



Safety Data Sheet

Effective Date: April 2022

Supersedes: June 2021

Xpert MTB/RIF
Xpert MTB/RIF Ultra
Xpert MTB/XDR
Xpert Omni MTB/RIF Ultra

Section 1 - Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifier

Product Name Xpert MTB/RIF; Xpert MTB/RIF Ultra; Xpert MTB/XDR
Product Code GXMTB/RIF-10; GXMTB/RIF-50; GXMTB/RIF-CN-10; GXMTB/RIF-US-10;
GXMTB/RIF-JP-10; CGXMTB/RIF-10; CGXMTB/RIF-50; GXMTB/RIF-ULTRA-10;
GXMTB/RIF-ULTRA-50; GXMTB/RIF-IN-10; CGXMTB/RIF-IN-50; 900-0772;
GXMTB/RIF-ULT-SA50; GXMTB/RIF-MII-10; GXMTB/RIF-MII-50; 900-0779;
900-0811; RMTB/XDR-10; GXMTB-ULTRA-MII-10; GXMTB-ULTRA-MII-50;
GXMTB/XDR-10; 900-0888; OMNIMTB/RIF-ULT-10

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Relevant identified use(s) Laboratory use

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
United States
www.cepheid.com
US: techsupport@cepheid.com

Telephone (General) (888) 838-3222 - US Option 2
Telephone (General) 1 (408) 541-4191 - Outside of the US
Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
www.cepheidinternational.com
support@cepheideurope.com

Telephone (General) +33 563 825 319 – EU
Cepheid India Private Limited
1, SIPCOT Industrial Growth Centre,
Oragadam, Kanchipuram,
Tamil Nadu - 602 105, India
www.cepheidinternational.com
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Telephone (Tech Support) +91 11 48353010
Cepheid Holdings Pty Ltd
Suite 2, Level 3, Building A
11 Talavera Road
Macquarie Park, NSW 2113
Australia
www.cepheidinternational.com
ANZ: TechSupportANZ@cepheid.com

Telephone (Australia) 1800 107 884

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1.4 Emergency Telephone Number

Manufacturer 1 (800) 535-5053 - INFOTRAC - 24 hr Emergency
 Manufacturer 1 (352) 323-3500 - Outside of the US

Section 2 - Hazards Identification

EU/EEC

According to: Regulation (EC) No 1272/2008 (CLP)/REACH 1907/2006 [amended by 453/2010]

2.1 Classification of the Substance or Mixture

CLP The following SDS is for the final finished mixture product only as used in the laboratory. The product contains beads and reagents in the cartridge or in off-board containers. 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).
 Flammable Liquids 3 - H226
 Skin Corrosion 1B - H314

2.2 Label Elements

CLP

DANGER



Hazard Statements H226 - Flammable liquid and vapour
 H314 - Causes severe skin burns and eye damage.

Precautionary Statements

Prevention P210 - Keep away from heat, sparks, open flames and/or hot surfaces. - No smoking.
 P233 - Keep container tightly closed.
 P260 - Do not breathe mists, vapours, and/or spray.
 P264 - Wash thoroughly after handling.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.

Response P370+P378 - In case of fire: Use appropriate media for extinction.
 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.
 P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P321 - Specific treatment, see supplemental first aid information.
 P363 - Wash contaminated clothing before reuse.
 P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

Storage/Disposal P501 - Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

2.3 Other Hazards

CLP According to Regulation (EC) No. 1272/2008 (CLP) this material is considered hazardous.

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UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2.1 Classification of the Substance or Mixture

UN GHS Flammable Liquids 3
 Skin Corrosion 1B
 Serious Eye Damage 1
 Germ Cell Mutagenicity 2
 Reproductive Toxicity 2
 Specific Target Organ Toxicity Repeated Exposure 2

2.2 Label Elements

UN GHS

DANGER



Hazard Statements

Flammable liquid and vapour
 Causes severe skin burns and eye damage.
 Causes serious eye damage
 Suspected of causing genetic defects.
 Suspected of damaging fertility or the unborn child.
 May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements

Prevention

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Keep away from heat, sparks, open flames and/or hot surfaces. - No smoking.
 Keep container tightly closed.
 Do not breathe mists, vapours, and/or spray.
 Wash thoroughly after handling.
 Wear protective gloves/protective clothing/eye protection/face protection.
 Use personal protective equipment as required.

Response

In case of fire: Use appropriate media for extinction.
 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 ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 Wash contaminated clothing before reuse.
 Specific treatment, see supplemental first aid information.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
 IF exposed or concerned: Get medical advice/attention.
 Get medical advice/attention if you feel unwell.

Storage/Disposal

Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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2.3 Other Hazards

UN GHS

According to the Globally Harmonized System for Classification and Labeling (GHS) this product is considered hazardous.

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

2.1 Classification of the Substance or Mixture

OSHA HCS 2012

Flammable Liquids 3
Skin Corrosion 1B
Serious Eye Damage 1
Germ Cell Mutagenicity 2
Reproductive Toxicity 2
Specific Target Organ Toxicity Repeated Exposure 2

2.2 Label Elements

OSHA HCS 2012

DANGER



Hazard Statements

Flammable liquid and vapour
Causes severe skin burns and eye damage.
Causes serious eye damage
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements

Prevention

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Keep away from heat, sparks, open flames and/or hot surfaces. - No smoking.
Keep container tightly closed.
Do not breathe mists, vapours, and/or spray.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

Response

In case of fire: Use appropriate media for extinction.
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 ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
Wash contaminated clothing before reuse.
Specific treatment, see supplemental first aid information.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
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Storage/Disposal Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

2.3 Other Hazards

OSHA HCS 2012

Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is considered hazardous.

Canada

According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS

Flammable Liquids - B2
Other Toxic Effects - D2A
Corrosive - E

2.2 Label Elements

WHMIS



Flammable Liquids - B2
Other Toxic Effects - D2A
Corrosive - E

2.3 Other Hazards

WHMIS

In Canada, the product mentioned above is considered hazardous under the Workplace Hazardous Materials Information System (WHMIS).

2.4 Other Information

All other reagents, beads, and other constituents 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.

Section 3 - Composition/Information on Ingredients

3.1 Substances

Material does not meet the criteria of a substance in accordance with Regulation (EC) No 1272/2008.

3.2 Mixtures

Composition					
Chemical Name	Identifiers	%	LD50/LC50	Classifications According to Regulation/Directive	Comments
Isopropyl alcohol	CAS: 67-63-0 EC Number: 200-661-7 EU Index: 603-117-00-0	10% TO 15%	Skin-Rabbit LD50 • 12800 mg/kg Ingestion/Oral-Rat LD50 • 5000 mg/kg Inhalation-Rat LC50 • 72600 mg/m ³	UN GHS: Flam. Liq. 2; Acute Tox. 5 (orl); Skin Irrit. 3; Eye Irrit. 2; Muta. 2; Repr. 2; STOT SE 3: Narc.; STOT SE 3: Resp. Irrit.; Asp. Tox. 2; STOT RE 2 (Eyes, Inhl) EU CLP: Annex VI, Table 3.1: Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3: Narc., H336 OSHA HCS 2012: Flam. Liq. 2; Eye Irrit. 2; Muta. 2; Repr. 2; STOT SE 3: Narc.; STOT SE 3: Resp. Irrit.; STOT RE 2 (Eyes, Inhl)	NDA
Sodium hydroxide	CAS: 1310-73-2 EC Number: 215-185-5 EU Index: 011-002-00-6	5% TO 8%	NDA	UN GHS: Skin Corr. 1B; Eye Dam. 1 EU CLP: Annex VI, Table 3.1: Skin Corr. 1B, H314 OSHA HCS 2012: Skin Corr. 1B; Eye Dam. 1	NDA

Section 4 - First Aid Measures

4.1 Description of First Aid Measures

Inhalation	Remove to fresh air. Administer oxygen if breathing is difficult. Give artificial respiration if victim is not breathing. If signs/symptoms continue, get medical attention.
Skin	Wash skin with soap and water. Get medical attention.
Eye	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get medical attention.
Ingestion	Rinse mouth. Never give anything by mouth to an unconscious person. Get medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed

Refer to Section 11 - Toxicological Information.

4.3 Indication of any Immediate Medical Attention and Special Treatment Needed

Notes to Physician	All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.
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Section 5 - Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media	Use water spray (fog), foam, dry powder, or carbon dioxide.
Unsuitable Extinguishing Media	No data available

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5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	This material is classified flammable, however it is in small vials and is unlikely to cause significant flammability hazard in use.
Hazardous Combustion Products	May emit toxic fumes of carbon oxides, sodium oxides, nitrogen oxides.

5.3 Advice for Firefighters

Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions	In the event a cartridge is broken these personal precautions are applicable. Wear appropriate protective clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate enclosed areas.
Emergency Procedures	No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

6.3 Methods and Material for containment and Cleaning Up

Containment/Clean-up Measures	For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain.
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6.4 Reference to Other Sections

Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

7.1 Precautions for Safe Handling

Handling	Use good safety and industrial hygiene practices. Use appropriate Personal Protective Equipment (PPE). Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.
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7.2 Conditions for Safe Storage, Including any Incompatibilities

Storage	Store according to product labeling.
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7.3 Specific End Use(s)

Refer to Section 1.2 - Relevant identified uses.

Section 8 - Exposure Controls/Personal Protection

8.1 Control Parameters

Exposure Limits/Guidelines				
	Result	ACGIH	NIOSH	OSHA
Sodium hydroxide (1310-73-2)	TWAs	Not established	Not established	2 mg/m3 TWA
	Ceilings	2 mg/m3 Ceiling	2 mg/m3 Ceiling	Not established
Isopropyl alcohol (67-63-0)	TWAs	200 ppm TWA	400 ppm TWA; 980 mg/m3 TWA	400 ppm TWA; 980 mg/m3 TWA
	STELs	400 ppm STEL	500 ppm STEL; 1225 mg/m3 STEL	Not established

8.2 Exposure Controls

Engineering Measures/Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face

Wear chemical splash safety goggles.

Skin/Body

Wear protective clothing

Environmental Exposure Controls

Follow best practice for site management and disposal of waste.

Key to abbreviations

ACGIH = American Conference of Governmental Industrial Hygiene
 NIOSH = National Institute of Occupational Safety and Health
 OSHA = Occupational Safety and Health Administration

TWA = Time-Weighted Averages are based on 8h/day, 40h/week exposures
 STEL = Short Term Exposure Limits are based on 15-minute exposures

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Section 9 - Physical and Chemical Properties
9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Beads are solid white components in cartridges; reagents are clear liquids which are primarily buffered in aqueous solutions. Components are odorless.
Color	White/clear	Odor	Data lacking
Odor Threshold	Data lacking		
General Properties			
Boiling Point	Data lacking	Melting Point/Freezing Point	Data lacking
Decomposition Temperature	Data lacking	pH	> 12.5
Specific Gravity/Relative Density	Data lacking	Water Solubility	Data lacking
Viscosity	Data lacking	Explosive Properties	Data lacking
Oxidizing Properties:	Data lacking		
Volatility			
Vapor Pressure	Data lacking	Vapor Density	Data lacking
Evaporation Rate	Data lacking		
Flammability			
Flash Point	Sample Reagent: 20°C	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	Data lacking		

9.2 Other Information

No additional physical and chemical parameters noted.

Section 10 - Stability and Reactivity
10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical Stability

Stable under normal temperatures and pressures.

10.3 Possibility of Hazardous Reactions

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

10.4 Conditions to Avoid

Heat, flames, sparks.

10.5 Incompatible Materials

Acids, oxidizing agents.



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10.6 Hazardous Decomposition Products

Carbon oxides, sodium oxides.

Section 11 - Toxicological Information

11.1 Information on Toxicological Effects

		Components
Sodium hydroxide (5% TO 8%)	1310-73-2	Irritation: Eye-Rabbit • 1 % • Severe irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Severe irritation; Mutagen: Cytogenetic analysis • Unreported Route-Hamster • Lung (Somatic cell) • 10 mmol/L
Isopropyl alcohol (10% TO 15%)	67-63-0	Acute Toxicity: Ingestion/Oral-Rat LD50 • 5000 mg/kg; Behavioral:General anesthetic; Inhalation-Rat LC50 • 16000 ppm 8 Hour(s); Inhalation-Guinea Pig TCLo • 980 mg/m ³ 24 Hour(s); Sense Organs and Special Senses:Ear:Other; Behavioral:General anesthetic; Lungs, Thorax, or Respiration:Other changes; Skin-Rabbit LD50 • 12800 mg/kg; Irritation: Eye-Rabbit • 100 mg • Severe irritation; Skin-Rabbit • 500 mg • Mild irritation; Multi-dose Toxicity: Inhalation-Mouse TCLo • 5000 ppm 6 Hour(s) 13 Week(s)-Intermittent; Behavioral:Somnolence (general depressed activity); Liver:Changes in liver weight; Blood:Pigmented or nucleated red blood cells; Inhalation-Rat TCLo • 1000 mg/m ³ 6 Hour(s) 4 Week(s)-Intermittent; Sense Organs and Special Senses:Eye:Optic nerve neuropathy; Inhalation-Rat TCLo • 500 mg/m ³ 4 Hour(s) 122 Day(s)-Intermittent; Liver:Multiple effects; Kidney, Ureter, and Bladder:Other changes; Nutritional and Gross Metabolic:Gross Metabolite Changes:Weight loss or decreased weight gain; Inhalation-Rat TCLo • 20 mg/m ³ 24 Hour(s) 90 Day(s)-Continuous; Brain and Coverings:Other degenerative changes; Lungs, Thorax, or Respiration:Other changes; Liver:Multiple effects; Inhalation-Rat TCLo • 100 mg/m ³ 4 Hour(s) 17 Week(s)-Intermittent; Kidney, Ureter, and Bladder:Other changes in urine composition; Blood:Changes in serum composition (e.g., TP, bilirubin cholesterol); Biochemical:Enzyme inhibition, induction, or change in blood or tissue levels:True cholinesterase; Mutagen: Cytogenetic analysis • Inhalation-Rat • 1030 µg/m ³ 16 Week(s)-Intermittent; Reproductive: Inhalation-Rat TCLo • 3500 ppm 7 Hour(s)(1-19D preg); Reproductive Effects:Effects on Embryo or Fetus:Fetotoxicity (except death, e.g., stunted fetus); Inhalation-Rat TCLo • 10000 ppm 7 Hour(s)(1-19D preg); Reproductive Effects:Effects on Fertility:Pre-implantation mortality; Reproductive Effects:Effects on Fertility:Post-implantation mortality; Reproductive Effects:Effects on Embryo or Fetus:Fetal death; Inhalation-Rat TCLo • 7000 ppm 7 Hour(s)(1-19D preg); Reproductive Effects:Specific Developmental Abnormalities:Musculoskeletal system



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GHS Properties	Classification
Respiratory sensitization	EU/CLP•Data lacking OSHA HCS 2012•Data lacking UN GHS•Data lacking
Serious eye damage/Irritation	EU/CLP•Data lacking OSHA HCS 2012•Serious Eye Damage 1 UN GHS•Serious Eye Damage 1
Acute toxicity	EU/CLP•Data lacking OSHA HCS 2012•Data lacking UN GHS•Data lacking
Aspiration Hazard	EU/CLP•Data lacking OSHA HCS 2012•Data lacking UN GHS•Data lacking
Carcinogenicity	EU/CLP•Data lacking OSHA HCS 2012•Data lacking UN GHS•Data lacking
Skin corrosion/Irritation	EU/CLP•Skin Corrosion 1B OSHA HCS 2012•Skin Corrosion 1B UN GHS•Skin Corrosion 1B
Skin sensitization	EU/CLP•Data lacking OSHA HCS 2012•Data lacking UN GHS•Data lacking
STOT-RE	EU/CLP•Data lacking OSHA HCS 2012•Specific Target Organ Toxicity Repeated Exposure 2 UN GHS•Specific Target Organ Toxicity Repeated Exposure 2
STOT-SE	EU/CLP•Data lacking OSHA HCS 2012•Data lacking UN GHS•Data lacking
Toxicity for Reproduction	EU/CLP•Data lacking OSHA HCS 2012•Toxic to Reproduction 2 UN GHS•Toxic to Reproduction 2
Germ Cell Mutagenicity	EU/CLP•Data lacking OSHA HCS 2012•Germ Cell Mutagenicity 2 UN GHS•Germ Cell Mutagenicity 2



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Potential Health Effects

Inhalation

Acute (Immediate)

May cause corrosive burns - irreversible damage.

Chronic (Delayed)

Repeated or prolonged exposure to corrosive fumes may cause bronchial irritation with chronic cough. May cause damage to eyes through prolonged or repeated inhalation.

Skin

Acute (Immediate)

Causes severe skin burns and eye damage.

Chronic (Delayed)

Repeated or prolonged exposure to corrosive materials will cause dermatitis.

Eye

Acute (Immediate)

Causes serious eye damage.

Chronic (Delayed)

Repeated or prolonged exposure to corrosive materials or fumes may cause conjunctivitis.

Ingestion

Acute (Immediate)

May cause irreversible damage to mucous membranes.

Chronic (Delayed)

Repeated or prolonged exposure to corrosive materials or fumes may cause gastrointestinal disturbances.

Mutagenic Effects

Repeated and prolonged exposure may cause mutagenic effects.

Reproductive Effects

Repeated and prolonged exposure may cause reproductive effects.

Key to abbreviations

LC = Lethal Concentration

LD = Lethal Dose

TC = Toxic Concentration

Section 12 - Ecological Information

12.1 Toxicity

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

12.2 Persistence and Degradability

Material data lacking.

12.3 Bioaccumulative Potential

Material data lacking.

12.4 Mobility in Soil

Material data lacking.

12.5 Results of PBT and vPvB assessment

No PBT and vPvB assessment has been conducted.

12.6 Other Adverse Effects

No studies have been found.

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Section 13 - Disposal Considerations
13.1 Waste Treatment Methods

Product Waste	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.
Packaging Waste	Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

13.2 Other Information

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.

Section 14 - Transport Information

	14.1 UN number	14.2 UN proper shipping name	14.3 Transport hazard class(es)	14.4 Packing group	14.5 Environmental hazards
DOT	UN2920	Corrosive liquids, flammable, n.o.s. (sodium hydroxide, isopropanol)	8,3	II	NDA
TDG	UN2920	CORROSIVE LIQUID, FLAMMABLE, N.O.S. (sodium hydroxide, isopropanol)	8,3	II	NDA
IMO/IMDG	UN2920	CORROSIVE LIQUID, FLAMMABLE, N.O.S. (sodium hydroxide, isopropanol)	8,3	II	NDA
IATA/ICAO	UN2920	Corrosive liquid, flammable, n.o.s. (sodium hydroxide, isopropanol)	8,3	II	NDA

14.6 Special Precautions for User

None specified.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code

Data lacking. Section 15 - Regulatory Information



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Section 15 - Regulatory Information

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SARA Hazard Classifications Acute, Chronic, Fire

Inventory						
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	EU ELNICS	TSCA
Isopropyl alcohol	67-63-0	Yes	No	Yes	No	Yes
Sodium hydroxide	1310-73-2	Yes	No	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

Isopropyl alcohol	67-63-0	B2, D2B (including 70%) E (including 0.04% in aqueous solution, 0.08%, 0.4% in aqueous solution,
Sodium hydroxide	1310-73-2	2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N)

Canada - WHMIS - Ingredient Disclosure List

Isopropyl alcohol	67-63-0	1 %
Sodium hydroxide	1310-73-2	1 %

Environment

Canada - CEPA - Priority Substances List

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

United States

Labor

U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed



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Environment

U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	1000 lb final RQ; 454 kg final RQ

U.S. - CERCLA/SARA - Radionuclides and Their Reportable Quantities

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

Isopropyl alcohol	67-63-0	1.0 % de minimis concentration (only if manufactured by the strong acid process, no supplier notification)
Sodium hydroxide	1310-73-2	Not Listed

U.S. - CERCLA/SARA - Section 313 - PBT Chemical Listing

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

United States - California

Environment

U.S. - California – Proposition 65 – Carcinogens List

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - California – Proposition 65 – Developmental Toxicity

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - California – Proposition 65 – Maximum Allowable Dose Levels (MADL)

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - California – Proposition 65 – No Significant Risk Levels (NSRL)

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - California – Proposition 65 – Reproductive Toxicity - Female

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed

U.S. - California – Proposition 65 – Reproductive Toxicity - Male

Isopropyl alcohol	67-63-0	Not Listed
Sodium hydroxide	1310-73-2	Not Listed



Safety Data Sheet

Effective Date: April 2022

Supersedes: June 2021

*Xpert MTB/RIF
Xpert MTB/RIF Ultra
Xpert MTB/XDR
Xpert Omni MTB/RIF Ultra*

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16 - Other Information

Disclaimer/Statement of Liability

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.

Key to abbreviations

NDA = No data available