



Material Safety Data Sheet

Effective Date: November 11, 2009

Supersedes: June 22, 2009

Xpert EV

1. Identification of the Material and Company/Undertaking

Product name: Xpert EV Catalog #: GXEV-100N-10
Common name: Not applicable
Compound name: Not applicable

Manufacturer:
Cepheid
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Sunnyvale, CA 94089
USA

Telephone Numbers:
(888) 838-3222 (6 AM – 5 PM Pacific time US)
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The following MSDS is for the final finished product only as used in the laboratory that contains nine (9) components, some of which are in cartridges. If manufacturing this product, consult the MSDSs for the individual ingredients and reagents.

2. Hazards Identification

Appearance: This product contains 9 parts – 5 of the parts are beads, which are freeze-dried white powders and are contained in cartridges. Four components are reagents that are liquids that are clear, colorless liquids.

Signal Word: **DANGER for handling of:**
Binding Reagent containing Ethanol

CAUTION for handling of all other kit components

Hazard Overview: **Binding Reagent contains ethanol which is a FLAMMABLE LIQUID. Harmful by inhalation, in contact with skin, and if swallowed. Irritating to eyes, respiratory system and skin.**

Lysis Reagent contains guanidine thiocyanate which is considered harmful to the aquatic environment and may cause long-term adverse effects on the aquatic environment.

Wash Reagent and Elution Reagent each are not considered hazardous under US hazard communication regulations (29 CFR 1910.1200), EU directives for classification and labeling of substances



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or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

Bead components as contained in cartridges 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, and if repeatedly contact may cause an allergic skin reaction.

Statement of Known

Hazard:

Binding Reagent is a FLAMMABLE LIQUID. Avoid skin contact, eye contact and inhalation. Keep away from sources of ignition – No smoking. Wear eye protection and skin protection to avoid contact.

Lysis Reagent is potentially toxic to the aquatic environment and may cause adverse effects on the aquatic environment.

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

EU Indicator of Danger: Binding Reagent – F (Flammable)

Lysis Reagent – Xn; N (Harmful to the environment)

All other components of this product: Not applicable

EU Risk Phrases:

Binding Reagent R11 - Highly Flammable

R20/21/22 - Harmful by inhalation, in contact with skin or inhalation

R36/37/38 – Irritating to eyes, respiratory tract or skin

Lysis Reagent R32 – Contact with acid liberates very toxic gas.

R52/53 – Harmful to aquatic environment; may cause long-term adverse effects on 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 five 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)	<10	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:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
HEPES Acid and Salt	7365-45-9 (For Acid)	230-907-9 (For Acid)	<15	R36/37/38
Tween-20	9005-64-5	200-315-5	<3	R36/37/38

All other ingredients of the **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)	<15	R36/37/38
Bovine serum albumin	9048-46-8	232-936-2	<3	R42
Tween-20	9005-64-5	200-315-5	<3	R36/37/38



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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.

Bead 4 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
Bovine Serum Albumin	9048-46-8	232-936-2	<3	R42
Tween-20	9005-64-5	200-315-5	<3	R36/37/38

All other ingredients of the **Bead 4** are either non-hazardous under US and EU regulations or GHS guidelines and/or at concentrations less than 1% in the mixture.

Bead 5 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
Bovine serum albumin	9048-46-8	232-936-2	<3	R42

All other ingredients of **Bead 5** are either non-hazardous under US and EU regulations or GHS guidelines and/or at concentrations less than 1% in the mixture.

Lysis Reagent contains the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Guanidine thiocyanate	593-84-0	209-812-1	45-55	R20/21/22/32/52/53

All other ingredients of **Lysis 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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Binding Reagent contains the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Ethanol	64-17-5	200-578-6	35-40	R11- 20/21/22-36/38-67

The other ingredient in **Binding Reagent** is considered non-hazardous under US and EU regulations or GHS guidelines.

Wash Reagent and **Elution Reagent** each contain 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.

4. First Aid Measures

For all components:

- Eye:** Immediately flush eyes thoroughly with water and notify supervisor, EHS personnel and medical personnel.
- Skin:** Immediately flush thoroughly with water and notify supervisor, EHS and medical personnel.
- 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.

5. Fire Fighting Measures

- Flammability/Explosivity:** **Binding Reagent is a FLAMMABLE LIQUID.** All other components are not flammable or explosive in the physical form and concentration in each component.
- Extinguishing Media:** CO₂, multipurpose dry chemical or vaporizing liquid fire extinguishers are preferred extinguishing media to extinguish the flammable liquid used in case of a fire.
- 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:** **Lysis Reagent** may release small quantities of cyanide in case of a fire. Other components may release small quantities of oxides of carbon in case of 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 liquid products, 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, 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).

7. Handling and Storage

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

Storage Requirements: Store according to product labeling.

8. Exposure Controls/Personal Protection

Occupational Exposure

Limits:

Ethanol is an ingredient of **Binding Reagent** has the following exposure limits: OSHA PEL of 1000 ppm (1900 mg/m³) as an 8-hour time-weighted average and an ACGIH TLV of 1000 ppm. 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.

9. Physical and Chemical Properties

Physical State: Beads are solid components in cartridges; reagents are liquids.

Odor: Components are odorless.

Vapor Pressure: With exception of Binding Reagent containing ethanol, minimal.

Evaporation Rate: With exception of Binding Reagent containing ethanol, minimal.

Viscosity: Reagents are aqueous; beads are freeze dried powders.

Boiling Point: With exception of Binding Reagent containing ethanol, liquid reagent boiling point is 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: 5-7 (liquid reagents); 7-9 (solids)

10. Stability and Reactivity

Chemical Stability: Stable under normal temperatures and pressures.

Conditions to Avoid: See Warnings for Binding Reagent regarding flammability of this kit component.

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. 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 – Ethanol has been well-studied and is considered a liver toxicant and central nervous system depressant from repeated administration in laboratory animals and humans. No other data identified on ingredients in beads or liquid formulations.

Reproductive (fertility) and Developmental (birth defects) toxicity – Ethanol is considered a developmental toxicant in laboratory animals and humans when ingested. None of the other ingredients are considered reproductive or developmental toxicants.

Mutagenicity and Carcinogenicity – None of the ingredients are listed by NTP, IARC or OSHA as carcinogens.

12. Ecological Information

Ecotoxicity: Of the ingredients, guanidine thiocyanate is considered harmful to aquatic organisms.

Environmental Fate: Ethanol is degraded readily by microorganisms; the reported half-life of ethanol in surface water, e.g., a river, ranged from 6.5 to 26 hours. No other data available

13. Disposal Considerations

All wastes containing the components of the product should be properly labeled. Dispose of any waste residues according to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

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14. Transport Information

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

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

The transport classification of **Binding Reagent containing ethanol** is:

Class 3, Packing Group II, UN1993.



Proper Shipping Name: Flammable Liquid, n.o.s. (Contains Ethanol)

15. Regulatory Information



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

Certain 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:

Binding Reagent

		<p>DANGER – FLAMMABLE LIQUID (contains ethanol) Harmful by inhalation, in contact with skin or swallowed. Irritating to eyes, respiratory tract and skin. Keep away from sources of ignition – No smoking. Avoid skin contact, eye contact or inhalation</p> <p>EU Risk and Safety Phrases: R 11, 20/21/22; 36/37/38 S16; 24/25</p>
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Lysis Reagent

		<p>CAUTION (contains guanidine thiocyanate) Contact with acid liberates very toxic gas. Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment. Avoid release to the environment; Refer to special instructions/safety data sheets</p> <p>EU Risk and Safety Phrases: R 32; 52/53; S61</p>
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Canada – WHMIS Classifications

Binding Reagent is a Flammable Liquid – Class C according to WHMIS classification.

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



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California Proposition 65

Ethanol is listed under California Proposition 65 as a developmental toxicant but by ingestion only. None of the other ingredients are listed under California Proposition 65.

SARA 313: Not listed.

CERCLA : None of the ingredients are listed under CERCLA.

RCRA: None of the ingredients are listed under RCRA.

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

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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