



Safety Data Sheet

Effective Date: February, 2022

Supersedes Date: June, 2020

Calibration Dyes and Buffer C
Xpert Nasopharyngeal Sample Collection Kit
Xpert Nasal Sample Collection Kit
Buffer 1-BA, Buffer 2-BA, Buffer 3-BA

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

1.1 Product Identifier

Product Name Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, Calibration Dyes and Buffer C

Product Code SWAB/B-100, SWAB/F-100, SWAB/M-100, 500-0018; 500-0028; 500-0029; 500-0030; 500-0065; 500-0501; 500-0503; 500-0517; 500-1000; 500-1001; 500-1008; 500-2581; 500-2582; 500-2583; 500-2584; 900-0120; 900-0121; 900-0122; 900-0127; 900-0128; 900-0129

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 - EU

Cepheid Holdings Pty Ltd
Suite 2, Level 3, Building A
11 Talavera Rd,
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

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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 liquids. 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 Revision 3

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

2.1 Classification of the Substance or Mixture

UN GHS The following SDS is for the final finished mixture product only as used in the laboratory. The product contains liquids. 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

UN GHS
Hazard Statements No label element(s) required
Precautionary Statements

2.3 Other Hazards

UN GHS According to the Globally Harmonized System for Classification and Labeling (GHS) this product is not considered hazardous.

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS



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2.1 Classification of the Substance or Mixture

OSHA HCS 2012

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

OSHA HCS 2012

Hazard Statements No label element(s) required

2.3 Other Hazards

OSHA HCS 2012

This product is not considered hazardous under the U.S. OSHA 29 CFR 1910.1200 Hazard Communication Standard.

Canada

According to: WHMIS

2.1 Classification of the Substance or Mixture

WHMIS

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

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

Dye constituents are at concentrations less than 1% of the entire article or not regulated as hazardous under US hazard communication regulations (29 CFR 1910.1200), EU Directives for classification and labeling of substances and mixtures, or the Global Harmonization System for classification and labeling of substances or mixtures.

Section 3: Composition/Information on Ingredients

3.1 Substances

Ingredients are not considered hazardous under EU directives for classification and labeling of substances or mixtures or the Global Harmonization System for classification and labeling of substances or mixtures.

3.2 Mixtures

Material does not meet the criteria of a mixture.

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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.
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Section 5: Firefighting Measures

5.1 Extinguishing Media

Suitable Extinguishing Media	In case of fire use media as appropriate for surrounding fire.
Unsuitable Extinguishing Media	No data available

5.2 Special Hazards Arising from the Substance or Mixture

Unusual Fire and Explosion Hazards	Not flammable or combustible.
Hazardous Combustion Products	No data available



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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. Ventilate enclosed areas. Wear appropriate protective clothing. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Emergency Procedures

No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

6.2 Environmental Precautions

Avoid run off to waterways and sewers.

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 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.

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Section 8: Exposure Controls/Personal Protection

8.1 Control Parameters

Exposure Limits/Guidelines No applicable exposure limits available for product or components.

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 In laboratory setting, wear gloves and lab coat at a minimum to minimize skin contact.

Environmental Exposure Controls Follow best practice for site management and disposal of waste.

Section 9: Physical and Chemical Properties

9.1 Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Dyes are solutions of varying color, components are odorless.
Color	Varying	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	6 to 9
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.

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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

No data available

10.5 Incompatible Materials

No data available

10.6 Hazardous Decomposition Products

No data available

Section 11: Toxicological Information

11.1 Information on Toxicological Effects

GHS Properties	Classification
Acute Toxicity	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
Skin Corrosion/Irritation	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
Serious Eye Damage/Irritation	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
Skin Sensitization	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
Respiratory Sensitization	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
Aspiration Hazard	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
Carcinogenicity	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
Germ Cell Mutagenicity	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking



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GHS Properties	Classification
Toxicity for Reproduction	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
STOT-SE	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking
STOT-RE	EU/CLP•Data lacking UN GHS 3•Data lacking OSHA HCS 2012•Data lacking

Potential Health Effects

Inhalation

Acute (Immediate) No symptoms expected.

Chronic (Delayed) No data available

Skin

Acute (Immediate) No symptoms expected.

Chronic (Delayed) No data available

Eye

Acute (Immediate) No symptoms expected.

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.



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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 mixed with beads should be treated as capable of transmitting infectious agents. Consult your institution’s environmental waste personnel on proper disposal of used specimens.

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	NDA	Not Regulated	NDA	NDA	NDA
TDG	NDA	Not Regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not Regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not Regulated	NDA	NDA	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 None

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out.



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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