generally considered toxic. Harmful if swallowed, can cause gastrointestinal irritation. Dust inhalation may irritate nose, throat and lungs.

EYE OR SKIN CONTACT: Dust may cause eye irritation and prolonged contact may cause skin irritation.

Avoid contact with eyes, skin and clothing. Avoid breathing dust. Keep in tightly closed container. Use adequate ventilation. Wash thoroughly after handling.

*KCl:*

INGESTION/ INHALATION: May be harmful if swallowed or inhaled. Material may be irritating to mucous membranes and upper respiratory tract. Ingestion of large quantities can cause weakness, gastrointestinal irritation and circulatory disturbances.

EYE OR SKIN CONTACT: may cause skin irritation and eye irritation.

**Tube H:**

*Clostridium difficile* ATCC 43255 genomic DNA:  
This product is not known to be hazardous.

**b. Chronic effects**

**Tubes A, D and H:**

*Tris:*  
Chronic dermatitis may follow skin contact.

*EDTA:*  
This component is not known to cause any significant chronic health effects.



**Tubes B and C:**

These components are not known to cause any significant chronic health effects.

**Tube D:**

*Ammonium sulfate*  
Organs affected by long-term exposure: respiratory system and lungs.

**Hazard identification for Tubes A, B, C, D and H of the BD GeneOhm™ Cdiff assay**

HAZARDOUS MATERIAL INFORMATION SYSTEM			
<b>HEALTH</b>		(BLUE)	<b>0</b>
<b>FLAMMABILITY</b>		(RED)	<b>0</b>
<b>REACTIVITY</b>		(YELLOW)	<b>0</b>
<b>PROTECTIVE EQUIPMENT</b>		<b>B</b>	
<b>Eyes</b> Goggles 	<b>Respiratory</b> See Section VIII	<b>Hands</b> Protective gloves 	<b>Body</b> See section VIII
For routine industrial applications			

## IV. First Aid Measures

### **Tubes A and H:**

#### *Tris:*

INGESTION: Consult a physician. Never give anything by mouth to an unconscious person.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

EYE CONTACT: Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Consult a physician.

SKIN CONTACT: Wash with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes and wash before wearing. Consult a physician.

#### *EDTA:*

INGESTION: If conscious, immediately rinse mouth with water and give water to drink. DO NOT induce vomiting. If large amounts were swallowed, seek immediate medical assistance. Do not give liquids to an unconscious person.

INHALATION: Remove victim from exposure- avoid becoming a casualty. Remove contaminated clothing and loosen remaining clothing. Allow patient to assume most comfortable position and keep warm. Keep at rest until fully recovered. If breathing labored ensure airways are clear and administer oxygen. If breathing has stopped, apply artificial respiration at once. Seek immediate medical assistance.

EYE CONTACT: Immediately irrigate with copious quantities of water for at least 15 minutes. Eyelids must be held open. Seek medical assistance.

SKIN CONTACT: Remove contaminated clothing. Wash affected area with large amounts of soap and water. If irritation develops seek immediate medical assistance.

### **Tube B:**

#### *Glass beads:*

INGESTION: Rinse the mouth with fresh water provided the person is conscious. Contact a physician.

Wash contaminated clothing before use.

INHALATION: Remove to fresh air. Give oxygen if breathing becomes difficult. If not breathing, give artificial respiration. Contact a physician.

EYE CONTACT: Immediately irrigate with copious quantities of water for at least 15 minutes. Eyelids must be held open. Seek medical assistance.

### **Tube C:**

#### *DNA polymerase complex:*

INGESTION: Immediately call a doctor.

INHALATION: Supply fresh air; consult doctor in case of complaints.

SKIN CONTACT: Immediately wash with water and soap and rinse thoroughly.

EYE CONTACT: Rinse opened eye for several minutes under running water then consult a doctor.

#### *BSA:*

INGESTION: Rinse the mouth with fresh water provided the person is conscious. Contact a physician.

INHALATION: Remove to fresh air. Give oxygen if breathing becomes difficult. If not breathing, give artificial respiration. Contact a physician.

EYE CONTACT: Flush thoroughly with water and contact a physician.

SKIN CONTACT: Wash the affected area with soap and copious quantities of water. Should irritation occur, contact a physician.

### **Tubes C and H:**

#### *D-Trehalose Dihydrate:*

INGESTION: Wash out the mouth with water provided person is conscious. Call a physician.

Wash contaminated clothing before reuse.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

EYE CONTACT: Immediately flush with copious amounts of water for at least 15 minutes.

SKIN CONTACT: Immediately flush with soap and copious amounts of water.

**Tubes C and D:***MgCl<sub>2</sub>:*

INGESTION: If victim is conscious and alert, give 2-4 cupfuls of milk or water. Get medical aid.

INHALATION: Get medical aid immediately. Remove from exposure to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

EYE CONTACT: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower lids. Get medical aid.

SKIN CONTACT: Immediately flush skin with plenty of soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops or persists.

All other components: N/Ap

**Tube D:***Ammonium sulfate:*

INGESTION: If the victim is conscious, give large amounts of water. Induce vomiting. Seek medical attention.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

EYE CONTACT: Immediately flush with plenty of water for at least 15 minutes.

SKIN CONTACT: Immediately flush skin with plenty water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse.

*KCl:*

INGESTION: Wash out the mouth with water provided person is conscious. Call a physician.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

EYE CONTACT: Immediately flush with copious amounts of water for at least 15 minutes.

SKIN CONTACT: Immediately flush with soap and copious amounts of water. Wash contaminated clothing before reuse.

## V. Firefighting Measures

**Tubes A and H:**

*EDTA:* FLASH POINT: Does not apply.  
 FLAMMABILITY: Not flammable.  
 EXPLOSION LIMITS: No data available.

Not considered to be a fire hazard. In sufficient quantity and reduced particle size, this material is capable of causing dust explosion.

EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire. Use water spray, dry chemical, carbon dioxide or foam.

SPECIAL FIREFIGHTING PROCEDURES: Wear self-contained breathing apparatus and full protective clothing when fighting fire. When heated to decomposition, irritating and highly toxic gases may be generated.

**Tubes A, D and H:**

*Tris:* FLASH POINT: Does not apply, non volatile  
 EXPLOSION: Not considered to be an explosion hazard.  
 EXTINGUISHING MEDIA: Carbon dioxide, dry chemical powder, polymer foam or water spray.  
 SPECIAL FIREFIGHTING PROCEDURE: Wear self-contained breathing apparatus and full protective clothing to prevent contact with skin and eyes.  
 UNUSUAL FIRE AND EXPLOSION HAZARDS: Upon thermal decomposition it may emit toxic gases.

**Tube B:***Glass beads:*

Non combustible

SPECIAL FIREFIGHTING PROCEDURE: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**Tubes C:**

*Internal control*

Stable. Hazardous polymerization will not occur.

*DNA polymerase complex:*

FLASH POINT: Does not apply

EXTINGUISHING MEDIA: Carbon dioxide (CO<sub>2</sub>), extinguishing powder or water spray. Fight larger fire with water spray or alcohol resistant foam.

PROTECTIVE EQUIPEMENT: Do not inhale explosion gases or combustion gases.

IGNITION TEMPERATURE: 400 °C.

AUTOIGNITION: Product is not self-igniting.

DANGER OF EXPLOSION: Product does not present an explosion hazard.

EXPLOSION LIMITS: Lower: 0.9 %.

*BSA:*

EXTINGUISHING MEDIA: Water spray, dry chemical powder, or appropriate foam.

Any organic powder can be potentially explosive if disbursed in air in certain concentrations. The concentration have not been determined.

*Escherichia coli ATCC 25922 genomic DNA:*

Stable. Hazardous polymerization will not occur.

**Tube C and H:**

*D-Trehalose Dihydrate*

EXTINGUISHING MEDIA: Water spray, carbon dioxide, dry chemical powder or appropriate foam.

SPECIAL FIREFIGHTING PROCEDURES: Wear NIOSH/MSHA approved SCBA and full protective equipment to prevent contact with skin and eyes.

UNUSUAL FIRE/EXPLOSION HAZARD: Emits toxic fumes under fire conditions.

**Tube C and D:**

*MgCl<sub>2</sub>:*

GENERAL INFORMATION: Material will not burn. Use water with caution and in flooding amounts. Contact with moisture or water may generate sufficient heat to ignite nearby combustible materials.

FLASH POINT: Does not apply.

EXTINGUISHING MEDIA: Use the most appropriate extinguishing media for surrounding fire.

AUTOIGNITION TEMPERATURE: Does not apply.

EXPLOSION LIMITS (Lower and upper): Does not apply.

NFPA RATING: Not published.

**Tube D:**

*Ammonium sulfate:*

FLASH POINT: Does not apply.

EXTINGUISHING MEDIA: Use appropriate media for surrounding fire.

SPECIAL FIREFIGHTING PROCEDURES: Fire fighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode.

AUTOIGNITION TEMPERATURE: Does not apply.

FIRE AND EXPLOSION HAZARDS: Contact with strong oxidizers may cause fire and explosion.

UPPER EXPLOSIVE/ FIRE LIMITS (Lower and upper): Nonflammable.

*KCl:*

FLASH POINT: Does not apply.

FLAMMABILITY: Does not apply.

SPECIAL FIREFIGHTING PROCEDURES: Fire fighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode.

EXTINGUISHING MEDIA: Water spray, carbon dioxide, dry chemical powder or appropriate foam.

AUTOIGNITION TEMPERATURE: Does not apply.

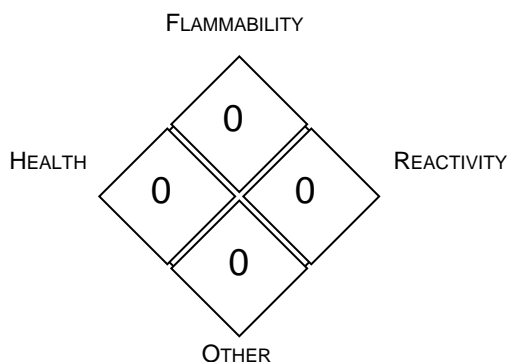
**Tube H:**

*Clostridium difficile ATCC 43255 genomic DNA:*

Stable. Hazardous polymerization will not occur.

All components:

### NFPA RATING



## VI. Accidental Release Measures

### Tubes A and H:

#### *EDTA:*

Wear proper protective equipment. Ventilate area. Respiratory protection is required in dusty environment. Sweep up spill but avoid generating dust. With a clean shovel, transfer spilled material into clean-labeled containers for disposal.

### Tubes A, D and H:

#### *Tris:*

Absorb on sand or vermiculite and place in a closed container for disposal. Ventilate area and wash spill site after material pick up is complete. Wear respirator, chemical safety goggles, rubber boots and chemical resistant gloves.

### Tube B:

#### *Glass Beads:*

Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pick up is complete.

### Tube C:

#### *Internal control*

Contain the spill and dispose of the material appropriately.

#### *DNA polymerase complex:*

Person-related safety precautions: Assure adequate ventilation.

Measures for environmental protection: Do not allow to enter sewers/surface or ground water.

Measures for cleaning / collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Additional information: No dangerous substances are released.

#### *BSA:*

SPILL: Wear respirator, safety glasses or goggles, protective clothing, and chemical resistant gloves. Carefully sweep up powder, place it in a closed container and hold for waste disposal. Avoid raising dust. Wash area thoroughly after clean up is complete.

#### *Escherichia coli ATCC 25922 genomic DNA:*

Contain the spill and dispose of the material appropriately.

**Tubes C and H***D-Trehalose dihydrate*

Use chemical safety goggles, protective clothing, gloves and NIOSH / MSHA approved mask. Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site after material pickup is complete.

WASTE DISPOSAL METHODS: Dissolve in water to a 5 % solution. Check the pH and adjust it to 7 if necessary. Pour solution down the drain while running water; continue to flush the drain for 10 minutes.

**Tubes C and D***MgCl<sub>2</sub>:*

GENERAL INFORMATION: Use proper personal protective equipment as indicated in section VIII.

SPILLS/ LEAKS: Sweep up or absorb material, then place into a suitable clean, dry, closed container for disposal. Avoid generating dusty conditions.

*KCl:*

Absorb on sand or vermiculite and place in a closed container for disposal. Ventilate area and wash spill site after material pick up is complete. Wear respirator, chemical safety goggles, rubber boots and chemical resistant gloves.

**Tube D:***Ammonium sulfate*

SPILL OR LEAK PROCEDURES: Wear self-contained breathing apparatus and protective clothing to keep material off skin. With a clean shovel, place material into clean, dry container and cover; remove from area. Flush spill area with water.

**Tube H:**

*Clostridium difficile* ATCC 43255 genomic DNA:

Contain the spill and dispose of the material appropriately.

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## VII. Handling and Storage

### STORAGE, HANDLING AND STABILITY of the BD GeneOhm™ Cdiff assay

Tubes containing assay Master Mix (TUBE C), Control DNA (TUBE H) and Diluent (TUBE D) can be stored unopened at 2-8 °C in their sealed protective pouch. They are stable until the expiration date indicated on the pouch. Once the original seal on the pouch is broken, re-seal the pouch with the zip seal after each use and store at 2-8 °C. Once opened, the reagents are stable for 1 month at 2-8 °C, provided bag is properly re-sealed with the zip seal after each use. Outside their protective pouch, Master Mix (TUBE C) and Control DNA (TUBE H) are stable for 2 hours at room temperature (15-25 °C). During storage, the reagents must always be protected from light. Tubes outside of their protective bag and unused within 2 hours should be discarded.

Tubes containing Sample Buffer (TUBE A) and lysis beads (TUBE B) can be stored unopened at 2-25 °C in their sealed protective pouch. They are stable until the expiration date indicated on the pouch. Once opened, Tube B is still stable until the expiration date indicated on the protective pouch while Tubes A is stable for 2 months. Although reagents can be stored at room temperature, they should be kept with their accompanying reagents of the same lot at 2-8 °C once the seal of the protective pouch is broken.

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## VIII. Exposure controls / Personal Protection

**Tubes A, D and H:**

*Tris:* Avoid contact with fabrics. Avoid prolonged or repeated exposure. Wash thoroughly after handling. The product should only be handled by qualified, experienced professionals.

SPECIAL PROTECTIVE EQUIPMENT: Wear suitable protective clothing, chemical resistant rubber gloves, rubber boots and chemical safety goggles.

RESPIRATORY PROTECTION AND VENTILATION: Self contained breathing apparatus or OSHA/MSHA approved respirator, handle in a fume hood with adequate ventilation.

**Tubes A and H:**

**EDTA:** Avoid skin and eye contact and inhalation of dust. Wear overalls, safety glasses or goggles and chemical resistant gloves and boots. An approved dust/mist respirator may be worn. Always wash hands before smoking, eating, drinking or using the toilet.

AIRBONE EXPOSURE LIMITS: None established

VENTILATION SYSTEM: A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminants at its source, preventing dispersion of it into the general work area.

PERSONAL RESPIRATORS (NIOSH APPROVED): For conditions of use where exposure to dust or mist is apparent and engineering controls are not feasible, a particulate respirator (NIOSH type N95 or better filters) may be worn.

**Tube B:**

**Glass beads:** Chemical safety goggles.  
Compatible chemical-resistant gloves.  
Avoid breathing dust.  
Avoid contact with eyes, skin and clothing.  
Avoid prolonged or repeated exposure.  
Wash thoroughly after handling.  
Irritant.

**Tube C:**

*Internal control:*

Special protection not required under normal usage. Use product in accordance with good laboratory practice.

*DNA polymerase complex:*

GENERAL PROTECTIVE AND HYGIENIC MEASURES: The usual precautionary measures for handling chemicals should be followed.

BREATHING EQUIPMENT: Not required.

PROTECTION OF HANDS: Protective gloves.

EYE PROTECTION: Tightly sealed goggles.

*BSA:*

RESPIRATORY PROTECTION: respirator or protective mask required.

PROTECTIVE GLOVES: Chemical-resistant gloves required.

EYE PROTECTION: Safety glasses or goggles required.

VENTILATION: Mechanical (general) or local exhaust required.

OTHER PROTECTION EQUIPMENT: safety shower and eye bath.

*Escherichia coli* ATCC 25922 genomic DNA:

Special protection not required under normal usage. Use product in accordance with good laboratory practice.

**Tubes C and H:**

*D-Trehalose dihydrate:*

RESPIRATORY PROTECTION: NIOSH / MSHA approved respirator in non ventilated areas and/or for exposure above the ACGIH TLV.

VENTILATION: Mechanical exhaust required.

PROTECTIVE GLOVES: Compatible chemical resistant gloves.

EYE PROTECTION: chemical workers goggles.

OTHER PROTECTIVE EQUIPMENT: safety shower and eye bath.

WORK HYGIENIC PRACTICES: wash thoroughly after handling.

SUPPLEMENTAL SAFETY AND HEALTH (waste disposal method): Dispose of product in accordance with all Federal, state provincial and local environmental regulations.

**Tubes C and D:***MgCl<sub>2</sub>:*

ENGINEERING CONTROLS: good general ventilation should be sufficient to control air bone levels.

PERSONAL PROTECTIVE EQUIPMENT (Eyes): wear chemical goggles.

SKIN: Wear appropriate protective gloves to prevent skin exposure.

CLOTHING: Wear appropriate protective clothing to prevent skin exposure.

RESPIRATORS: Follow the OSHA respirator regulations found in 29CFR 1910.134 or EUROPEAN STANDARD EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

**Tube D:***Ammonium sulfate:*

RECOMMENDED WORK / HYGIENE PROCEDURES: Use precaution when handling material. Avoid breathing dust. Wash thoroughly after handling material. Use proper personal protective clothing.

RESPIRATORY REQUIREMENTS: Respirator is not required where adequate ventilation conditions exist. Avoid breathing dust. Use local exhaust system if dusty conditions prevail. Where dusty or misty conditions require it, use a NIOSH-approved dust or mist respirator for needed protection. If air bone concentration is high, use a half-face cartridge respirator with filter cartridges.

RESPIRATORY PROTECTION AND VENTILATION: Self contained breathing apparatus or OSHA/MSHA approved respirator, handle in a fume hood with adequate ventilation.

HAND PROTECTION REQUIREMENTS: Use chemical resistant gloves of neoprene, natural rubber, or PVC.

EYE PROTECTION REQUIREMENTS: Under dusty conditions, wear chemical safety goggles. Safety goggles are recommended where material can come in contact with the eyes.

PROTECTIVE CLOTHING REQUIREMENTS: Wear clothing that protects the skin from chemical contact.

WASH REQUIREMENTS: Wash thoroughly after handling material.

*KCl:*

Avoid contact with fabrics. Avoid prolonged or repeated exposure. Wash thoroughly after handling. The product should only be handled by qualified, experienced professionals.

SPECIAL PROTECTIVE EQUIPMENT: Wear suitable protective clothing, chemical resistant rubber gloves, rubber boots and chemical safety goggles.

**Tube H:***Clostridium difficile* ATCC 43255 genomic DNA:

Special protection not required under normal usage. Use product in accordance with good laboratory practice.

**IX. Physical and Chemical Properties****Tubes A, D and H:**

*Tris:* APPEARANCE: colorless aqueous liquid.  
ODOR: Slight characteristic odor.  
pH: 10.4 (0.1M solution)  
DENSITY: no information found.  
BOILING POINT: 219-220 °C (426-428 °F)

**Tubes A and H:**

*EDTA:* APPEARANCE: white to off white crystalline powder.  
ODOR: odorless.  
pH (1 % solution): 11.0-11.5  
BULK DENSITY: approx. 0.65g/cm<sup>3</sup>  
MELTING POINT: 240 °C (464 °F)  
BOILING POINT: no data available.  
VAPOUR PRESSURE (20 °C): no data available.

**Tube B:**

*Glass beads:* APPEARANCE, PHYSICAL STATE: solid.  
ODOR: odorless.

**Tube C:**

*Internal control:* APPEARANCE: Frozen suspension.

**DNA polymerase complex:**

APPEARANCE: fluid.  
COLOR: according to product specification.  
ODOR: characteristic.  
pH (AT 20 °C): 8.0  
DENSITY: not determined.  
MELTING POINT: undetermined.  
BOILING POINT: undetermined.  
VAPOR PRESSURE AT 20 °C: 0.1 hPa

*BSA:* APPEARANCE: Pale green lyophilized powder.

*Escherichia coli* ATCC 25922 genomic DNA:  
APPEARANCE: Frozen suspension.

**Tubes C and H:****D-Trehalose dihydrate:**

APPEARANCE: white crystalline powder.  
ODOR: odorless.

**Tubes C and D:**

*MgCl<sub>2</sub>:* PHYSICAL STATE: solid.  
APPEARANCE: white and grey white.  
ODOR: none reported.  
pH: 7.0 (solution).  
VAPOR PRESSURE: not available.  
VAPOR DENSITY: not available.  
SPECIFIC GRAVITY/DENSITY: 1.569  
VISCOSITY: not available.  
FREEZING/MELTING POINT: 118 °C  
BOILING POINT: 1412 °C  
DECOMPOSITION TEMPERATURE: 100 °C  
CHEMICAL FORMULA: MgCl<sub>2</sub>·6H<sub>2</sub>O

**Tube D:****Ammonium sulfate:**

PHYSICAL STATE: solid.  
APPEARANCE: brown-grey white crystals or granules.  
ODOR: odorless.  
pH (1.3 % solution): 5.5  
VAPOR PRESSURE: Does not apply.  
SPECIFIC GRAVITY: 1.77 (water = 1)  
BULK DENSITY: 1.77  
EVAPORATION RATE: Does not apply.  
PERCENT VOLATILES: 0 (by volume at 21 °C)  
SOLUBILITY IN WATER: appreciable (>10 %)  
SOLVENT SOLUBILITY: insoluble in alcohol and acetone.  
MELTING POINT: 280 °C (536 °F) (at 765 mmHg)  
MOLECULAR WEIGHT: 132.14 g/mol  
CHEMICAL FORMULA: (NH<sub>4</sub>)<sub>2</sub>SO<sub>4</sub>  
CHEMICAL FAMILY: ammonium salts.

**KCl:**

APPEARANCE: Solid.  
 ODOR: Odorless.  
 pH: 7 (solution).  
 VAPOR PRESSURE: Does not apply.  
 VAPOR DENSITY: Does not apply.  
 SPECIFIC GRAVITY: 1.98 g/cm<sup>3</sup>  
 BP/BP RANGE: 1500 °C (at 750 mmHg)  
 FREEZING POINT: Does not apply.  
 SATURATED VAPOR CONC.: Does not apply.  
 VOC Content: Does not apply.  
 VISCOSITY: Does not apply.  
 SURFACE TENSION: Does not apply.  
 REFRACTIVE INDEX: Does not apply.  
 OPTICAL ROTATION: Does not apply.  
 PERCENT VOLATILES: 0 (by volume at 21 °C)  
 SOLUBILITY IN WATER: Soluble.  
 MELTING POINT: 770 °C (at 765 mmHg)  
 MOLECULAR WEIGHT: 74.56 g/mol

**Tube H:**

*Clostridium difficile* ATCC 43255 genomic DNA:  
 Frozen suspension.

## X. Stability and Reactivity

**Tubes A, D and H:**

*Tris*: STABILITY: This product is stable under normal handling conditions.  
 INCOMPATIBILITIES: Bases and oxidizing agents.  
 DECOMPOSITION PRODUCTS: Burning may produce carbon monoxide, carbon dioxide and nitrogen oxides.  
 HAZARDOUS POLYMERIZATION: Will not occur.  
 CONDITIONS TO AVOID: Heat, incompatibilities.

**Tubes A and H:**

*EDTA*: STABILITY: This product is stable under normal temperatures and pressures.  
 INCOMPATIBLE WITH STRONG OXIDIZING AGENTS: Avoid contact with aluminum, zinc, nickel, copper and copper alloys. Avoid dust generation.  
 HAZARDOUS DECOMPOSITION PRODUCTS: burning may produce carbon monoxide, carbon dioxide, nitrogen oxides.  
 HAZARDOUS POLYMERISATION: Will not occur.

**Tube B:**

*Glass beads*:  
 STABILITY: This product is stable.  
 INCOMPATIBILITIES: Strong oxidizing agents, hydrofluoric acid, magnesium.  
 HAZARDOUS POLYMERISATION: Will not occur.

**Tube C:**

*Internal control*:  
 STABILITY: This product is stable.

*DNA polymerase complex:*

THERMAL DECOMPOSITION: No decomposition if used according to specifications.  
 DANGEROUS PRODUCTS OF DECOMPOSITION: No dangerous decomposition products known.  
 DANGEROUS REACTIONS: react with acids, alkalis and oxidizing agents.

**BSA:** STABILITY: This product is stable.  
HAZARDOUS POLYMERISATION: Will not occur.

*Escherichia coli* ATCC 25922 genomic DNA:  
STABILITY: This product is stable.

**Tubes C and H:**

*D-Trehalose dihydrate:*

STABILITY: This product is stable.  
MATERIALS TO AVOID: Strong oxidizing agents.  
HAZARDOUS DECOMPOSITION PRODUCTS: carbon monoxide, carbon dioxide (toxic fumes).  
HAZARDOUS POLYMERIZATION: not relevant.  
CONDITIONS TO AVOID: none specified by manufacturer.

**Tubes C and D:**

*MgCl<sub>2</sub>:* CHEMICAL STABILITY: Stable under normal temperatures and pressures.  
INCOMPATIBILITIES WITH OTHER MATERIALS: Explosive when combined with 2-furan per carboxylic acid. Magnesium chloride dissolves in aqueous solutions giving off considerable amounts of heat; incompatible with strong oxidizers.  
HAZARDOUS DECOMPOSITION PRODUCTS: Hydrogen chloride, chlorine.  
HAZARDOUS POLYMERIZATION: Will not occur.  
CONDITIONS TO AVOID: Contact with water, heating to decomposition.

**Tube D:**

*Ammonium sulfate:*

INSTABILITY CONDITIONS: Avoid contact with heat. Temperature above 280 °C (536 °F) causes material to decompose.  
INCOMPATIBILITIES: Contact with strong oxidizers may cause fire or explosion. Incandescent reaction on heating with potassium chlorate. Reaction with sodium hypochlorite forms the unstable explosive trichloride. Copper, brass, bronze, strong acids.  
DECOMPOSITION PRODUCTS: Ammonia and sulfur oxides  
HAZARDOUS POLYMERIZATION: Will not occur.

*KCl:*

CHEMICAL STABILITY: Stable under normal temperature and pressure conditions.  
MATERIAL TO AVOID: Strong oxidizers, strong acids  
HAZARDOUS DECOMPOSITION PRODUCTS: Hydrogen chloride gas, potassium oxides  
HAZARDOUS POLYMERIZATION: Will not occur.

**Tube H:**

*Clostridium difficile* ATCC 43255 genomic DNA:  
This product is stable.

**XI. Toxicological information**

**Tubes A, D and H:**

*Tris:* RTECS # : Tris (hydroxymethyl) aminomethane- TY2900000  
Oral rat LD<sub>50</sub>: 5900 mg/kg  
NTP carcinogen: known: No anticipated: No IARC Category: None

**Tubes A and H:**

*EDTA:* NTP carcinogen: known: No anticipated: No IARC Category: None

**Tube B:**

*Glass beads:*

ACUTE EFFECTS: May be harmful by inhalation or ingestion or skin absorption. Material is irritating to mucous membranes and upper respiratory tract. To the best of our knowledge the chemical, physical, and toxicological properties have not been thoroughly investigated.

**Tube C:**

*Internal control:* N/A

*DNA polymerase complex:*

ACUTE TOXICITY; PRIMARY IRRITANT EFFECT:

SKIN EFFECTS: irritation to skin and mucous membranes.

EYE EFFECTS: irritation.

SENSITIZATION: sensitizing effect through inhalation is possible with prolonged exposure.

Sensitizing effect by skin contact is possible with prolonged exposure.

ADDITIONAL TOXICOLOGICAL INFORMATION: the product is not subject to classification according to internally approved calculation methods for preparation.

*BSA:* Complete toxicological properties have yet to be determined.

*Escherichia coli* ATCC 25922 genomic DNA: N/A

**Tubes C and H:**

*D-Trehalose Dihydrate:*

No data available

**Tubes C and D:**

*MgCl<sub>2</sub>:* LD<sub>50</sub>/LC<sub>50</sub>: Oral, mouse LD<sub>50</sub> = 7600 mg/kg Oral, rat LD<sub>50</sub> = 8100 mg/kg

CARCINOGENICITY: not listed by ACGIH, IARC, NIOSH, NTP or OSHA

EPIDEMIOLOGY: No data available.

TERATOGENICITY: No data available.

REPRODUCTIVE EFFECTS: No data available.

NEUROTOXICITY: No data available.

MUTAGENICITY: No data available.

**Tube D:**

*Ammonium sulfate:*

ROUTES OF EXPOSURE: inhalation, ingestion, skin contact, eye contact.

EFFECTS OF ACUTE EXPOSURE: causes irritation

SYMPTOMS: irritation, harmful if swallowed.

EYE EFFECTS: irritation.

SKIN EFFECTS: irritation.

ACUTE ORAL EFFECTS: TDL<sub>o</sub> 1500 mg/kg, man;

LD<sub>50</sub> 3000 mg/kg, rat.

The sulfur ion may cause vomiting.

ACUTE INHALATION EFFECTS: Respiratory irritation.

CHRONIC EFFECTS/ CARCINOGENICITY: this agent is not considered a carcinogen by NTP, IARC, or OSHA.

ORGANS AFFECTED BY LONG-TERM: Respiratory system and lungs.

*KCl:*

ROUTE OF EXPOSURE

SKIN CONTACT: May cause skin irritation.

SKIN ABSORPTION: May be harmful if absorbed through the skin.

EYE CONTACT: May cause eye irritation.

INHALATION: May be harmful if inhaled. Material may be irritating to mucous membranes and upper respiratory tract.

INGESTION: May be harmful if swallowed.

ADDITIONAL TOXICOLOGICAL INFORMATION:

ORAL: Rat, 2600 mg/Kg LD<sub>50</sub>

ORAL: Mouse 1500 mg/Kg LD<sub>50</sub>

MATERIAL SAFETY DATA SHEET BD GeneOhm™ Cdiff

IRRITATION DATA: Eyes, Rabbit 500 mg 24H (remarks: Mild irritation effect)

CHRONIC EXPOSURE-MUTAGEN:

Species: Rat  
Route: Oral  
Dose 1500 UG/KG  
Mutation test: Unscheduled DNA synthesis

Species: Hamster  
Dose 260 MMOL/L  
Mutation test: DNA damage

Species: Hamster  
Dose 180 MMOL/L  
Mutation test: Sister chromatid exchange

Species: Hamster  
Dose 140 MMOL/L  
Mutation test: Cytogenetic analysis – Cell type ovary

**Tube H:**

*Clostridium difficile* ATCC 43255 genomic DNA: N/A

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## XII. Ecological information

**Tubes A, D and H:**

*Tris:* SOLUBILITY IN WATER: 55-80 g/100 mL (20 °C)

**Tubes A and H:**

*EDTA:* ENVIRONMENTAL FATE: When released into the soil, this material is expected to leach into groundwater, may biodegrade to a moderate extent and is not expected to evaporate significantly. When released into water, this material is not expected to evaporate significantly. This material is not expected to significantly bioaccumulate. When released into the air, this material is expected to be readily degraded by photolysis.

ENVIRONMENTAL TOXICITY: This material is not expected to be toxic to aquatic life. The LC<sub>50</sub>/96-hour values for fish are over 100 mg/L.

SOLUBILITY IN WATER: 60 g/100 mL at 22 °C

**Tube B:**

*Glass Beads:* No data available.

**Tube C:**

*Internal control:* No data available.

*DNA polymerase complex:*

GENERAL NOTES: Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SOLUBILITY IN WATER: fully miscible.

*Other constituents:* No data available.

**Tubes C and D:**

*MgCl<sub>2</sub>:* SOLUBILITY: soluble in water and alcohol.

**Tube D:**

*Ammonium sulfate:*

If discarded to waterways, it may promote eutrophication.

Aquatic Toxicity: 25 HR. TL<sub>m</sub>: 423 mg/L

50 HR. TL<sub>m</sub>: 433 mg/L

100 HR. TL<sub>m</sub>: 292 mg/L

*KCl:* No data available.

**Effect of material on plants or animals:** Due to the small product size and high dilution of the constituents, no unusual effects on plants or animals are expected if this product is released into the environment.

**Effect of chemical on aquatic life:** Due to the small product size and high dilution of the constituents, this product is not anticipated to cause adverse effects on aquatic life.

### XIII. Disposal Considerations

**Tubes A, D and H:**

*Tris:* Dissolve or mix a combustible solvent and burn in a chemical incinerator equipped with an after burn and scrubber.

**Tubes A and H:**

*EDTA:* Dispose in accordance with federal, state or local regulations

**Tube B:**

*Glass beads:* Bury in a landfill site approved for the disposal of chemical and hazardous wastes. Observe all federal, state and local environmental regulations

**Tube C:**

*DNA polymerase complex:* PRODUCT: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.  
 UNCLEANNED PACKAGINGS: Disposal must be made according to official regulations.  
 RECOMMENDED CLEANSING AGENT: water, if necessary with cleansing agents.  
 WASTE DISPOSAL METHOD: Dispose of waste according to federal, state, local, or other applicable standards.

EPA WASTE NUMBER: Not applicable.

### XIV. Transportation Information

**Specimens:**

BD GeneOhm™ Cdiff assay is a qualitative *in vitro* diagnostic test for the rapid detection of *C. difficile* toxin B gene (*tcdB*) in human faecal specimens. **Those specimens should be kept between 2°C and 25°C during transport. Protect against freezing or exposure to excessive heat. Specimens stored between 2 °C and 8 °C are stable for up to 5 days. Specimens that can be tested within 48 hours can be kept at room temperature (15-25 °C).**

**Components of BD GeneOhm™ Cdiff:**

According to Transport Canada Transportation of dangerous goods regulations: **THESE MATERIALS ARE NOT CONSIDERED AS DANGEROUS GOODS.**

All assay tubes are enveloped in foil bags with desiccant pouches. These foil bags are then enclosed in a cardboard packaging, to ensure compliance with the minimum packing requirements of the Regulations.

Proper shipping name:	N/Ap
Hazard class number and description	N/Ap
UN identification number	N/Ap
Packing group	N/Ap
Dot label(s) required	N/Ap
North American emergency response guidebook number	N/Ap
Marine Pollutant	N/Ap (49 CFR 172.101, Appendix B)

## XV. Regulatory Information

### Information on NON DILUTED CONCENTRATION of constituents.

**CAUTION!** MAY CAUSE SKIN AND EYE IRRITATION. MAY CAUSE DISCOMFORT IF SWALLOWED OR INHALED. Do not taste or swallow. Do not get on skin, in eyes, in clothes. Avoid prolonged or repeated skin contact. Avoid breathing mists or sprays. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves and goggles. FIRST-AID: In case of contact, immediately flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If ingested, do not induce vomiting. Get medical attention if necessary. IN CASE OF FIRE: Use water fog, dry chemical, CO<sub>2</sub>, or alcohol foam. IN CASE OF SPILL: Absorb spill and place in suitable container. Consult Material Safety Data Sheet for additional information.

TARGET ORGANS: Respiratory system, lungs and kidneys

WHMIS SYMBOLS: Not applicable

### BD GeneOhm™ Cdiff assay

**The BD GeneOhm™ Cdiff assay is for *in vitro* diagnostic use only.**

**CAUTION!** Reagents are not interchangeable between lots. Reseal protective pouches of Master Mix and controls quickly with the zip seal after each use. Never pool reagents from different tubes even if they are of the same lot. Do not use the reagents after their expiration date. Do not interchange caps among reagents as contamination may occur and compromise test results. Avoid microbial and deoxyribonuclease (DNase) contamination of reagents when removing aliquots from tubes. The use of sterile DNase-free disposable filter-blocked or positive displacement pipettor tips is recommended. Use a new tip for each specimen or reagent. Do not pipet by mouth. Do not smoke, drink, or eat in areas where specimens or assay reagents are being handled. Wear protective clothing and disposable gloves while handling assay reagents. Wash hands thoroughly after performing the test. Always handle specimens as if infectious in accordance with safe laboratory procedures such as those described in *Biosafety in Microbiological and Biomedical Laboratories*<sup>1</sup> and in the CLSI MM3 and C24<sup>ii, iii</sup>

## XVI. Definitions of terms

A large number of abbreviations and acronyms appear on this MSDS. Some of these which are commonly used include the following:

**Cdiff:** *Clostridium difficile*

**DNA:** Deoxyribonucleic acid

**ATCC:** American Type Culture Collection

**N/Ap:** Non Applicable

**N/A:** Non Available

**CAS #:** This is the Chemical Abstract Service Number which uniquely identifies each constituent. It is used for computer-related searching.

### EXPOSURE LIMITS IN AIR:

**ACGIH** American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

**TLV (Threshold Limit Value)** An air bone concentration of a substance which represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour **Time Weighted Average (TWA)**, the 15-minute **Short Term Exposure Limit (STEL)**, and the instantaneous **Ceiling Level (CL)**. Skin absorption effects must also be considered.

**OSHA** U.S. Occupational Safety and Health Administration

**PEL (Permissible Exposure Limit)** This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register: 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase "Vacated 1989 PEL" is placed next to the PEL which was vacated by Court Order.

**IDLH (Immediate Dangerous to Life and Health)** This level represents a concentration from which one can escape within 30 minutes without suffering escape-preventing or permanent injury.

**The DFG-MAK** is the Republic of Germany's Maximum Institute Exposure Level, similar to the U.S. PEL. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (OSHA). NIOSH issues exposure guidelines called Recommended Exposure Levels (RELs). When no exposure guidelines are established, an entry of NE is made for reference.

**MSHA:** Mine Safety and Health Administration

### HAZARD RATINGS:

#### Hazardous Materials Identification System:

**Health Hazard:** 0 (minimal acute or chronic exposure hazard); 1 (slight acute or chronic exposure hazard); 2 (moderate acute or significant chronic exposure hazard); 3 (severe acute exposure hazard; onetime overexposure can result in permanent injury and may be fatal); 4 (extreme acute exposure hazard; onetime overexposure can be fatal)

**Flammability Hazard:** 0 (minimal hazard); 1 (materials that require substantial pre-heating before burning); 2 (combustible liquid or solids; liquids with a flash point of 38-93 °C (100-200 °F)); 3 (Class 1B and 1C flammable liquids with flash points below 38 °C (100°F)); 4 (Class 1A flammable liquids with flash point below 23 °C (73 °F) and boiling points below 38 °C (100 °F)).

**Reactivity Hazard:** 0 (normally stable); 1 (materials that can become unstable at elevated temperatures or which can react slightly with water); 2 (materials that are unstable but do not detonate or which can react violently with water); 3 (materials that can detonate when initiated or which can react explosively with water); 4 (materials that can detonate at normal temperatures or pressures).

#### National Fire Protection Association (NFPA):

**Health Hazard:** 0 (material that on exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials); 1 (materials that on exposure under fire conditions could cause irritation or minor residual injury); 2 (materials that on intense or continued exposure under fire conditions could cause temporary incapacitation or possible residual injury); 3 (materials that can on short exposure could cause serious temporary or residual injury); 4 (materials that under very short exposure could cause death or major residual injury).

**Flammability Hazard and Reactivity Hazard:** Refer to definitions for "Hazardous Materials Identification System".

#### Flammability Limits in Air

Much of the information related to fire and explosion is derived from the NFPA.

Flash Point: Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air.

Autoignition Temperature: The minimum temperature required to initiate combustion in air with no other source of ignition.

LEL: the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

**TOXICOLOGICAL INFORMATION:****Toxicological Information**

Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: LD<sub>50</sub>- Lethal Dose (solids and liquids) which kills 50 % of the exposed animals; LC<sub>50</sub>- Lethal Concentration (gases) which kills 50 % of the exposed animals; ppm: concentration expressed in parts of material per million parts of air or water; mg/m<sup>3</sup>: concentration expressed in weight of substance per volume of air; mg/kg: quantity of material, by weight, administered to a test subject, based on their body weight in kg; Data from several sources are used to evaluate the cancer-causing potential of the material. The sources are: IARC- the International Agency for Research on Cancer, NTP- the National Toxicology Program, RTECS- the Registry of Toxic Effects of Chemical Substances, OSHA and CAL/OSHA. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with ranking from 1 to 4. Subrankings (2A, 2B, etc.) are also used. Other measures of toxicity include TDLo, the lowest dose to cause a symptom and TCLo, the lowest concentration to cause a symptom; BEI – Biological Exposure Indices, represents the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

**Regulatory Information**

This section explains the impact of various laws and regulations on the material. EPA is the U.S. Environmental Protection Agency. WHMIS is the Canadian Workplace Hazardous Materials Information System. DOT and TC are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (SARA); the Canadian Domestic Substances List (DSL); the U.S. Toxic Substance Control Act (TSCA); Marine Pollutant status according to the DOT; California's Safe Drinking Water act (Proposition 65); the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund); and various state regulations. This section also includes information on the precautionary warnings which appear on the materials package label.

<sup>i</sup> Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. Richmond JY and McKinney RW (eds) (1993). HHS Publication number (CDC) 93-8395.

<sup>ii</sup> Clinical and Laboratory Standards Institute. Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline. Document MM3. (Refer to the latest edition).

<sup>iii</sup> Clinical and Laboratory Standards Institute.. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline – Second Edition, Document C24 (Refer to the latest edition).