

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

1.1 Product Identifier

Product Name	Xpert GBS LB XC
Product Code	GXGBSLBXC-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

Manufacture -	
Manufacturer	Cepheid
	904 Caribbean Drive
	Sunnyvale, CA 94089
	United States
	www.cepheid.com
	US: techsupport@cepheid.com
Telephone (General)	1 (888) 838-3222 - US Option 2
Telephone (General)	1 (408) 541-4191 - Outside of the US
Supplier	Cepheid AB
	Röntgenvägen 5
	SE-171 54 Solna
	Sweden
	www.cepheidinternational.com
	EU: support@cepheideurope.com
Telephone (General)	+33 563 825 319
	Cepheid Holdings Pty Ltd
	Suite 2, Level 3, Building A
	11 Talavera Road
	Macquarie Park, NSW 2113
	Australia
	www.cepheidinternational.com
	ANZ: <u>TechSupportANZ@cepheid.com</u>
Telephone (Australia)	1800 107 884

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	Skin Irritation 2 - H315
	Eye Irritation 2 - H319



2.2 Label Elements

CLP



	▼
Hazard Statements	H315 - Causes skin irritation
	H319 - Causes serious eye irritation
Precautionary Statements	
Prevention	P264 - Wash thoroughly after handling.
	P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Response	P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
	P321 - Specific treatment, see supplemental first aid information.
	P362 - Take off contaminated clothing and wash before reuse.
	P332+P313 - If skin irritation occurs: Get medical advice/attention.
	P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes.
	Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+P313 - If eye irritation persists: Get medical advice/attention.
2.3 Other Hazards	
CLP	According to Regulation (EC) No. 1272/2008 (CLP) this material is considered

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	Skin Irritation 2
	Eye Irritation 2

2.2 Label Elements

UN GHS



WARNING

hazardous.

Hazard Statements Causes skin irritation Causes serious eye irritation

Precautionary Statements Prevention Wash thor

Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

Xpert GBS LB XC

Xpert GBS LB XC



Safety Data Sheet Effective Date: July 2022 Supersedes Date: N/A

Response	IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing and wash before reuse. Specific treatment, see supplemental first aid information. 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 persists: Get medical advice/attention.
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 191	10.1200 HCS
2.1 Classification of the S	ubstance or Mixture
OSHA HCS 2012	Skin Irritation 2 Eye Irritation 2
2.2 Label Elements OSHA HCS 2012	WARNING
Hazard Statements	Causes skin irritation Causes serious eye irritation
Precautionary Statements	
Prevention	Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If on skin: Wash with plenty of water . Take off contaminated clothing and wash before reuse. Specific treatment, see supplemental first aid information. 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 persists: Get medical advice/attention.
2.3 Other Hazards	
OSHA HCS 2012	According to 29 CFR 1910.1200 - Hazard Communication Standard, this product is

According to: WHMIS 2015

2.1 Classification of the Substance or Mixture WHMIS Eye Irritation 2

Skin Irritation 2

considered hazardous.



2.2 Label Elements

WHMIS



\mathbf{V}
Causes skin irritation
Causes serious eye irritation
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.
If on skin: Wash with plenty of water .
Take off contaminated clothing and wash before reuse.
Specific treatment, see supplemental first aid information.
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 persists: Get medical advice/attention.

2.3 Other Hazards	
WHMIS	According to the Workplace Hazardous Materials Information System (WHMIS) this
	product is considered hazardous.

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.

3.2 Mixtures

Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Sodium hydroxide	CAS: 1310-73-2 EC Number: 215-185-5 EU Index: 011-002-00-6	0.5 – 1.5%	UN GHS: Skin Corr. 1B; Eye Dam. 1 EU CLP: Skin Corr. 1A, H314 OSHA HCS 2012: Skin Corr. 1B; Eye Dam. 1

Xpert GBS LB XC



Section 4: First Aid Measures

4.1 Description of First Aid Measures

Inhalation	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move victim to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing.
Skin	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. For minor skin contact, avoid spreading material on unaffected skin. In case of contact with substance, immediately flush skin with running water for at least 20 minutes. Remove and isolate contaminated clothing.
Еуе	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. In case of contact with substance, immediately flush eyes with running water for at least 20 minutes. If eye irritation persists: Get medical advice/attention.
Ingestion	First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. If swallowed, rinse mouth with water (only if the person is conscious) Do NOT induce vomiting. Do not use mouth-to-mouth method if victim ingested the substance. Obtain medical attention immediately if ingested.

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.

Section 5: Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media	LARGE FIRES: Dry chemical, CO2, alcohol-resistant foam or water spray. SMALL FIRES: Dry chemical, CO2 or water spray.
Unsuitable Extinguishing Media	No data available
5.2. Special Herende Aviaina from the Substance or Mixture	

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	May emit toxic vapors of carbon oxides, nitrogen oxides.
Hazardous Combustion Products	No data available



5.3 Advice for Firefighters

Structural firefighters' protective clothing provides limited protection in fire situations ONLY; it is not effective in spill situations where direct contact with the substance is possible.

Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection.

Wear positive pressure self-contained breathing apparatus (SCBA).

SMALL FIRES: Move containers from fire area if you can do it without risk.

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/ For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain. **Clean-up Measures**

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

No special handling necessary. If cartridge is broken avoid contact with spilled reagents.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Storage

Store according to product labeling. Keep container/package tightly closed in a cool, well-ventilated place. Keep away from incompatible materials.

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	TWAs	Not established	Not established	2 mg/m3 TWA			
(1310-73-2)	Ceilings	2 mg/m3 Ceiling	2 mg/m3 Ceiling	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 Equipmen	t
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

Section 9: Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description					
Physical Form	Liquid	Appearance/Description	Reagents are clear, colorless liquids with no odor which are primarily buffered in aqueous solutions.		
Color	Clear	Odor	Odorless		
Odor Threshold	Data lacking				

General Properties			
Boiling Point	100 °C(212 °F)	Melting Point/Freezing Point	0 °C(32 °F)
Decomposition Temperature	Data lacking	pH	8.1 - 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	Data lacking	UEL	Data lacking
LEL	Data lacking	Autoignition	Data lacking
Flammability (solid, gas)	Data lacking		
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

10.3 Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4 Conditions to Avoid

Excess heat. Heat, contact with acids may liberate very toxic gas.

10.5 Incompatible Materials

Acids, oxidizing agents.

10.6 Hazardous Decomposition Products

Carbon oxides, sodium oxides.

Section 11: Toxicological Information

11.1 Information on Toxicological Effects

Components				
Sodium hydroxide	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 		

GHS Properties	Classification		
	EU/CLP•Data lacking		
Acute Toxicity	UN GHS•Data lacking		
	OSHA HCS 2012•Data lacking		
	EU/CLP•Skin Irritation 2		
Skin Corrosion/Irritation	UN GHS•Skin Irritation 2		
	OSHA HCS 2012•Skin Irritation 2		
	EU/CLP•Eye Irritation 2		
Serious Eye Damage/Irritation	UN GHS•Eye Irritation 2		
	OSHA HCS 2012•Eye Irritation 2		
	EU/CLP•Data lacking		
Skin Sensitization	UN GHS•Data lacking		
	OSHA HCS 2012•Data lacking		
	EU/CLP•Data lacking		
Respiratory Sensitization	UN GHS•Data lacking		
	OSHA HCS 2012•Data lacking		
	EU/CLP•Data lacking		
Aspiration Hazard	UN GHS•Data lacking		
	OSHA HCS 2012•Data lacking		
	EU/CLP•Data lacking		
Carcinogenicity	UN GHS•Data lacking		
	OSHA HCS 2012•Data lacking		



Safety Data Sheet

Effective Date: July 2022 Supersedes Date: N/A Xpert GBS LB XC

GHS Properties	Classification	
	EU/CLP•Data lacking	
Germ Cell Mutagenicity	UN GHS•Data lacking	
	OSHA HCS 2012•Data lacking	
	EU/CLP•Data lacking	
Toxicity for Reproduction	UN GHS•Data lacking	
	OSHA HCS 2012•Data lacking	
	EU/CLP•Data lacking	
STOT-SE	UN GHS•Data lacking	
	OSHA HCS 2012•Data lacking	
	EU/CLP•Data lacking	
STOT-RE	UN GHS•Data lacking	
	OSHA HCS 2012•Data lacking	

Potential Health Effects

.

Inhalation	
Acute (Immediate)	May cause irritation.
Chronic (Delayed)	No data available
Skin	
Acute (Immediate)	Causes skin irritation.
Chronic (Delayed)	No data available
Eye	
Acute (Immediate)	Causes serious eye irritation.
Chronic (Delayed)	No data available
Ingestion	
Acute (Immediate)	No data available
Chronic (Delayed)	No data available

Section 12: Ecological Information

12.1 Toxicity

Material data lacking.

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.



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	UN3266	Corrosive liquid, basic, inorganic, n.o.s., (sodium hydroxide)	8	Ш	NDA		
TDG	UN3266	Corrosive liquid, basic, inorganic, n.o.s., (sodium hydroxide)	8	111	NDA		
IMO/IMDG	UN3266	Corrosive liquid, basic, inorganic, n.o.s., (sodium hydroxide)	8	111	NDA		
IATA/ICAO	UN3266	Corrosive liquid, basic, inorganic, n.o.s., (sodium hydroxide)	8	111	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

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

SARA Hazard Classifications Acute

Inventory							
Component CAS Canada DSL Canada NDSL EU EINECS EU ELNICS TSCA							
Sodium hydroxide	1310-73-2	Yes	No	Yes	No	Yes	

Canada

Labor

Canada - WHMIS - Classifications of Substances

	•Sodium hydroxide	1310-73-2	aqueous solution, 0.08%, 0.4% in aqueous solution, 2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N)
	Canada - WHMIS - Ingredient Disclosure List	1310-73-2	1 %
	•Sodium hydroxide	1310-73-2	1 70
En	vironment Canada - CEPA - Priority Substances List •Sodium hydroxide	1310-73-2	Not Listed
Un	ited States		
La	bor		
	U.S OSHA - Process Safety Management - Highly Hazardous Chemicals •Sodium hydroxide	1310-73-2	Not Listed
	U.S OSHA - Specifically Regulated Chemicals	4040 70 0	Net Lister
E 10	•Sodium hydroxide vironment	1310-73-2	Not Listed
ЕП	U.S CAA (Clean Air Act) - 1990 Hazardous Air Pollutants		
	•Sodium hydroxide	1310-73-2	Not Listed
	U.S CERCLA/SARA - Hazardous Substances and their Reportable Quantities •Sodium hydroxide	1310-73-2	1000 lb final RQ; 454 kg final RQ
	U.S CERCLA/SARA - Radionuclides and Their Reportable Quantities		-
	•Sodium hydroxide U.S CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1310-73-2	Not Listed
	•Sodium hydroxide	1310-73-2	Not Listed
	U.S CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs •Sodium hydroxide	1310-73-2	Not Listed
	U.S CERCLA/SARA - Section 313 - Emission Reporting	1010-10-2	
	•Sodium hydroxide	1310-73-2	Not Listed
	U.S CERCLA/SARA - Section 313 - PBT Chemical Listing •Sodium hydroxide	1310-73-2	Not Listed
	5		

Xpert GBS LB XC

E (including 0.04% in



Safety Data Sheet

Effective Date: July 2022 Supersedes Date: N/A

United States - California

Environment

U.S California - Proposition 65 - Carcinogens List •Sodium hydroxide	1310-73-2	Not Listed
U.S California - Proposition 65 - Developmental Toxicity •Sodium hydroxide	1310-73-2	Not Listed
U.S California - Proposition 65 - Maximum Allowable Dose Levels (MADL) •Sodium hydroxide	1310-73-2	Not Listed
U.S California - Proposition 65 - No Significant Risk Levels (NSRL) •Sodium hydroxide	1310-73-2	Not Listed
U.S California - Proposition 65 - Reproductive Toxicity - Female •Sodium hydroxide	1310-73-2	Not Listed
U.S California - Proposition 65 - Reproductive Toxicity - Male •Sodium hydroxide	1310-73-2	Not Listed

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 Xpert GBS LB XC