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

1.1 Product Identifier

Product Name **Xpert Flu/RSV XC; Xpert Xpress Flu/RSV; Xpert Flu; Xpert Xpress Flu; Xpert Xpress SARS-COV-2; Xpert Xpress SARS-CoV-2/Flu/RSV; Xpert Xpress CoV-2 *plus*; Xpert Mpox**

Product Code GXFLU/RSV-10; GXFLU/RSV-CE-10; XPRSFLU/RSV-CN-10; RXPFLU/RSV-10; XPRSFLU/RSV-CE-10; RFLU/RSV-10; GXFLU-CE-10; XPRSFLU/RSV-10; XPRSFLU-10; XPRSFLU/RSV-NP-10 XPRSARS-COV2-10; 700-6944; XPSARS-COV2-MII-10; 900-0889; 900-0890; 900-0892; XPCOV2/FLU/RSV-10; XPRSARS-COV2-DOD; 900-0918; 900-0919; XP3SARS-COV2-10; 900-1079; GXMPX-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) 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: TechSupportANZ@cepheid.com

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

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).
Not classified

2.2 Label Elements

CLP

Hazard Statements No label element(s) required

2.3 Other Hazards

CLP According to Regulation (EC) No. 1272/2008 (CLP) this material is not considered hazardous.

UN GHS (Labeling Content Used on Products)

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

2.1 Classification of the Substance or Mixture

UN GHS

Acute Toxicity Oral 5
Skin Mild Irritation 3
Eye Mild Irritation 2B

2.2 Label Elements

UN GHS

WARNING

Hazard statements

Harmful if swallowed
May be harmful in contact with skin
Causes eye irritation

Precautionary statements

Prevention Wash hands thoroughly after handling.

Response 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.
Call a POISON CENTER or doctor/physician if you feel unwell.

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 Eye Mild Irritation 2B

2.2 Label Elements

OSHA HCS 2012

Hazard statements
Harmful if swallowed
May be harmful in contact with skin
Causes eye irritation

Precautionary statements

Prevention Wash hands thoroughly after handling.

Response 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 Under United States Regulations (29 CFR 1910.1200 - Hazard Communication Standard), this product is not considered hazardous.

Canada
According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS Not classified

2.2 Label Elements

WHMIS No label element(s) required.

2.3 Other Hazards

WHMIS In Canada, the product mentioned above is not 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.

3.2 Mixtures

Composition					
Chemical Name	**Identifiers**	**%**	**LD50/LC50**	**Classifications According to Regulation/Directive**	**Comments**
Guanidine Thiocyanate	**CAS:** 593-84-0 **EINECS:** 209-812-1	10% - 20%	593 mg/kg	**EU CLP:** Acute Tox. 5, H302, H313, H320 **UN GHS:** Acute Tox. 5 (Orl); Skin Irrit. 3; Eye Irrit. 2B **OSHA HCS 2012:** Acute Tox. 5 (Orl); Eye Irrit. 2B	NDA

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.

Eye 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 Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	Plastic cartridge containing reagents may emit toxic vapors of carbon oxides, sulfur 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/ Clean-up Measures	For small spills, wear gloves and absorb spill with paper towel. Do not dispose spilled materials down drain.

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. Avoid contact with skin and eyes.

7.2 Conditions for safe storage, including any incompatibilities

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

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**
Guanidinium thiocyanate	TWA	Not established	Not established	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 Respiratory equipment is not expected to be necessary if material is used under ordinary conditions and as recommended. Otherwise, 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
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	Color	Colorless
Odor	Odorless	Odor Threshold	Data lacking
General Properties			
Boiling Point	212 °F(100 °C)	Melting Point/Freezing Point	32 °F(0 °C)
Decomposition Temperature	Data lacking	pH	3.3 to 8.8
Specific Gravity/Relative Density	= 1 Water=1	Water Solubility	Soluble 100 %
Viscosity	Data lacking	Explosive Properties	Data lacking
Oxidizing Properties:	Data lacking		
Volatility			
Vapor Pressure	Minimal	Vapor Density	Data lacking
Evaporation Rate	Minimal		
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

Incompatible materials. Burning plastic cartridge containing reagents may liberate toxic byproducts

10.5 Incompatible materials

Acids.

10.6 Hazardous decomposition products

Burning plastic cartridge containing reagents may liberate toxic byproducts.

Section 11: Toxicological Information

11.1 Information on toxicological effects

Components		
Guanidinium thiocyanate	593-84-0	**Acute Toxicity:** Intraperitoneal-Mouse LD50 • 593 mg/kg

GHS Properties	Classification
Acute Toxicity	**EU/CLP**•Data lacking **UN GHS**•Acute Toxicity - Oral 5 **OSHA HCS 2012**•Data lacking
Skin Corrosion/Irritation	**EU/CLP**•Data lacking **UN GHS**•Skin Mild Irritation 3 **OSHA HCS 2012**•Data lacking
Serious Eye Damage/Irritation	**EU/CLP**•Data lacking **UN GHS**•Eye Mild Irritation 2B **OSHA HCS 2012**•Eye Mild Irritation 2B
Skin Sensitization	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Respiratory Sensitization	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Carcinogenicity	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Germ Cell Mutagenicity	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
Toxicity for Reproduction	**EU/CLP**•Data lacking **UN GHS**•Data lacking **OSHA HCS 2012**•Data lacking
STOT-SE	**EU/CLP**•Data lacking **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 mild skin irritation.
Chronic (Delayed) No data available

Eye
Acute (Immediate) Causes eye irritation.
Chronic (Delayed) No data available

Ingestion
Acute (Immediate) May be harmful if swallowed.
Chronic (Delayed) No data available

Key to abbreviations
LD = Lethal Dose

Section 12: Ecological Information

12.1 Toxicity
LC50 (guppy): 89.1 mg/l @ 96 h

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, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional diposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO (World Health Organization) medical waste handling and disposal guidelines.

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	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable
TDG	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable
IMO/IMDG	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable
IATA/ICAO	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Applicable

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

Not relevant.

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**
Guanidinium thiocyanate	593-84-0	Yes	No	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

•Guanidinium thiocyanate	593-84-0	Not Listed

Canada - WHMIS - Ingredient Disclosure List

•Guanidinium thiocyanate	593-84-0	Not Listed

Environment

Canada - CEPA - Priority Substances List

•Guanidinium thiocyanate	593-84-0	Not Listed

United States

Labor

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

•Guanidinium thiocyanate	593-84-0	Not Listed

U.S. - OSHA - Specifically Regulated Chemicals

•Guanidinium thiocyanate	593-84-0	Not Listed

Environment

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

•Guanidinium thiocyanate	593-84-0	Not Listed

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

•Guanidinium thiocyanate	593-84-0	Not Listed

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

•Guanidinium thiocyanate	593-84-0	Not Listed

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

•Guanidinium thiocyanate	593-84-0	Not Listed

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

•Guanidinium thiocyanate	593-84-0	Not Listed

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

•Guanidinium thiocyanate	593-84-0	Not Listed

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

•Guanidinium thiocyanate	593-84-0	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Developmental Toxicity		
•Guanidinium thiocyanate	593-84-0	*Not Listed*
U.S. - California - Proposition 65 - Maximum Allowable Dose Levels (MADL)		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
•Guanidinium thiocyanate	593-84-0	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
•Guanidinium thiocyanate	593-84-0	Not Listed

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.

Section 16: Other Information

Relevant Phrases (code & full text)

H302 - Harmful if swallowed
H313 - May be harmful in contact with skin
H320 - Causes eye irritation

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