



**Material Safety Data Sheet**  
Effective Date: May 26<sup>th</sup>, 2011  
Supersedes: September 8<sup>th</sup>, 2010

Xpert *C. difficile*/Epi  
Xpert *C. difficile*

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## 1. Identification of the Material and Company/Undertaking

**Product name:** Xpert *C. difficile*/Epi Catalog #: GXCDIFF/EPI-10  
Catalog #: RCDIFFICILE-10  
Xpert *C. difficile* Catalog #: GXCDIFFICILE-10  
Catalog #: GXCDIFFICILE-120  
Catalog #: GXCDIFFICILE-CE-10

**Common name:** Not applicable  
**Compound name:** Not applicable

**Manufacturer:**  
Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA

Cepheid AB  
Röntgenvägen 5  
SE-171 54 Solna  
Sweden

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Outside of the US: 1 (703) 741-5500  
**US E-mail:** techsupport@cepheid.com  
**EU E-mail:** techsupport@cepheideurope.fr

The following MSDS is for the final finished product only as used in the laboratory that contains six (6) components, some of which are in cartridges. If manufacturing this product, consult the MSDSs for the individual ingredients and reagents.

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## 2. Hazards Identification

**Appearance:** Reagents On Board Products:  
This product contains 6 components – 5 of the components (3 beads, which are freeze-dried white powders, and 2 clear, colorless liquid reagents) are contained in cartridges. The other component is a reagent that is a clear, colorless liquid that is contained in a vial.

Reagents Off Board Products (Reagents 1 & 2 in ampoules):  
This product contains 6 components – 3 of the components (beads, which are freeze-dried white powders) are contained in cartridges. The other three components are reagents that are liquids that are clear, colorless liquids.



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**Signal Word:**           **DANGER for handling of:**  
Reagent 2 containing Sodium Hydroxide

**CAUTION for handling of** all other kit components

**Hazard Overview:**   **Reagent 2 contains 0.5 N Sodium Hydroxide solution, which is a CORROSIVE LIQUID. Causes burns to skin and eyes if directly contacted. Causes irritation to mucous membranes and respiratory tract if inhaled.** For Reagents On Board Products, Reagent 2 is contained in the cartridge; for Reagents Off Board Products, Reagent 2 is contained in an ampoule.

**Bead components (Bead 1, Bead 2, Bead 3) are contained in cartridges and will not present a hazard under normal use conditions; if cartridge is broken or damaged and beads are spilled or released, contact may cause reversible skin and eye irritation.**

**Sample Reagent contains guanidine thiocyanate which is considered toxic to the aquatic environment.**

**Reagent 1 is not considered hazardous under US hazard communication regulations (29 CFR 1910.1200), EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.** For Reagents On Board Products, Reagent 1 is contained in the cartridge; for Reagents Off Board Products, Reagent 1 is contained in an ampoule.

### Statement of Known

**Hazard:**               **Reagent 2 is a CORROSIVE LIQUID.** Avoid skin contact, eye contact and inhalation. Wear eye protection and skin protection to avoid contact.

**Sample Reagent is a hazard to the aquatic environment.** Dispose of according to local, state and federal regulations.

Other components of this product would not be considered hazardous under normal conditions of use.



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**EU Indicator of Danger: Reagent 2 – C (Corrosive)**

**Sample Reagent – Xn; N (Harmful; Dangerous to the environment)**

**All other components of this product: Not applicable**

**EU Risk Phrases: Reagent 2 – R34 Causes Burns.**

**Sample Reagent – R 32** Contact with acids liberates very toxic gas

**R 52/53** Harmful to the aquatic environment; may cause long-term effects to the aquatic environment

**All other components of this product: Not applicable**

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### 3. Composition Information on Ingredients

This product consists of a cartridge with three reagent beads to which aqueous reagents are added as part of an assay.

**Bead 1** is a freeze-dried powder bead as contained in the cartridge with the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
HEPES Acid and Salt	7365-45-9 (For Acid)	230-907-9 (For Acid)	<5	R36/37/38
Magnesium Chloride	7786-30-3	232-094-6	<5	R36/37/38
Bovine Serum Albumin	9048-46-8	232-936-2	<3	R42

All other ingredients of Bead 1 are either non-hazardous under US and EU regulations or GHS guidelines and/or at concentrations less than 1% in the mixture.

**Bead 2** is a freeze-dried powder bead as contained in the cartridge with the following hazardous ingredients:



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Magnesium Chloride	7786-30-3	232-094-6	<5	R36/37/38
HEPES Acid and Salt	7365-45-9 (For Acid)	230-907-9 (For Acid)	<5	R36/37/38
Bovine Serum Albumin	9048-46-8	232-936-2	<3	R42

All other ingredients of Bead 2 are either non-hazardous under US and EU regulations or GHS guidelines and/or at concentrations less than 1% in the mixture.

**Bead 3** is a freeze-dried powder bead as contained in the cartridge with the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
HEPES Acid and Salt	7365-45-9 (For Acid)	230-907-9 (For Acid)	<10	R36/37/38

All other ingredients of Bead 3 are either non-hazardous under US and EU regulations or GHS guidelines and/or at concentrations less than 1% in the mixture.

**Reagent 1** contains ingredients that are either considered non-hazardous under US and EU regulations or GHS guidelines and/ or at concentrations less than 1% in the mixture.

**Reagent 2** contains the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Sodium Hydroxide	1310-73-2	215-185-5	2%	R34 (for 2% solution)

**Sample Reagent** contains the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Guanidine thiocyanate	593-84-0	209-812-1	20-30	R20/21/22/32/52/53

All other ingredients in Sample Reagent are either non-hazardous under US and EU regulations or GHS guidelines and/or at concentrations less than 1% in the mixture.



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## 4. First Aid Measures

**For Reagent 2** containing sodium hydroxide:

- Eye:** Flush thoroughly with water and notify supervisor and EHS personnel. Get medical aid.
- Skin:** Flush thoroughly with water and notify supervisor and EHS personnel. Get medical attention.
- 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 unless directed to do so by medical personnel.
- Inhalation:** Remove to fresh air and get medical attention for any breathing difficulty.

**For all other parts of the kit if contacted:**

- Eye:** Flush thoroughly with water and notify supervisor and EHS personnel. If an irritation develops, get medical aid.
- Skin:** Flush thoroughly with water and notify supervisor and EHS personnel. If an irritation develops, get medical attention.
- 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 unless directed to do so by medical personnel.
- Inhalation:** Remove to fresh air and get medical attention for any breathing difficulty.

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## 5. Fire Fighting Measures

- Flammability/Explosivity:** None of the components of the kit are considered flammable or explosive.
- Extinguishing Media:** CO<sub>2</sub>, multipurpose dry chemical or vaporizing liquid fire extinguisher.

**Special Fire Fighting Procedures:**

Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode for surrounding fire. Decontaminate all equipment after use.

**Hazardous Decomposition Products:**

**Sample Reagent** may emit small quantities of cyanide in a fire.



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## 6. Accidental Release Measures

### For all components if spilled:

If product/material is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment. For small spills, wear gloves and absorb spill with paper towel. **For small spills of Reagent 2 containing sodium hydroxide, avoid skin and eye contact by using rubber or nitrile gloves and wearing of eye protection to avoid contact.** Dispose of material according to local, State and Federal waste disposal regulations (see Section 13).

For larger spills, wear personal protective clothing to minimize exposure such as overgarment, gloves and eye protection (goggles), cover spill with absorbent material. **For larger spills of Reagent 2 containing sodium hydroxide, wear overgarment and personal protective equipment to avoid skin contact including goggles and rubber or nitrile gloves.** Collect spilled material, absorbent, and rinse waters into suitable containers for proper disposal in accordance with applicable local, state or Federal waste disposal regulations (see Section 13).

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## 7. Handling and Storage

**Handling Precautions:** Avoid skin contact, eye contact and inhalation.

**Storage Requirements:** Store according to product labeling.

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## 8. Exposure Controls/Personal Protection

### Occupational Exposure

**Limits:** **Reagent 2** contains sodium hydroxide which has ACGIH TLV and NIOSH REL of 2 mg/m<sup>3</sup> as a ceiling value not to be exceeded for any 15-minute period and an OSHA 8-hour time weighted average of 2 mg/m<sup>3</sup>. None of the other ingredients contained in this product have occupational exposure limits established by OSHA, NIOSH, ACGIH or Cepheid.

**Engineering Controls:** None normally required. When practicable, handle material in enclosed or contained processes or in processes with effective local exhaust ventilation.

**Eye Protection:** Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face.



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**Respiratory Protection:** When possible, handle material in enclosed processes or containers. If it is properly handled with effective ventilation or containment, respiratory protection should not be needed.

**Skin Protection:** Rubber gloves are recommended to minimize potential for skin contact. In laboratory setting, wear lab coat or other protective overgarment at a minimum to minimize skin contact. Base the choice of protection on the job activity and potential for skin contact.

**Other:** Facilities storing or using this product should be equipped with an eyewash station and a safety shower. 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

**Physical State:** Beads are solid components in cartridges; reagents are liquids which are primarily buffered aqueous solutions.

**Odor:** Components are odorless.

**Vapor Pressure:** Minimal.

**Evaporation Rate:** Minimal.

**Viscosity:** Reagents are aqueous.

**Boiling Point:** Liquid reagents near 100 degrees C .

**Freezing/Melting Point:** Liquid reagents near 0 degrees C

**Solubility:** Reagents are already aqueous; beads are soluble in aqueous solutions

**pH:** >12.5 (**Reagent 2**); 6.6 – 8.6 (Solids & Other liquid reagents)

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## 10. Stability and Reactivity

**Chemical Stability:** Stable under normal temperatures and pressures.

**Conditions to Avoid:** Incompatible materials.

**Incompatibilities with Other materials:** Strong oxidizing agents, peroxides, strong acids and bases, acid chlorides, acid anhydrides, alkali metals, ammonia.

**Hazardous Decomposition Products:** Carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, sodium oxides, potassium oxides, hydrogen chloride, cyanide.

**Hazardous Polymerization:** Will not occur.



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## 11. Toxicological Information

**Acute Toxicity:** The cartridges containing freeze-dried powders should not present an acute toxicity hazard unless the beads are released or spilled. Magnesium chloride has low to moderate acute toxicity with oral LD50 of 2800 mg/kg in the rat. Sodium hydroxide is acutely toxic orally due to its corrosivity. Guanidine thiocyanate has an acute oral LD50 of 593 mg/kg.

**Irritation/Sensitization:** HEPES Salt and HEPES acid are considered skin and eye irritants. Bovine serum albumin, as a foreign protein is considered a potential allergen but because it is contained in the bead within the cartridge, the potential to cause an allergic reaction under normal use conditions is considered low.

**Repeated dose toxicity** – No data identified on ingredients.

**Reproductive (fertility) and Developmental (birth defects) toxicity** – No data identified. None of the ingredients are considered reproductive or developmental toxicants.

**Mutagenicity and Carcinogenicity** – No data identified on mutagenicity. None of the ingredients are listed by NTP, IARC or OSHA as carcinogens.

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## 12. Ecological Information

**Ecotoxicity:** Of the ingredients, guanidine thiocyanate is considered harmful to aquatic organisms. As sodium hydroxide adjusts pH, it has the potential to have harmful effects in the environment if not properly disposed of.

**Environmental Fate:** No data identified.

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## 13. Disposal Considerations

Biological specimens, including used cartridges, should be treated as capable of transmitting infectious agents. Consult your institution's environmental waste personnel on proper disposal of used cartridges and unused reagents. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations. Institutions outside the USA should check their country hazardous waste disposal requirements.

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## 14. Transport Information

Transport in accordance with all federal, state, and local transportation regulations.

With the exception of Reagent 2, all of the other components are not regulated by US DOT or IATA.

The transport classification of **Reagent 2 containing 0.5N Sodium Hydroxide** is:

**Class 8, Packing Group II, UN1824.**

Proper Shipping Name: Sodium Hydroxide Solution.

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## 15. Regulatory Information

**US OSHA:** This MSDS complies with the requirements under 29 CFR 1910.1200

**Two of the components of the kit require labeling under either or both of US and EU regulations and therefore labeling of this product should contain the following.**



**For Reagent 2** - Contains Sodium Hydroxide Solution

### DANGER

Causes burns.

Keep out of reach of children.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

EU Risk and Safety Phrases: R 34; S2/26/37/39/45



**For Sample Reagent** - Contains Guanidine Thiocyanate

### CAUTION

Contact with acids liberates very toxic gas.

Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

Avoid release to environment; refer to special instructions/Safety data sheets.

EU Risk and Safety Phrases: R 32; 52/53; S 61



LBL PN: 300-7645, Rev D

### Canada – WHMIS Classifications

Reagent 2 is a Corrosive – Class E according to WHMIS classification.

All other components are not classified according to WHMIS classification criteria.



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**California Proposition 65**

None of the ingredients are listed under California Proposition 65.

**SARA 313:** Not listed.

**CERCLA :** Sodium hydroxide has a reportable quantity limit of 1000 lbs; no other ingredients are regulated under CERCLA.

**RCRA:** Not listed.

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

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**16. Other Information**

No other data available.

Abbreviations:

- ACGIH: American Conference of Governmental Industrial Hygienists
- CAS#: Chemical Abstract Services Number
- CFR Code of Federal Regulations
- CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act
- DOT: Department of Transportation
- EINECS: European Inventory of New and Existing Chemical Substances
- EU: European Union
- GHS: Global Harmonization System
- IARC: International Agency for Research on Cancer
- IATA: International Air Transport Association
- OSHA: Occupational Safety and Health Administration
- NTP: National Toxicology Program
- RCRA: Resource Conservation and Recovery Act
- SARA: Superfund Amendments and Reauthorization Act
- TSCA: Toxic Substances Control Act

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