



Material Safety Data Sheet

Effective Date: April 22nd, 2009

Supersedes: Feb 9th, 2009

Biothreat 3-Agent Assay

For Biothreat 3-Agent Assay:

1. Product and Company Information

Product name: Biothreat 3-Agent Assay

Synonyms: Not applicable

Cepheid part numbers: 700-2261, 700-2272

Applied Biosystems part numbers: 4368791, 4368791

Distributed by:

Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Manufactured by:

Applied Biosystems
850 Lincoln Centre Drive
Foster City, CA 94404
USA

Emergency Tel. No: 1-888-838-3222 (Technical Support)

* This Material Safety Data Sheet is for the use of customers only; for hazards in the manufacture of this product, consult MSDSs for the ingredients.

2. Composition/Information on Ingredients

This product is composed of 3 Reagents, each containing a proprietary buffered detection system contained on a bead / pellet, to which an aqueous solution is added as part of the assay.

With the exception of bovine serum albumin (Chemical Abstract Service # 9048-46-8, EINECs Number 232-936-2) (1-2%), all other ingredients are not considered hazardous or dangerous at the concentrations contained in the product.

During its use (i.e., when in aqueous solutions), the ingredients in Reagents 1, 2 and 3 meet the above criteria (not at concentrations that are considered dangerous or hazardous).



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3. Hazard Identification

EMERGENCY OVERVIEW

Based on percentages of hazardous ingredients in this product, this product is not classified as hazardous under US OSHA Hazard Communication regulations or “dangerous” under EU Directives. As contained in cartridges they do not present a health or safety hazard. If the cartridges are broken or contents of cartridges are spilled or released, the product if contacted may cause mild reversible irritation of the skin and eyes. Avoid skin and eye contact

Acute: If contents of cartridge(s) are released, contact may cause mild reversible skin and eye irritation. If accidentally ingested, not expected to be an acute hazard.

Chronic: Not expected to be a chronic hazard based on percentage of hazardous ingredients.

Reproductive, Developmental, Mutagenicity and Carcinogenicity: None of the ingredients contained in the products are considered reproductive, developmental, mutagenic or carcinogenic hazards. None of the ingredients are listed by NTP, IARC or OSHA as a carcinogen.

Occupational Exposure Limits: None of the ingredients or the product itself has Occupational Exposure Limits currently established by OSHA, ACGIH, or Cepheid.

Medical Conditions Aggravated by Exposure: None known or reported.

Target Organs: Not applicable

4. First Aid Measures/Routes of Entry

Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes. If an irritation develops, notify medical personnel and supervisor.

Skin Contact: Immediately wash thoroughly with soap and water for 15 minutes. If an irritation develops, notify medical personnel and supervisor.

Inhalation: Immediately move to fresh air and notify medical personnel and supervisor.



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Accidental Ingestion: Drink a moderate amount (8-12 oz. or 250 ml) of water and immediately notify medical personnel and supervisor.

5. Fire and Explosion Data

Flashpoint: Not applicable

Upper and Lower flammable limits: Not applicable

Flammable classification: Not applicable

General fire hazard information: Not applicable

Explosion Hazards: Not applicable

Extinguishing media: Will not be expected to burn based on water content. If contents are dried out and burning, use water jets, mist, foam, carbon dioxide or other dry agents.

Fire fighting equipment: If contents are broken and contents are allowed to dry out, may give off very small quantities of carbon and nitrogen oxides. Wear breathing apparatus and protective clothing.

6. Accidental Release Measures

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment (at a minimum an overgarment such as a lab coat, and gloves). Soak up material with absorbent, e.g., paper towels, and wash spill area thoroughly with soap and water. Alternatively, use an industrial vacuum cleaner equipped with a high efficiency particulate filter. Dispose of collected material in accordance with applicable waste disposal regulations.

7. Handling and Storage

Store in a cool and dry location.

8. Exposure Control/Personal Protection

Engineering Controls: Use in enclosed equipment as per kit directions.



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Respiratory Protection: Not normally required. If the material is spilled or released, base the choice of protection on the job activity and the potential for inhalation of mists.

Skin Protection: Protective gloves are recommended to minimize potential for skin contact when handling. Wear long sleeves and other protective overgarment, such as a lab coat. Base the choice of protection on the job activity and potential for skin contact.

Eye Protection: Wear safety glasses with side shields. If the material is spilled or released, base the choice of protection on the job activity and potential for contact with eyes or face.

Exposure Guidelines: No occupational exposure limits established

Other: Wash hands, face and other potentially exposed areas immediately after handling material (especially before eating, drinking, or smoking). Decontaminate all protective equipment after use.

9. Physical and Chemical Properties⁽¹⁾

Appearance: Each reagent is a powder bead in aqueous solution

Odor: None

pH: No data identified.

Boiling Pt./range: >100°C.

Melting Pt./range: Not applicable

Flash point: Not determined (aqueous solution)

Flammability: Not expected to be flammable

Explosive properties: Not expected to be explosive

Vapor pressure: Not determined

Relative density: Not determined

Solubility: Water - No data identified

Other solvents - No data identified

Partition coefficient⁽²⁾: Log P_o (Octanol/water) = not determined

10. Stability and Reactivity

Conditions to avoid: None known.

Materials to avoid: Not determined.

Hazardous decomposition products: Not determined.



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Stability: Stable under ordinary conditions of use and storage.

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Acute effects: This formulation has not been tested. Based on its components, it is not classified as hazardous under US OSHA hazard communication or “dangerous” under EU regulations. However, since it has not been fully tested, precautions should be taken to avoid exposure.

Chronic effects: No known chronic effects.

12. Ecological Information

This formulation has not been tested for its ecotoxicological effects, mobility, persistence and degradability in the environment and bioaccumulation potential. Therefore, avoid discharge to water systems.

13. Disposal Considerations

All wastes containing the material should be properly labeled. Dispose of any waste according to prescribed federal, state, national and local guidelines.

14. Transport Information

Proper DOT Shipping Name: Not classified as dangerous for transport

UN No.: None

Symbol: None

Hazard Class: None

ADR/RID Item No: None

IATA/DGR limits: None

IMDG/IMO Code: None



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15. Regulatory Information

California Proposition 65: **This product does not contain chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.**

National Inventory Status (TSCA): Not listed on inventory. This product is sold only for use with the Cepheid GeneXpert® Detection System for environmental detection of designated microbial agents.

SARA 302: Not Applicable

SARA 313: Not Applicable

For R&D consumers, products are to be used only for R&D purposes.

16. Other Information

References: (1) In-house files.

(2) Annex I to Dangerous Substance Directive 67/548/EEC

The format of this Safety Data Sheet conforms to the requirements of US ANSI/CMA guidelines and EC Directive 91/155/EEC.

Disclaimer: *Although reasonable care has been taken in the preparation of this document to assess and summarize the hazard properties of the product, the user must satisfy himself that the information contained herein is pertinent to permit safe handling under his use conditions, since the supplier cannot foresee all conditions of use. The information contained herein is not intended as a product specification.*

For Biothreat Reagent 1:

1. Product and Company Information

Product name: Biothreat Reagent 1

Common name: Sodium Hydroxide Solution, 1.0 N

Compound name: NaOH in H₂O

Manufacturer:

Telephone Numbers:



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Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

(888) 838-3222
24-Hour Emergency Telephone:
CHEMTREC (800) 424-9300

2. Composition/Hazardous Ingredients

This product consists of an aqueous solution of sodium hydroxide in a bottle.

HAZARDOUS INGREDIENTS:

CAS#	Chemical Name	OSHA PEL
1310-73-2	Sodium Hydroxide, 4%	2 mg/m ³

3. Hazards Identification

Emergency Overview

Corrosive. Causes burns. Harmful if swallowed.
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POTENTIAL HEALTH EFFECTS:

Eye: May cause eye irritation.

Skin: May cause skin irritation.

Ingestion: May cause gastrointestinal discomfort

Inhalation: May cause irritation of the respiratory tract.

Chronic: No information found.

NFPA Hazard Rating: Health 3; Flammability 0; Instability: 1

4. First Aid Measures

Eye: Flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Get medical advice if irritation persists.



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- Skin:** Flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes, wash before reuse. Get medical advice if irritation develops or persists.
- Ingestion:** If swallowed, wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do not induce vomiting.
- Inhalation:** Remove to fresh air and get medical attention for any breathing difficulty.

5. Fire Fighting Measures

Extinguishing Media: Dry chemical. Do not use water.

Flash Point: Not available.

Auto-ignition Temperature: Not available.

Explosion: Not considered an explosion hazard.

Explosion Limits, Upper: Not available.

NFPA Rating: Health: 3; Flammability: 0; Instability: 1

Firefighting: Emits toxic fumes under fire conditions. Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. Accidental Release Measures

Use proper personal protective equipment as indicated in Section 8. Absorb with inert material. Place residues in a suitable container for waste disposal. After removal, ventilate contaminated area and flush thoroughly with water.

7. Handling and Storage

Use with adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion. Keep container tightly closed and store away from incompatible substances (acids and metals). Do not reuse container. Container may be hazardous when empty.

8. Exposure Controls/Personal Protection

Exposure Limits: OSHA PEL 2 mg/m³.



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PERSONAL PROTECTIVE EQUIPMENT:

- Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles.
- Skin:** Wear appropriate protective gloves to prevent skin exposure. Wash hands in case of contact.
- Respirators:** Depending on actual exposure conditions, use of a respirator in accordance with 29 CFR 1910.134 may be necessary.
- Ventilation:** A system of local or general exhaust is recommended.
- Work Practices:** Facilities storing or using this product should be equipped with an eyewash station and a safety shower.

9. Physical and Chemical Properties

Appearance: Bottle containing clear solution.
Physical State: Liquid.

- Odor:** Odorless.
- Vapor Pressure:** Not available.
- Evaporation Rate:** Not available.
- Boiling Point:** Not available.
- Decomposition Temperature:** Not available.
- Specific Gravity/Density:** Not available.
- Molecular Weight:** 40 AMU.
- pH:** >12.
- Vapor Density:** Not available.
- Viscosity:** Not available.
- Freezing/Melting Point:** Not available.
- Solubility:** Not applicable.
- Molecular Formula:** NaOH in H₂O.

10. Stability and Reactivity

- Chemical Stability:** Stable under normal temperatures and pressures.
- Conditions to Avoid:** Absorbs CO₂ from air. Heat.
- Incompatibilities with Other materials:** Acids, organic materials, chlorinated solvents, aluminum, phosphorus, tin/tin oxides, zinc.
- Hazardous Decomposition Products:** Sodium/sodium oxides.
- Hazardous Polymerization:** Will not occur.

11. Toxicological Information

CAS #	Name	LD50/LC50	Carcinogenicity
1310-73-2	Sodium Hydroxide	40 mg/kg (mouse intraperitoneal)	NTP - No



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		500 mg/kg (rabbit oral)	
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(Only select data presented here. See Registry of Toxic Effects of Chemical Substances database for complete information.)

12. Ecological Information

Ecotoxicity: No data found.

Environmental Fate: No data found.

13. Disposal Considerations

Dispose of in accordance with all federal, state, and local waste regulations.

14. Transport Information

Proper shipping name: Sodium hydroxide solution

UN#: 1824

Class: 8

Packing group: II

Hazard label: Corrosive

15. Regulatory Information

CAS#	Name	CERCLA RQ	SARA 302 EHS	SARA 313
1310-73-2	Sodium Hydroxide	1000 lb.	No	No

For R&D consumers, products are to be used only for R&D purposes.

16. Other Information

Cepheid makes no warranties as to the accuracy or completeness of this information and disclaims any liability in connection with its use. Cepheid's obligations shall be only as set forth in Cepheid's standard terms and conditions of sale for this product. In no case will Cepheid be liable for any incidental, indirect or consequential damages arising out of the sale, resale, use or misuse of the product.



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For Biothreat 3-Agent Reagent 2:

1. Product and Company Information

Product name: Biothreat 3-Agent Buffer 2

Common name: Not applicable

Compound name: Not applicable

Cepheid part numbers: 700-2193; 900-0377

Company: Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Emergency Tel. No: 1-888-838-3222 (Technical Support)

Manufactured for Applied Biosystems by American Biological Technologies, Inc.
Distributed by Cepheid.

2. Composition/Information on Ingredients

This product is a proprietary mixture composed >99 % water.
Product contains sodium azide at a concentration below threshold amounts for reporting according to US OSHA hazard communication regulations (1%), but at a concentration that should be considered for disposal and other environmental considerations.

3. Hazard Identification

Emergency Overview

This material does not meet the definition of a hazardous material as defined by US Federal OSHA, 29 Code of Federal Regulations, 1910.1200, Hazard Communication Standard



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POTENTIAL HEALTH EFFECTS:

Skin contact: Prolonged but constant contact with liquid may cause a reversible mild irritation and dermatitis.

Eye contact: Prolonged but constant contact with liquid may cause reversible eye irritation resulting in redness and watering.

Inhalation: Inhalation should not present a significant hazard as hazardous ingredients are not present at concentrations > 1% . .

Ingestion: Excessive ingestion of liquid form can cause gastric distress and mild diarrhea.

Medical Conditions Aggravated By Exposure: None known or reported.

Target Organs: Not considered to affect target organs as not considered hazardous under US OSHA regulation.

4. First Aid Measures/Routes of Entry

Skin contact: Wash with soap and water. If an irritation develops, contact medical personnel.

Eye contact: Immediately flush eyes with plenty of water. If an irritation develops, contact medical personnel.

Inhalation: Remove to fresh air, seek medical attention if symptoms persist.

Ingestion: Drink a small amount of water. If symptoms develop, contact medical personnel.

5. Fire and Explosion Data

Flashpoint: Not applicable

Upper and Lower flammable limits: Not applicable

Flammable classification: Not applicable

General fire hazard information: Not applicable

Explosion hazards: Not applicable



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Extinguishing media: Use extinguishing media appropriate for surrounding fire.
Fire fighting equipment: Firefighters should wear self-contained breathing apparatus for surrounding fire with a full-face piece operated in the positive pressure demand mode when fighting fires.

6. Accidental Release Measures

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment (at a minimum an overgarment such as a lab coat, and gloves). Soak up material with absorbent, e.g., paper towels or spill pillows, and wash spill area thoroughly with soap and water. Dispose of collected material in accordance with applicable waste disposal regulations.

7. Handling and Storage

Avoid contact with skin, eyes or clothing. Store in a cool and dry location.

8. Exposure Control/Personal Protection

Engineering Controls: Use in enclosed equipment as per kit directions.

Respiratory Protection: Not normally required. If the material is spilled or released, base the choice of protection on the job activity and the potential for inhalation of mists.

Skin Protection: Protective (nitrile or rubber) gloves are recommended to minimize potential for skin contact when handling. Wear long sleeves and other protective overgarment, such as a lab coat. Base the choice of protection on the job activity and potential for skin contact.

Eye Protection: Wear safety glasses with side shields. If the material is spilled or released, base the choice of protection on the job activity and potential for contact with eyes or face.

Other: Wash hands, face and other potentially exposed areas immediately after handling material (especially before eating, drinking, or smoking). Decontaminate all protective equipment after use.



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9. Physical and Chemical Properties

Appearance: Clear liquid
Specific Gravity (Water = 1): Not available
Odor: None known
Evaporation Rate: Not available
Physical State: Liquid
Water/Oil Partition Coefficient: Not available
Boiling Point: Not available
Freezing point: Not available
Vapor Pressure: Not available

pH: 8.0
Density: Not available
Volatility: Not available
Solubility: Not available
Odor Threshold: Not available

10. Stability and Reactivity

Stability: Stable
Conditions to Avoid: Exposure to direct current electricity. Strong acids and bases can cause rapid heating. Reaction with sodium metal can result in explosion.
Materials to Avoid: Incompatible with oxidizing materials, and may produce toxic fumes upon decomposition.
Hazardous Polymerization: Will not occur.

11. Toxicological Information

LD₅₀/LC₅₀: Not available
Effects of Acute Overexposure: None known
Effects of Chronic Overexposure: None known

Sensitization of Material: None known
Carcinogenicity: None of the ingredients which are present at equal to or greater than 0.1% of the product, are listed by OSHA, NTP, or IARC as suspect carcinogens.
Reproductive Toxicity: None reported
Teratogenicity: None reported
Mutagenicity: None reported
Toxicologically Synergistic Products: None reported



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12. Ecological Information

Environmental Fate: No data for product.

Environmental Toxicity: No data for product. Product contains a low concentration (=0.05%) of sodium azide, which is toxic to the environment.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be flushed to sewer in compliance with the facility permit and local regulation. If material becomes contaminated during use, dispose of accordingly. Use appropriate methods based on federal and provincial statutes and

regulations and local by-laws. Contact local environmental agency for specific rules and instruction.

14. Transport Information

The transport of this product is not regulated or restricted.

Proper DOT Shipping Name: Not applicable/ Not regulated

DOT Hazard Classification: Not applicable/Not regulated

15. Regulatory Information

California Proposition 65: This product does not contain chemicals known to the state of California to cause cancer, birth defects, or other reproductive harm.

TSCA: All applicable chemicals in this product are listed under the TSCA chemical inventory.

SARA 302: Not Applicable. A small amount of sodium azide is present. The amount should be well below the reportable quantity (1000 lbs) but should be taken into consideration in facilities with multiple sources of azide.

SARA 313: Not Applicable. Sodium azide is below the de minimus concentration for SARA 313 reporting.

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