

Material Safety Data Sheet*Effective Date: November 17th, 2011**Supersedes: February 2nd, 2010**Xpert MTB/RIF*

1. Product and Company Identification

Product name: Xpert MTB/RIF
Product number: GXMTB/RIF-10, RMTB/RIF-10

Manufacturer:
Cepheid
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Sunnyvale, CA 94089
USA

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Outside of the US: 1 (408) 541-4191
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Cepheid AB
Röntgenv 5
171 54 Solna
Sweden

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Tel: + 46 8 684 370 00
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Relevant identified uses of the mixture and uses advised against:

The following SDS is for the final finished product only as used in the laboratory.

2. Hazards Identification

Exemptions for disclosing some component information are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200(g)(2)(i)(C)(1)&(2). The below applies to the Sample Reagent containing Isopropyl alcohol and Sodium Hydroxide

Classification of the substance or mixture: Flammable liquid (Category 2)
Regulation (EC) 1272/2008 [GHS] Serious eye damage (Category 1)
Skin irritation (Category 2)
Specific target organ toxicity – single exposure (Category 3)

Label Elements (See section 15 of this SDS)

CLP/GHS hazard pictogram





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CLP/GHS signal word **Danger**

**CLP/GHS
Hazard
and Precautionary
statements**

H225 – Highly Flammable liquid and vapor.
H303 – May be harmful if swallowed.
H315 – Causes skin irritation.
H318 – Causes serious eye damage.
H336 – May cause drowsiness or dizziness.

P210 – Keep away from heat/sparks/open flames/hot surfaces. P261 – Avoid breathing dust/fume/gas/mist/vapors/spray. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/eye protection/face protection. P302 + P352 – IF ON SKIN: Wash with plenty of soap and water. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 – Call a POISON CENTER or physician if you feel unwell. P501 - Dispose of contents/container to location in accordance with local and regional/national/international regulations.

US Hazard Overview Corrosive, Flammable

Note The GHS classifications are based on Regulation EC 1272/2008 (EU CLP) and the calculation procedure of the ‘Globally Harmonized System of Classification and Labelling of Chemicals (GHS)’ in the latest version.

3. Composition Information on Ingredients

This product consists of a cartridge with five beads and two clear, colorless aqueous reagents as part of an assay. The following classifications (EU Risk phrases and CLP/GHS H-phrases) apply to the Sample Reagent containing Isopropyl alcohol and Sodium Hydroxide.

Sample reagent is a clear, colorless liquid with the following hazardous ingredients:

Ingredient	CAS#	EINECs / ELINCS #	% Composition	EU Risk Phrase	CLP/GHS Classification
Isopropyl alcohol	67-63-0	200-661-7	< 20	R11, R22, R36, R67	H225, H303, H336
Sodium hydroxide	1310-73-2	215-185-5	< 10	R22, R35	H303, H315, H318



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Other reagent and bead ingredients are at concentrations less than 1% in the mixture or 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.

4. First Aid Measures

- Eye:** Causes serious eye damage. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult a physician.
- Skin:** Causes skin irritation. Wash with plenty of soap and water. Consult a physician.
- Ingestion:** May be harmful if swallowed. Rinse mouth with water. Never give anything by mouth to an unconscious person. Consult a physician.
- Inhalation:** May cause drowsiness or dizziness. If breathing difficulty should occur, remove person to fresh air and consult a physician.

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 oxides, sodium oxides, nitrogen oxides.

Flammability/Explosivity: None expected.

Advice for Firefighters: Wear full protective clothing and a self-contained breathing apparatus if necessary.

Hazardous

Decomposition Products: See Section 10.

6. Accidental Release Measures

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. Do not dispose spilled materials down drain. 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 and eye contact.**Storage Requirements:** Store according to product labeling.

8. Exposure Controls/Personal Protection**Occupational Exposure Limits:**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>Limit</u>
Isopropyl alcohol	US OSHA	8-HR TWA	400 ppm
	ACGIH	8-HR TLV	200 ppm
	ACGIH	STEL	400 ppm
Sodium hydroxide	US OSHA, ACGIH	8-HR TWA	2 mg/m ³
	NIOSH	Ceiling	2 mg/m ³

Engineering Controls: None normally required.**Eye Protection:** Wear safety glasses with side shields or chemical splash goggles. Base the choice of protection on the job activity and potential for contact with eyes or face.**Respiratory Protection:** None normally required.**Skin Protection:** In laboratory setting, wear gloves and lab coat 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 a sink and eyewash station. Wash hands and other potentially exposed areas immediately after handling material (especially before eating, drinking, or smoking).

9. Physical and Chemical Properties**Appearance:** Beads are solid white components in cartridges; reagents are clear liquids which are primarily buffered in aqueous solutions.**Odor:** Components are odorless**Odor threshold:** No information identified.**pH:** > 12.5 (Sample reagent)**Melting point/freezing point:** No information identified.**Initial boiling point and boiling range:** 82 °C (Isopropyl alcohol).**Flash point:** 12 °C (Isopropyl alcohol)**Evaporation rate:** 3.0 (Isopropyl alcohol)

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Flammability (solid, gas): No information identified.

Upper/lower flammability or explosive limits: 2% lower, 12.7% upper (Isopropyl alcohol).

Vapor pressure: 43.2 hPa (32.4 mmHg) at 20.0 °C (Isopropyl alcohol)

Vapor density: No information identified.

Relative density: No information identified.

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

Partition coefficient: n-octanol/water: No information identified.

Auto-ignition temperature: 425 °C (Isopropyl alcohol).

Decomposition temperature: No information identified.

Viscosity: No information identified.

10. Stability and Reactivity

Reactivity: No information identified.

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

Possibility of Hazardous reactions: Isopropyl alcohol may form explosive mixture in air. For all other ingredients, no potential for hazardous reactions identified.

Conditions to Avoid: Heat, flames, sparks

Incompatible Materials: Acids, oxidizing agents.

Hazardous Decomposition Products: Carbon oxides, sodium oxides

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Acute Toxicity: Isopropyl alcohol has an acute oral LD50 of 5,045 mg/kg (rat); Sodium hydroxide has an acute oral LD50 of 4,090 mg/kg (rat).

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.



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

12. Ecological Information

Ecotoxicity: Sample reagent containing sodium hydroxide > 12.5 pH has the potential for harmful effects in the environment if not properly disposed.

Persistence and degradability: No data identified.

Bioaccumulative potential: No data identified.

Mobility in soil: No data identified.

Other adverse effects: No data identified.

13. Disposal Considerations

Biological specimens, including used MTB cartridges, should be treated as capable of transmitting infectious agents. Dispose used cartridges as hazardous health-care waste in durable waste containers per WHO [World Health Organization] medical waste handling and disposal guidelines.

WHO website links for suggested medical waste disposal practices:

http://www.who.int/water_sanitation_health/medicalwaste/167to180.pdf

http://www.healthcarewaste.org/en/115_overview.html

14. Transport Information

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

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

Transport	Based on the available data, Sample Reagent (which contains < 10% Sodium Hydroxide and < 20% Isopropyl alcohol) is regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	UN2920
UN proper shipping name	Corrosive liquid, flammable, n.o.s. (Sodium Hydroxide, Isopropanol)



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Transport hazard classes and packing group Hazard Class – 8 (3); Packing Group II.

Environmental hazards Marine pollutant: No

15. Regulatory Information

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 signal word and hazard/precautionary statements are included in this SDS. Exemptions for including some of this information on product label are pursuant to CLP Article 1(5)(d) and 29 CFR 1910.1200 (g)(2)(i)(C)(1)&(2).

OSHA Hazardous Sample reagent is corrosive and flammable

National Fire Protection Agency (NFPA) Rating **Sample Reagent:**
Health – 3
Flammability – 3
Reactivity - 0

WHMIS classification Sample reagent is a corrosive – Class E, and Class B- Flammable. All other components are not classified according to WHIMIS classification criteria.

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

SARA section 313 Isopropyl alcohol is listed under SARA Section 313.

California proposition Not listed.

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Product label



For Sample Reagent – Contains Sodium Hydroxide and Isopropyl Alcohol

DANGER

Flammable Liquid and Vapor: Keep away from heat/sparks/open flames/hot surfaces.

Causes severe skin burns and eye damage.

Wash hands thoroughly after handling. Wear protective gloves and eye protection. Do not breathe dust/mist/vapors/spray.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation occurs: Get medical advice/attention.

IF SWALLOWED: Rinse mouth. Call a POISON CENTER / physician if you feel unwell.

Consult Safety Data Sheet for other precautionary statements.

Dispose of contents/container in accordance with local and regional / national/ international regulations.

16. Other Information

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, protections and disposal 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. 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.