



Material Safety Data Sheet

Effective Date: September 8th, 2010

Supersedes: February 2nd, 2010

Xpert BCR-ABL

1. Identification of the Material and Company/Undertaking

Product name:	Xpert BCR-ABL	Catalog Number: RBCR-100N-010
Common name:	Not applicable	BCR-100N-10
Compound name:	Not applicable	900-0436 900-0441 900-0464

Manufacturer:
Cepheid
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USA

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The following MSDS is for the final finished product only as used in the laboratory that contains ten (10) 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 10 parts – 4 of the parts (beads, which are freeze-dried white powders) are contained in cartridges. Five components are reagents that are liquids that are clear, colorless liquids. It also contains one empty vial.

Signal Word: **DANGER for handling of:**
Wash Reagent containing Ethanol and Guanidine thiocyanate

CAUTION for handling of all other kit components

Hazard Overview: **Wash 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. Wash Reagent also contains guanidine thiocyanate which is considered harmful to the aquatic environment and may cause long-term adverse effects on the aquatic environment.**



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Proteinase K solution in micro-vials contains Proteinase K, which is irritating to the skin, eyes, mucous membranes and respiratory tract and may cause allergic sensitization by inhalation.

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

Rinse Reagent contains sodium azide, which at the concentration contained in the solution (<0.1%) is not considered acutely toxic, but 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.

Lysis Reagent is considered an eye and skin irritant based on the ingredients

Bead components (Bead 1; Bead 2, Bead 3 and Bead 4) 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.

Statement of Known

Hazard:

Wash Reagent is a FLAMMABLE LIQUID and an environmental hazard to the aquatic environment. Avoid skin contact, eye contact and inhalation. Wear eye protection and skin protection to avoid contact. Dispose of according to local, state and federal regulations.

Proteinase K liquid may cause an allergic response if repeatedly contacted or inhaled. Avoid skin contact, eye contact and inhalation. Wear eye protection and skin protection to avoid contact.

Elution 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



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the aquatic environment. Dispose of according to local, state and federal regulations.

Rinse 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

Lysis Reagent is considered an eye and skin irritant. Avoid eye and skin contact. Wear appropriate personal protective equipment including gloves, lab coat and safety glasses with side shields as a minimum.

EU Indicator of Danger: **Wash Reagent – F, Xn; N** (Flammable; Harmful; Dangerous to the environment)

Proteinase K – Xi (Irritant; Sensitizer)

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

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

Lysis Reagent – Xi (Irritant)

All other components of this product: Not applicable

EU Risk Phrases:

Wash Reagent **R11 - Highly Flammable**
R20/21/22 – Harmful by inhalation, in contact with skin or swallowed
R32 – Contact with acid liberates very toxic gas
R36/37/38 – Irritating to eyes, respiratory tract or skin
R52/53 – Harmful to aquatic environment; may cause long-term adverse effects on the aquatic environment.

Proteinase K **R36/37/38 – Irritating to eyes, respiratory tract or skin**
R42 – May cause sensitization by inhalation

Elution Reagent **R52/53 – Harmful to aquatic environment; may cause long-term adverse effects on the aquatic environment.**
R32 – Contact with acid liberates very toxic gas



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Rinse Reagent R52/53 – Harmful to aquatic environment; may cause long-term adverse effects on the aquatic environment.

R32 – Contact with acid liberates very toxic gas

Lysis Reagent R36/38 – Irritating to skin and eyes.

All other components of this product: Not applicable

3. Composition Information on Ingredients

This product consists of a cartridge with four 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 the **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)	<10	R36/37/38

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 (in quantity of two beads total) with the following hazardous ingredients:



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Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
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)	<10	R36/37/38
Bovine Serum Albumin	9048-46-8	232-936-2	<3	R42

All other ingredients of the **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
Bovine Serum Albumin	9048-46-8	232-936-2	<3	R42
HEPES Acid and Salt	7365-45-9 (For Acid)	230-907-9 (For Acid)	<10	R36/37/38

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

Proteinase K liquid contains the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Proteinase K	39450-01-6	254-457-8	<1	R36/37/38 -42

All other ingredients of the **Proteinase K** liquid solution 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 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 of **Elution 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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Lysis Reagent contains the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Guanidine hydrochloride	50-01-1	200-002-3	30-40	R22/36/37/38
Tween-20	9005-64-5	200-315-5	<15	R36/37/38
Tris buffer	77-86-1	201-064-4	<5	R 36/37/38
EDTA	60-00-4	200-449-4	<5	R 28-36
Sodium lauryl sulfate	151-21-3	205-788-1	<2	R10-20/21/22-36/37/38

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
Ethanol	64-17-5	200-578-6	45-50	R11- 20/21/22-36/37/38
Guanidine thiocyanate	593-84-0	209-812-1	25-35	R20/21/22/32/52/53

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.

Rinse Reagent contains the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase
Sodium azide	26628-22-8	247-852-1	<0.1	R 28-32-50/53

All other ingredients in **Rinse Reagent** are either 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.



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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: **Wash Reagent is a FLAMMABLE LIQUID.** All other components are not flammable or explosive in the physical form and concentration in each component. **Elution and Rinse Reagent** each 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: 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 and Wash Reagents** each may release small quantities of cyanide in case of a fire. **Elution 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.

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.**



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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 **Wash 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. **Sodium azide** is an ingredient in both Elution Reagent and Rinse Reagent and has the following exposure limits: ACGIH TLV Ceiling of 0.29 mg/m³ for all forms and ceiling 0.11 ppm as hydrazoic acid vapor; and NIOSH has a REL of 0.3 mg/m³ 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.

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 Wash Reagent containing ethanol, minimal.

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

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

Boiling Point: With exception of Wash 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 (Solids & liquid reagents)

10. Stability and Reactivity

Chemical Stability: Stable under normal temperatures and pressures.

Conditions to Avoid: **Elution and Rinse Reagent** each 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.

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 azide is acutely toxic both by oral and dermal routes with an oral LD₅₀ values in the rat of 27 mg/kg and a dermal LD₅₀ in the rabbit of 20 mg/kg. Guanidine hydrochloride has an oral LD₅₀ of 475 mg/kg in the rat and 571 mg/kg in the mouse; it has a dermal LD₅₀ > 2 g/kg in the rabbit. Tween-20 has low acute oral toxicity. Ethanol has low acute oral toxicity in laboratory animals with an oral LD₅₀ in the rat and mouse of 7060 and 3450 mg/kg in the rat and mouse, respectively. Sodium lauryl sulfate has an oral LD₅₀ in the rat of 1288 mg/kg. EDTA is acutely toxic with an oral LD₅₀ in the rat of 30 mg/kg.



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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. Proteinase K, as a foreign protein is considered a potential allergen. Guanidine hydrochloride is a moderate eye irritant and a severe skin irritant in the rabbit. Sodium lauryl sulfate at the concentration in the product is a mild skin irritant; at increasing concentration, it will cause moderate to severe skin reactions.

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. Tween-20 has low repeated dose toxicity in laboratory animals. Administration of sodium azide has been shown to produce hypotension in laboratory animals and humans. No other data identified on ingredients in beads or liquid formulations.

Reproductive (fertility) and Developmental (birth defects) toxicity – A reproduction study in rats using calcium EDTA dosages up to the equivalent of 13 g/day in humans did not reveal evidence of harm to the fetus; however, dosages up to the human equivalent of 25-50 g/day was associated with fetal malformations. 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 ingredients are listed by NTP, IARC or OSHA as carcinogens.

12. Ecological Information

Ecotoxicity: Of the ingredients, guanidine thiocyanate is considered harmful and sodium azide 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

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 **Wash Reagent**, all of the other components are not regulated by US DOT or IATA.

The transport classification of **Wash 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:

For Wash Reagent – Contains Ethanol and Guanidine Thiocyanate



DANGER – FLAMMABLE LIQUID

Harmful by inhalation, in contact with skin or swallowed.

Contact with acids liberates very toxic gas. Irritating to eyes, respiratory tract and skin.

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.

Keep away from sources of ignition – No smoking. Avoid skin contact, eye contact or inhalation.

EU Risk and Safety Phrases: R 11; 20/21/22, 32; 52/53 S16; 24/25; 61

LBL PN: 300-6925, Rev F

For Proteinase K – Contains Proteinase K



CAUTION

Irritating to eyes, respiratory tract and skin.

May cause sensitization by skin contact.

Avoid skin contact, eye contact or inhalation.

EU Risk and Safety Phrases: R 36/37/38; 42; S24/25.

For Elution Reagent; Rinse Reagent – Contains Sodium Azide



CAUTION

Contact with acid liberates 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.

EU Risk and Safety Phrases: R 32; 52/53; S61

For Lysis Reagent – Contains Guanidine Hydrochloride



CAUTION

Irritating to eyes and skin.

Avoid skin contact and eye contact.

EU Risk and Safety Phrases: R 36/38; S24/25

Canada – WHMIS Classifications

Wash 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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