

08/27/2007

Kit Components

Product code	Description
441240	BD GeneOhm™ StrepB Assay

Components:

441240a	Diluent
441240b	Sample Buffer
441240c	Positive Control
441240d	Master Mix
441240e	Lysis Tube



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

1 Identification of substance:

- **Product name:** *Diluent*
(*BD GeneOhm™ StrepB Assay*)
- **Catalog number:** 441240
- **Manufacturer/Supplier:**
BD Diagnostics
2050 boul. René-Lévesque O., 4^e étage,
Ste-Foy, Québec, Canada G1V 2K8
- **Information department:** Customer Service
- **Emergency information:**
In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostics, at (888) 436-3646, or ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- **Chemical characterization**
- **Description:** Mixture consisting of the following components.
- **Dangerous components:** Void

3 Hazards identification

- **Hazard description:**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 91/155/EEC, and 93/112/EC.
- **Classification system**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

4 First aid measures

- **General information** No special measures required.
- **After inhalation**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Seek medical advice.
In case of unconsciousness place patient on side position for transportation.
- **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** Seek immediate medical advice.
- **Information for doctor** Show this product label or this MSDS.

CDN

(Contd. on page 2)

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Diluent
(BD GeneOhm™ StrepB Assay)

(Contd. of page 1)

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

6 Accidental release measures

- **Person-related safety precautions:**
Use respiratory protective device.
Wear protective clothing.
- **Measures for environmental protection:** Wipe up with damp sponge or mop.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
- **Additional information:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Information for safe handling:** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** 2 - 30 C
- **Information about storage in one common storage facility:**
Store away from oxidizing agents.
Do not store together with alkaline material.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal Protective Equipment**
- **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.

(Contd. on page 3)

CDN

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Diluent
(BD GeneOhm™ StrepB Assay)

(Contd. of page 2)

· **Protection of hands:**



Chemical resistant gloves (i.e. nitrile, or equivalent).

· **Eye protection:** Safety glasses

· **Body protection:** Protective work clothing (lab coat).

9 Physical and chemical properties:

· **General Information**

Form:	Liquid
Color:	Clear
Odor:	Characteristic

· **Change in condition**

Melting point/Melting range: Not determined

Boiling point/Boiling range: Not determined

· **Flash point:** Not applicable

· **Auto igniting:** Product is not self igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· **Solubility in / Miscibility with**

Water: Soluble

· **pH-value:** 8.8 +/- 0.1

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

· **Dangerous reactions** No dangerous reactions known

· **Dangerous products of decomposition:**

Ammonia (NH₄)

Sulfur oxides (SO_x)

Hydrogen chloride (HCl)

Chlorine (Cl)

CDN

(Contd. on page 4)



Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Diluent
(BD GeneOhm™ StrepB Assay)

(Contd. of page 3)

11 Toxicological information

· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

77-86-1 tris base

Oral	LD50	5900 mg/kg (rat)
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· **Primary irritant effect:**

· **on the skin:** May cause irritation to skin and mucous membranes.

· **on the eye:** May cause irritation

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to OSHA classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

· **Ecotoxic effects:**

· **Acquatic toxicity:**

This material is not expected to be toxic to aquatic life. The LC50/96-hour values for fish are greater than 100 mg/l

· **General notes:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

13 Disposal considerations

· **Product:**

· **Recommendation**

Must not be disposed of with solid waste.

Must adhere to official regulations.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to state and federal regulations.

· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

· **DOT regulations:**

· **Hazard class:** -

· **Land transport ADR/RID (cross-border)**

· **ADR/RID class:** -

· **Maritime transport IMDG:**

· **IMDG Class:** -

· **Marine pollutant:** No

(Contd. on page 5)



Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Diluent
(BD GeneOhm™ StrepB Assay)

(Contd. of page 4)

- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

· **Transport/Additional information:**

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulations

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

77-86-1	tris base
7783-20-2	ammonium sulfate
7447-40-7	potassium chloride

· **California Proposition 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **Product related hazard information:**

Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations pertaining to regulations on hazardous materials.
This product has been classified according to the hazard criteria of the Controlled Products Regulations (CPR), and the MSDS contains all of the information required by the CPR.

· **Hazard-determining components of labeling:**

tris base

(Contd. on page 6)



Material Safety Data Sheet
acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Diluent
(BD GeneOhm™ StrepB Assay)

(Contd. of page 5)

- **National regulations**
- **Water hazard class:** *Water hazard class 1 (Self-assessment): slightly hazardous for water.*

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

- **Department issuing MSDS:**
Safety and Environment Department
MSDS created by Michael J. Spinazzola
- **Contact:** *Customer Service Representative*

CDN



Material Safety Data Sheet

acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

1 Identification of substance:

- **Product name:** Sample Buffer
(BD GeneOhm™ Strep B Assay)
- **Catalog number:** 441240
- **Manufacturer/Supplier:**
BD Diagnostics
2050 boul. René-Lévesque O., 4^e étage,
Ste-Foy, Québec, Canada G1V 2K8
- **Information department:** Customer Service
- **Emergency information:**
In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostics, at (888) 436-3646, or ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- **Chemical characterization**
- **Description:** Mixture consisting of the following components.
- **Dangerous components:** Void

3 Hazards identification

- **Hazard description:**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 91/155/EEC, and 93/112/EC.
- **Classification system**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

4 First aid measures

- **General information** No special measures required.
- **After inhalation**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Seek medical advice.
In case of unconsciousness place patient on side position for transportation.
- **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** Seek immediate medical advice.
- **Information for doctor** Show this product label or this MSDS.

CDN

(Contd. on page 2)



Material Safety Data Sheet

acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Sample Buffer
(BD GeneOhm™ Strep B Assay)

(Contd. of page 1)

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

6 Accidental release measures

- **Person-related safety precautions:**
Use respiratory protective device.
Wear protective clothing.
- **Measures for environmental protection:** Wipe up with damp sponge or mop.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
- **Additional information:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Information for safe handling:** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** 2 - 30 C
- **Information about storage in one common storage facility:**
Store away from oxidizing agents.
Do not store together with alkaline material.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal Protective Equipment**
- **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.

(Contd. on page 3)

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Sample Buffer
(BD GeneOhm™ Strep B Assay)

(Contd. of page 2)

· Protection of hands:



Chemical resistant gloves (i.e. nitrile, or equivalent).

· Eye protection: Safety glasses

· Body protection: Protective work clothing (lab coat).

9 Physical and chemical properties:

· General Information

Form: Liquid
Color: Clear
Odor: Characteristic

· Change in condition

Melting point/Melting range: Not determined
Boiling point/Boiling range: Not determined

· Flash point: Not applicable

· Auto igniting: Product is not self igniting.

· Danger of explosion: Product does not present an explosion hazard.

· Density: Not determined

· Solubility in / Miscibility with

Water: Soluble

· pH-value: 8.0 +/- 0.1

10 Stability and reactivity

· Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

· Dangerous reactions No dangerous reactions known

· Dangerous products of decomposition:

Nitrogen oxides (NO_x)

Carbon monoxide (CO) and carbon dioxide (CO₂)

11 Toxicological information

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

77-86-1 tris base

Oral	LD50	5900 mg/kg (rat)
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(Contd. on page 4)



Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Sample Buffer
(BD GeneOhm™ Strep B Assay)

(Contd. of page 3)

- **Primary irritant effect:**
- **on the skin:** May cause irritation to skin and mucous membranes.
- **on the eye:** May cause irritation
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to OSHA classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

- **Ecotoxicological effects:**
- **Acquatic toxicity:**
This material is not expected to be toxic to aquatic life. The LC50/96-hour values for fish are greater than 100 mg/l
- **General notes:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

13 Disposal considerations

- **Product:**
- **Recommendation**
Must not be disposed of with solid waste.
Must adhere to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to state and federal regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **DOT regulations:**
- **Hazard class:** -
- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -
- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No
- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

(Contd. on page 5)



Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Sample Buffer
(BD GeneOhm™ Strep B Assay)

(Contd. of page 4)

· Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulations

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

· SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act)

77-86-1 tris base

60-00-4 EDTA

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenicity categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· Product related hazard information:

Observe the general safety regulations when handling chemicals

The product is not subject to identification regulations pertaining to regulations on hazardous materials.

This product has been classified according to the hazard criteria of the Controlled Products Regulations (CPR), and the MSDS contains all of the information required by the CPR.

· National regulations

· Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

CDN

(Contd. on page 6)



Material Safety Data Sheet
acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Sample Buffer
(BD GeneOhm™ Strep B Assay)

(Contd. of page 5)

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

- **Department issuing MSDS:**
Safety and Environment Department
MSDS created by Michael J. Spinazzola
- **Contact:** Customer Service Representative

CDN



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

1 Identification of substance:

- **Product name:** *Positive Control*
(BD GeneOhm™ Strep B Assay)
- **Catalog number:** 441240c
- **Manufacturer/Supplier:**
BD Diagnostics
2050 boul. René-Lévesque O., 4^e étage,
Ste-Foy, Québec, Canada G1V 2K8
- **Information department:** Customer Service
- **Emergency information:**
In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostics, at (888) 436-3646, or ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- **Chemical characterization**
- **Description:** Mixture consisting of the following components.
- **Dangerous components:** Void

3 Hazards identification

- **Hazard description:**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 91/155/EEC, and 93/112/EC.
- **Classification system**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

4 First aid measures

- **General information** No special measures required.
- **After inhalation**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Seek medical advice.
In case of unconsciousness place patient on side position for transportation.
- **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** If symptoms persist consult doctor.
- **Information for doctor** Show this product label or this MSDS.

CDN

(Contd. on page 2)



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

**Product name: Positive Control
(BD GeneOhm™ Strep B Assay)**

(Contd. of page 1)

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

6 Accidental release measures

- **Person-related safety precautions:**
Ensure adequate ventilation
Use respiratory protective device.
Wear protective clothing.
- **Measures for environmental protection:** Wipe up with damp sponge or mop.
- **Measures for cleaning/collecting:** No special measures required.
- **Additional information:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Information for safe handling:** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** 2 - 30 C
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal Protective Equipment**
- **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.

(Contd. on page 3)

CDN

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Positive Control
(BD GeneOhm™ Strep B Assay)

(Contd. of page 2)

· **Protection of hands:**



Chemical resistant gloves (i.e. nitrile, or equivalent).

· **Eye protection:** Safety glasses

· **Body protection:** Protective work clothing (lab coat).

9 Physical and chemical properties:

· **General Information**

Form:	Solid.
Color:	White
Odor:	Characteristic

· **Change in condition**

Melting point/Melting range: Not determined

Boiling point/Boiling range: Not determined

· **Flash point:** Not applicable

· **Auto igniting:** Product is not self igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· **Solubility in / Miscibility with**

Water: Soluble

· **pH-value:** Not applicable

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

· **Materials to be avoided:** Incompatible material: strong oxidizers.

· **Dangerous reactions** No dangerous reactions known

· **Dangerous products of decomposition:** Carbon monoxide (CO) and carbon dioxide (CO₂)

11 Toxicological information

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** May cause irritation to skin and mucous membranes.

· **on the eye:** May cause irritation

· **Sensitization:** Sensitizing effect through inhalation is possible with prolonged exposure.

(Contd. on page 4)



Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Positive Control
(BD GeneOhm™ Strep B Assay)

(Contd. of page 3)

· Additional toxicological information:

The product is not subject to OSHA classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

· Ecotoxicological effects:

· Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

· General notes: *Generally not hazardous for water.*

13 Disposal considerations

· Product:

· Recommendation

Must not be disposed of with solid waste.

Must adhere to official regulations.

· Uncleaned packagings:

· Recommendation: *Disposal must be made according to state and federal regulations.*

· Recommended cleansing agent: *Water, if necessary with cleansing agents.*

14 Transport information

· DOT regulations:

· Hazard class: -

· Land transport ADR/RID (cross-border)

· ADR/RID class: -

· Maritime transport IMDG:

· IMDG Class: -

· Marine pollutant: *No*

· Air transport ICAO-TI and IATA-DGR:

· ICAO/IATA Class: -

· Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulations

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

(Contd. on page 5)



Material Safety Data Sheet
acc. to ISO/DIS 11014

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Product name: Positive Control
(BD GeneOhm™ Strep B Assay)

(Contd. of page 4)

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

99-20-7 trehalose

9048-46-8 BSA

7786-30-3 Magnesium Chloride

· **California Proposition 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **Product related hazard information:**

Observe the general safety regulations when handling chemicals

The product is not subject to identification regulations pertaining to regulations on hazardous materials.

This product has been classified according to the hazard criteria of the Controlled Products Regulations (CPR), and the MSDS contains all of the information required by the CPR.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

· **Department issuing MSDS:**

Safety and Environment Department

MSDS created by Michael J. Spinazzola

· **Contact:** Customer Service Representative



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

1 Identification of substance:

- **Product name:** Master Mix
(BD GeneOhm™ Strep B Assay)
- **Catalog number:** 441240
- **Manufacturer/Supplier:**
BD Diagnostics
2050 boul. René-Lévesque O., 4^e étage,
Ste-Foy, Québec, Canada G1V 2K8
- **Information department:** Customer Service
- **Emergency information:**
In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostics, at (888) 436-3646, or ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- **Chemical characterization**
- **Description:** Mixture consisting of the following components.
- **Dangerous components:** Void
- **Additional information**
Note: The *Staphylococcus epidermidis* ATCC 14990 genomic DNA has been inactivated such that they do not pose a health risk.

3 Hazards identification

- **Hazard description:**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 91/155/EEC, and 93/112/EC.
- **Classification system**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

4 First aid measures

- **General information** No special measures required.
- **After inhalation**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Seek medical advice.
In case of unconsciousness place patient on side position for transportation.
- **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** If symptoms persist consult doctor.
- **Information for doctor** Show this product label or this MSDS.

CDN

(Contd. on page 2)



Material Safety Data Sheet acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Master Mix
(BD GeneOhm™ Strep B Assay)

(Contd. of page 1)

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.

6 Accidental release measures

- **Person-related safety precautions:**
Ensure adequate ventilation
Use respiratory protective device.
Wear protective clothing.
- **Measures for environmental protection:** Wipe up with damp sponge or mop.
- **Measures for cleaning/collecting:** No special measures required.
- **Additional information:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Information for safe handling:** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** 2 - 30 C
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal Protective Equipment**
- **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.

(Contd. on page 3)

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Master Mix
(BD GeneOhm™ Strep B Assay)

(Contd. of page 2)

· Protection of hands:



Chemical resistant gloves (i.e. nitrile, or equivalent).

· Eye protection: Safety glasses

· Body protection: Protective work clothing (lab coat).

9 Physical and chemical properties:

· General Information

Form:	Solid.
Color:	White
Odor:	Characteristic

· Change in condition

Melting point/Melting range: Not determined

Boiling point/Boiling range: Not determined

· Flash point: Not applicable

· Auto igniting: Product is not self igniting.

· Danger of explosion: Product does not present an explosion hazard.

· Density: Not determined

· Solubility in / Miscibility with

Water: Soluble

· pH-value: Not applicable

10 Stability and reactivity

· Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

· Materials to be avoided: Incompatible material: strong oxidizers.

· Dangerous reactions No dangerous reactions known

· Dangerous products of decomposition: Carbon monoxide (CO) and carbon dioxide (CO₂)

11 Toxicological information

· Acute toxicity:

· Primary irritant effect:

· on the skin: May cause irritation to skin and mucous membranes.

· on the eye: May cause irritation

· Sensitization: Sensitizing effect through inhalation is possible with prolonged exposure.

(Contd. on page 4)



Material Safety Data Sheet

acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Master Mix
(BD GeneOhm™ Strep B Assay)

(Contd. of page 3)

· Additional toxicological information:

The product is not subject to OSHA classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

· Ecotoxicological effects:

· Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

· General notes: *Generally not hazardous for water.*

13 Disposal considerations

· Product:

· Recommendation

Must not be disposed of with solid waste.

Must adhere to official regulations.

· Uncleaned packagings:

· Recommendation: *Disposal must be made according to state and federal regulations.*

· Recommended cleansing agent: *Water, if necessary with cleansing agents.*

14 Transport information

· DOT regulations:

· Hazard class: -

· Land transport ADR/RID (cross-border)

· ADR/RID class: -

· Maritime transport IMDG:

· IMDG Class: -

· Marine pollutant: *No*

· Air transport ICAO-TI and IATA-DGR:

· ICAO/IATA Class: -

· Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulations

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

(Contd. on page 5)



Material Safety Data Sheet
acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Master Mix
(BD GeneOhm™ Strep B Assay)

(Contd. of page 4)

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

99-20-7	trehalose
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9048-46-8	BSA
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· **California Proposition 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **California Proposition 65 - Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **Product related hazard information:**

Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations pertaining to regulations on hazardous materials.
This product has been classified according to the hazard criteria of the Controlled Products Regulations (CPR), and the MSDS contains all of the information required by the CPR.

· **National regulations**

· **Water hazard class:** Generally not hazardous for water.

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

· **Department issuing MSDS:**

Safety and Environment Department
MSDS created by Michael J. Spinazzola

· **Contact:** Customer Service Representative



Material Safety Data Sheet

acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

1 Identification of substance:

- **Product name:** Lysis Tube
(BD GeneOhm™ Strep B Assay)
- **Catalog number:** 441240
- **Manufacturer/Supplier:**
BD Diagnostics
2050 boul. René-Lévesque O., 4^e étage,
Ste-Foy, Québec, Canada G1V 2K8
- **Information department:** Customer Service
- **Emergency information:**
In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostics, at (888) 436-3646, or ChemTrec at (800) 424-9300.

2 Composition/Data on components:

- **Chemical characterization**
- **Description:** Mixture consisting of the following components.
- **Dangerous components:** Void

3 Hazards identification

- **Hazard description:**
This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200, the Canada's Workplace Hazardous Materials Information System (WHMIS) and the European Directive 91/155/EEC, and 93/112/EC.
- **Classification system**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

4 First aid measures

- **General information** No special measures required.
- **After inhalation**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Seek medical advice.
In case of unconsciousness place patient on side position for transportation.
- **After skin contact**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** Seek immediate medical advice.
- **Information for doctor** Show this product label or this MSDS.

CDN

(Contd. on page 2)



Material Safety Data Sheet

acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Lysis Tube
(BD GeneOhm™ Strep B Assay)

(Contd. of page 1)

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, ABC multipurpose dry chemical or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Protective equipment:**
Wear fully protective suit.
Use respiratory protective device.

6 Accidental release measures

- **Person-related safety precautions:**
Ensure adequate ventilation
Use respiratory protective device.
Wear protective clothing.
- **Measures for environmental protection:** Wipe up with damp sponge or mop.
- **Measures for cleaning/collecting:** No special measures required.
- **Additional information:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Information for safe handling:** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Storage**
- **Requirements to be met by storerooms and receptacles:** 2 - 30 C
- **Information about storage in one common storage facility:** Store away from oxidizing agents.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.

8 Exposure controls and personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Personal Protective Equipment**
- **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure, use a chemical fume hood or a NIOSH/MSHA-approved respirator.

(Contd. on page 3)

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Lysis Tube
(BD GeneOhm™ Strep B Assay)

(Contd. of page 2)

· **Protection of hands:**



Chemical resistant gloves (i.e. nitrile, or equivalent).

· **Eye protection:** Safety glasses

· **Body protection:** Protective work clothing (lab coat).

9 Physical and chemical properties:

· **General Information**

Form:	Solid.
Color:	Clear
Odor:	Characteristic

· **Change in condition**

Melting point/Melting range: Not determined

Boiling point/Boiling range: Not determined

· **Flash point:** Not applicable

· **Auto igniting:** Product is not self igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density:** Not determined

· **Solubility in / Miscibility with**

Water: Insoluble

· **pH-value:** Not applicable

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

· **Materials to be avoided:** Incompatible material: strong oxidizers.

· **Dangerous reactions** No dangerous reactions known

· **Dangerous products of decomposition:** No dangerous decomposition products known.

11 Toxicological information

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** May cause irritation to skin and mucous membranes.

· **on the eye:** May cause irritation

· **Sensitization:** No sensitizing effects known.

(Contd. on page 4)



Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Lysis Tube
(BD GeneOhm™ Strep B Assay)

(Contd. of page 3)

· Additional toxicological information:

The product is not subject to OSHA classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

· Ecotoxicological effects:

· Other information:

The ecological effects have not been thoroughly investigated, but currently none have been identified.

· General notes: *Generally not hazardous for water.*

13 Disposal considerations

· Product:

· Recommendation

Smaller quantities can be disposed of with solid waste.

Must adhere to official regulations.

· Uncleaned packagings:

· Recommendation: *Disposal must be made according to state and federal regulations.*

· Recommended cleansing agent: *Water, if necessary with cleansing agents.*

14 Transport information

· DOT regulations:

· Hazard class: -

· Land transport ADR/RID (cross-border)

· ADR/RID class: -

· Maritime transport IMDG:

· IMDG Class: -

· Marine pollutant: *No*

· Air transport ICAO-TI and IATA-DGR:

· ICAO/IATA Class: -

· Transport/Additional information:

If a dashed line appears in the Hazard Class section for the type of transportation, this indicates the product is not regulated for transportation.

15 Regulations

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

(Contd. on page 5)



Material Safety Data Sheet
acc. to ISO/DIS 11014

Date Prepared: 08/27/2007

Reviewed On: 08/22/2007

Product name: Lysis Tube
(BD GeneOhm™ Strep B Assay)

(Contd. of page 4)

· SARA Section 313 (specific toxic chemical listings)

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act)

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause cancer

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· California Proposition 65 - Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenicity categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· Product related hazard information:

Observe the general safety regulations when handling chemicals

The product is not subject to identification regulations pertaining to regulations on hazardous materials.

This product has been classified according to the hazard criteria of the Controlled Products Regulations (CPR), and the MSDS contains all of the information required by the CPR.

· National regulations

· Water hazard class: Generally not hazardous for water.

16 Other information:

To the best of our knowledge, the information contained herein is accurate. However, neither Becton, Dickinson and Company or any of its subsidiaries assumes any liabilities whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

· Department issuing MSDS:

Safety and Environment Department

MSDS created by Michael J. Spinazzola

· Contact: Customer Service Representative