



**Material Safety Data Sheet**  
Effective Date: May 3<sup>rd</sup>, 2011  
Supersedes: November 9<sup>th</sup>, 2010

*Xpert Flu*

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

**Product name:** Xpert Flu Catalog Numbers: GXFLU-10  
**Common name:** Not applicable GXFLU-CE-10  
**Compound name:** Not applicable

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

**Telephone Numbers:**  
US: (888) 838-3222 (6 AM – 5 PM Pacific time US)  
EU: +33.563.82.53.19  
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CHEMTREC (800) 424-9300  
Outside of the US: 1 (703) 741-5500  
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**EU E-mail:** [techsupport@cepheideurope.fr](mailto:techsupport@cepheideurope.fr)

The following MSDS is for the final finished product only as used in the laboratory that contains seven (7) 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:** This product contains 7 parts – 6 of the parts (3 beads, which are freeze-dried white powders, and 3 clear, colorless liquid reagents) are contained in cartridge. The other component is a reagent that is a clear, colorless liquid that is contained in an ampoule.

**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 hydrochloride which is considered harmful if swallowed and an eye and skin irritant.**

**Wash Reagent contains sodium azide, which at the concentration contained in the solution (<0.05%) is not considered acutely toxic, but**



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**it should be evaluated for its disposal as if allowed to accumulate in metal piping it has the potential to form explosive mixtures. Sodium azide also has the potential to be toxic to the aquatic environment; may cause long –term adverse effects on the aquatic environment.**

**Elution Reagent 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.**

**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** contains guanidine hydrochloride which is considered harmful if swallowed and a skin and eye irritant.

**Wash Reagent** contains sodium azide, which at the concentration contained in the product may liberate gas if contacting acids or if allowed to accumulate in metal piping cause an explosive reaction. It is also toxic to the aquatic environment and has potential to cause adverse effects on 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.

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

**Lysis Reagent – Xi; (Irritant) Xn (Harmful)**

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

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

**EU Risk Phrases: Binding Reagent R11 - Highly Flammable**



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**R20/21/22 - Harmful by inhalation, in contact with skin or swallowed**  
**R36/37/38 – Irritating to eyes, respiratory tract or skin**  
**Lysis Reagent R36/38 Irritant to skin and eyes**  
**Wash 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 three reagent beads to which aqueous reagents are added as part of an assay.

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

**EZR Bead** 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
Magnesium Chloride	7786-30-3	232-094-6	<5	R36/37/38
Tween 20	9005-64-5	200-315-5	<5	R36/37/38
Bovine Serum Albumin	9048-46-8	232-936-2	<3	R42

All other ingredients of the **EZR Bead** 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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**TSR Bead** 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
Magnesium Chloride	7786-30-3	232-094-6	<5	R36/37/38
Tween 20	9005-64-5	200-315-5	<5	R36/37/38
Bovine Serum Albumin	9048-46-8	232-936-2	<3	R42

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

**Elution Reagent** 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.

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

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Guanidine Hydrochloride	50-01-1	200-002-3	25-35	R22/36/37/38
Tween-20	9005-64-5	200-315-5	< 10	R36/37/38
Trizma Hydrochloride	1185-53-1	214-684-5	< 3	R36/37/38

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.

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

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Sodium Azide	26628-22-8	247-852-1	≤0.05	R 28-32-50/53

All other ingredients in **Wash 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 ingredients in **Binding 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 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.

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## 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.

**Wash Reagent** contains sodium azide which has the potential to react with copper, lead, brass, or solder in the plumbing system to form an accumulation of lead and/or copper azide which is potentially explosive.

**Extinguishing Media:**

CO<sub>2</sub>, 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:**

**Wash Reagent** may release small quantities of azide 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).

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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:

**Ethanol** is an ingredient of **Binding Reagent** has the following exposure limits: OSHA PEL of 1000 ppm (1900 mg/m<sup>3</sup>) as an 8-hour time-weighted average and an ACGIH TLV of 1000 ppm. **Sodium Azide** is an ingredient in **Wash Reagent** and has the following exposure limits: ACGIH TLV Ceiling of 0.29 mg/m<sup>3</sup> for all forms and ceiling 0.11 ppm as hydrazoic acid vapor; and NIOSH has a REL of 0.3 mg/m<sup>3</sup> for all forms. 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.

**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:** 6-9 (liquid reagents); 7-8 (solids)

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## 10. Stability and Reactivity

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

**Conditions to Avoid:** **Wash Reagent** contains sodium azide, which at the concentration contained in the product may liberate gas if contacting acids or if allowed to accumulate in metal piping cause an explosive reaction.

**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 LD<sub>50</sub> of 2800 mg/kg in the rat. Sodium azide is acutely toxic both by oral and dermal routes with an oral LD<sub>50</sub> values in the rat of 27 mg/kg and a dermal LD<sub>50</sub> in the rabbit of 20 mg/kg. Guanidine hydrochloride has an oral LD<sub>50</sub> of 475 mg/kg in the rat and 571 mg/kg in the mouse; it has a dermal LD<sub>50</sub> > 2 g/kg in the rabbit. Ethanol has low acute oral toxicity in laboratory animals with an oral LD<sub>50</sub> of 7060 and 3450 mg/kg in the rat and mouse, respectively. Tween-20 has low acute oral toxicity.

**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. Guanidine hydrochloride is a moderate eye irritant and a severe skin irritant in the rabbit. Trizma hydrochloride is an irritant to the skin, eyes, and mucous membranes.

**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. Administration of sodium azide has been shown to produce hypotension in laboratory animals and humans. Tween-20 has low repeated dose toxicity in laboratory animals. 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:**

Sodium azide has positive mutagenic properties, primarily due to its active azide group; the relevance of this result for human health is not fully known. None of the other ingredients are listed by NTP, IARC or OSHA as carcinogens.

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## 12. Ecological Information

**Ecotoxicity:** sodium azide is considered toxic 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

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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

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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.

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

	<p><b>CAUTION (Contains Guanidine Hydrochloride)</b>  <b>Irritating to eyes and skin.</b>  <b>Avoid skin and eye contact.</b></p> <p><b>EU Risk and Safety Phrases: R 36/38; S24/25</b></p>
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### Wash Reagent

		<p><b>CAUTION (Contains Sodium Azide)</b>  <b>Contact with acids liberates very toxic gas.</b>  <b>Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment.</b>  <b>Avoid release to the environment; Refer to special instructions/safety data sheets</b>  <b>EU Risk and Safety Phrases: R 32; 52/53; S61</b></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.

### 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.**

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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



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TSCA: Toxic Substances Control Act

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