



Material Safety Data Sheet

Effective Date: September 2nd, 2011

Supersedes: October 15th, 2010

Xpert MRSA

1. Identification of the Material and Company/Undertaking

Product Identifier:	Xpert MRSA	Catalog Numbers: GXM RSA-100N-10
Synonyms:	Not applicable	GXM RSA-120
Trade names:	Not applicable	

Manufacturer:
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
USA

Telephone Numbers:
(888) 838-3222 (6 AM – 5 PM Pacific time US)
Outside of the US: 1 (408) 541-4191
24-Hour Emergency Telephone:
CHEMTREC (800) 424-9300
Outside of the US: 1 (703) 741-5500
E-mail: techsupport@cepheid.com

Relevant identified uses of the substance or mixture and uses advised against: Clinical diagnostic product.

Note: The following SDS is for the final finished product only as used in the laboratory. It contains six (6) components, some of which are in cartridges. Exemptions for disclosing information are pursuant to CLP Article 1 (5)(d). and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2).

2. Hazards Identification

Classification of the substance or mixture

**Regulation (EC)
1272/2008 [GHS]**

Reagent 1 (Sodium Hydroxide): Skin Corrosion - Category 1B (eye damage included).

Elution Reagent: Chronic Aquatic Toxicity - Category 3. Contact with acids emits very toxic gas.

Material Safety Data Sheet*Effective Date: September 2nd, 2011**Supersedes: October 15th, 2010**Xpert MRSA***Directive 67/548/EEC
or 1999/45/EC*****Reagent 1 (Sodium Hydroxide):***
C: R35**Label Elements*****Elution Reagent:***

Xn: R32, R52/53

(See section 15 of this SDS)

EU Pictogram

C – Corrosive

(Sodium Hydroxide Solution)

Xn - Harmful

(Elution Reagent)**CLP/GHS hazard
pictogram*****Reagent 1 (Sodium Hydroxide)*****CLP/GHS signal word*****Reagent 1 (Sodium Hydroxide):*** Danger***Elution Reagent:*** Warning

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CLP/GHS Hazard and Precautionary statements

Reagent 1 (Sodium Hydroxide): H314 – Causes severe skin burns and eye damage.

Elution Reagent: EUH032 – Contact with acids liberates very toxic gas. H412 – Harmful to aquatic life with long lasting effects.

Reagent 1 (Sodium Hydroxide): P260 - Do not breathe dust/mist/vapors/spray P264 - Wash hands thoroughly after handling. P280 - Wear eye/face protection. P301 + P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303 + P361 + P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P363 – Wash contaminated clothing before reuse. P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P310 – Immediately call a POISON CENTER or doctor/physician. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P405 – Store locked up. P501 - Dispose of contents/container to location in accordance with local and regional/national/international regulations.

CLP/GHS precautionary statements

Elution Reagent: P273 - Avoid release to the environment. P501 - Dispose of contents/container to location in accordance with local and regional/national/international regulations.

US Signal word

Danger

US Hazard Overview

Reagent 1 contains Sodium Hydroxide (4% solution) in a cartridge, which is a CORROSIVE LIQUID. Can cause burns to skin and eyes if directly contacted. Can cause irritation to mucous membranes and respiratory tract if inhaled.

Reagent 2 is not considered hazardous and is contained in a cartridge.

Elution Reagent contains guanidinium thiocyanate and is considered to be a harmful to the aquatic environment. Dispose of according to local, state and federal regulations.



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Note

This product is classified as dangerous/hazardous according to Directive 67/548/EEC and Directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP), and applicable US regulations. The GHS classifications are based on Regulation EC 1272/2008 (EU CLP). See Section 16 for full text of EU and GHS classifications.

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. **There are 6 parts** – 5 of the parts (3 beads, which are freeze-dried white powders at concentrations < 0.1% in the cartridge), and 2 clear, colorless liquid reagents are contained in cartridges. The other component is a reagent that is a clear, colorless liquid that that is contained in a vial.

The following classifications (EU Risk phrases and CLP/GHS H-phrases) are for the pure ingredients included in this mixture.

Reagent 1 contains the following:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase	CLP/GHS Classification
Sodium Hydroxide	1310-73-2	215-185-5	4%	R35	H314

Reagent 2 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.

Elution Reagent contains the following ingredients

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase	CLP/GHS Classification
Guanidinium Thiocyanate	593-84-0	209-812-1	20-30	R22, R32, R52/53	EUH032, H302, H412

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

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4. First Aid Measures

For all ingredients:

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.

5. Fire Fighting Measures

Extinguishing Media: Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

Specific hazards arising from substance or mixture: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen cyanide, ammonia.

Flammability/Explosivity: None expected.

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

Hazardous

Decomposition Products: Elution Reagent may emit small quantities of cyanide in 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 small spills of Reagent 1 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).

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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: Reagent 1 contains sodium hydroxide which has an ACGIH TLV and NIOSH REL of 2 mg/m³ as a ceiling value that is not to be exceeded for any 15-minute period and an OSHA 8-hour time weighted average of 2 mg/m³.

Sodium Hydroxide	ACGIH, Czech Republic, Denmark, Finland, NIOSH REL, Portugal, Spain, Sweden, Australia, Mexico	Ceiling	2 mg/m ³
	Austria, Belgium, Bulgaria, Finland, France, Hungary, Lithuania, Slovak Republic, Slovenia, Spain, US OSHA	TWA-8 HR	2 mg/m ³
	Austria	STEL (8 x 5 min)	4 mg/m ³
	Hungary, Ireland, Slovenia, Singapore	STEL	2 mg/m ³
	Latvia, Poland	TWA-8 HR	0.5 mg/m ³
	NIOSH	IDLH	10.0 mg/m ³
	Poland	STEL	1.0 mg/m ³



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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.

9. Information on Basic Physical and Chemical Properties

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

Color: Beads 1, 2, 3 are freeze-dried white powders; reagents are clear colorless solutions.

Odor: Components are odorless

Odor Threshold: No information identified.

pH: >12.5 (Reagent 1), 6.6 – 8.6 (solids and other liquid reagents)

Melting point/freezing point: Liquid reagents near 0 °C.

Initial boiling point and boiling range: Liquid reagents near 100 °C.



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Flash point: No information identified.

Evaporation rate: Minimal

Flammability (solid, gas): No information identified.

Upper/lower flammability or explosive limits: No information identified.

Vapor pressure: Minimal

Vapor density: No information identified.

Relative density: No information identified.

Water solubility: Reagents are already aqueous; beads are soluble in aqueous solutions.

Solvent solubility: No information identified.

Partition coefficient: No information identified.

(n-octanol/water)

Autoignition temperature: No information identified.

Decomposition temperature: No information identified

Viscosity: Reagents are aqueous

Explosive properties: No information identified.

Oxidizing properties: No information identified.

Molecular weight: **Reagent 1** – 39.99 (Sodium Hydroxide)
 Elution Reagent – 118.16 (Guanidinium Thiocyanate)

Molecular formula: **Reagent 1** – NaOH
 Elution Reagent – contains C₂H₆N₄S

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10. Stability and Reactivity

Reactivity: No information identified.

Chemical Stability: Stable under ordinary conditions of use and storage.

Possibility of Hazardous reactions: Exothermic with acids (applies to Reagent 1 only). Heating to decomposition or contact with acids or acid vapors can liberate poisonous cyanide gas/vapors (applies to Elution Reagent only). For all other ingredients, no potential for hazardous reactions identified.

Conditions to Avoid: Heat, incompatibles, moisture (Reagent 1). Heat, incompatibles (Elution Reagent).

Incompatible Materials: Acids, organic halogen compounds (Reagent 1). Strong oxidizing agents, acids (Elution Reagent).

Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, ammonia, hydrogen cyanide and/or cyanide (Elution Reagent).

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Acute Toxicity: Sodium hydroxide is acutely toxic orally due to its corrosivity. Guanidinium thiocyanate has an acute oral LD50 of 593 mg/kg.

Irritation/Sensitization: No data identified on ingredients.

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, guanidinium 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.

13. Disposal Considerations

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.

14. Transport Information

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

With the exception of **Reagent 1**, all of the other components are not regulated by US DOT or IATA.

Transport	Based on the available data, Reagent 1 (which contains 1.0N Sodium Hydroxide) is regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
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UN number	UN1824
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UN proper shipping name Sodium Hydroxide Solution.

Transport hazard classes and packing group	Hazard Class - 8; Packing Group II.
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Environmental hazards	Based on the available data, this substance is not regulated as an environmental hazard or a marine pollutant.
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Special precautions for users	Avoid skin contact, eye contact, and inhalation. Wear eye protection and skin protection to avoid contact with corrosive solution (4% Sodium Hydroxide).
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Transport in bulk Not applicable.
according to Annex II of
MARPOL73/78 and the
IBC Code

15. Regulatory Information

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 1 - Contains 4% Sodium Hydroxide



DANGER
 Causes severe skin burns and eye damage.
 Do not breathe dust/mist/vapors/spray.
 Wash hands thoroughly after handling.
 Wear eye/face protection.
 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
 IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing.
 Rinse skin with water/shower. Wash contaminated clothing before reuse.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

For Elution and Sample Reagents - Contains Guanidine Thiocyanate

WARNING
 Contact with acids liberates very toxic gas.
 Harmful to aquatic organisms with long lasting effects.
 Avoid release to the environment.
 Consult Safety Data Sheet for other precautionary statements.
 Dispose of contents/container to location in accordance with local and regional/national/international regulations.

LBL PN: 300-6924, Rev G

Safety, health and environmental regulations/legislation specific for the substance or mixture

This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Labeling information under CLP, including pictogram, signal word, and hazard/precautionary statements are included in this SDS. Exemptions for including some of this information on product label are per CLP Article 29.

Chemical safety assessment

Not conducted.

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Reagent 1 contains Sodium Hydroxide (4% solution) in a cartridge, which is a CORROSIVE LIQUID that can cause burns to skin and eyes upon direct contact. Can cause irritation to mucous membranes and respiratory tract if inhaled.

Elution Reagent combined with acids may release small quantities of toxic gas (hydrogen cyanide).

National Fire Protection Agency (NFPA) Rating**Reagent 1:**

Health - 3

Flammability - 0

Reactivity - 1

Special - N/A

Elution Reagent :

Health - 3

Flammability - 0

Reactivity - 1

Special - N/A

All other ingredients:

Not applicable as used.

WHMIS classification

Class E - Corrosive material

Reagent 1 is classified as Class E - Corrosive Material. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

TSCA status

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

SARA section 313

Not listed.

California proposition 65

Not listed.

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16. Other Information

**Full text of
R phrases
and EU
Classifications**

C – Corrosive. Xn – Harmful. Xi – Irritant. R22 – Harmful if swallowed. R32 – Contact with acids liberates very toxic gas. R34 – Causes burns. R35 – Causes severe burns. R52/53 – Harmful to the environment with long lasting effects.

**Full text of H
phrases,
P phrases and
GHS classification**

SC1 – Skin Corrosion Category 1B. H302 – Harmful if swallowed. H314 – Causes severe skin burns and eye damage. AA1- Acute aquatic toxicity Category 3. H412 – Harmful to aquatic life with long lasting effects. EUH032 - Contact with acids emits very toxic gas.

Abbreviations:

ACGIH - American Conference of Governmental Industrial Hygienists
ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail
AIHA - American Industrial Hygiene Association
CAS# - Chemical Abstract Services Number
DNEL - Derived No Effect Level
DOT - Department of Transportation
EINECS - European Inventory of New and Existing Chemical Substances
ELINCS - European List of Notified Chemical Substances
EU - European Union
GHS - Globally Harmonized System of Classification and Labelling of Chemicals
IARC - International Agency for Research on Cancer
IDLH - Immediately Dangerous to Life or Health
IATA - International Air Transport Association
IMDG - International Maritime Dangerous Goods
LOEL - Lowest Observed Effect Level
LOAEL - Lowest Observed Adverse Effect Level
NIOSH - The National Institute for Occupational Safety and Health
NOEL - No Observed Effect Level
NOAEL - No Observed Adverse Effect Level
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PBT - Persistent, Bioaccumulative and Toxic
PNEC - Predicted No Effect Concentration
SARA - Superfund Amendments and Reauthorization Act
STEL - Short Term Exposure Limit
TDG - Transport Dangerous Goods



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TSCA - Toxic Substances Control Act

TWA - Time Weighted Average

WHMIS - Workplace Hazardous Materials Information System

Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.