

Safety Data Sheet

Specimen Lysis Tube

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name Specimen Lysis Tube

1.2. Relevant identified uses of the substance or mixture and uses advised against

Specific use(s) Aptima SARS-CoV-2 Assay

Recommended Use US Only: For Emergency Use Authorization (EUA) Only / CE-IVD

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121-4362
USA

1.4. Emergency telephone number

24 Hour Emergency Phone Number Chemtrec, Chemtrec International +1-703-527-3887.

For further information, please contact: MolecularSupport@hologic.com

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

Signal word

None

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

Mixtures 3.2

Mixtures

Component name	CAS No	%	EC No	Classification according to Regulation (EC) No.	REACH Registration
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Specimen Lysis Tube

				1272/2008 [CLP]	Number
Lauryl Sulfate Lithium Salt	2044-56-6	1 - 5	Present	no data available	-

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove to fresh air. If symptoms persist, call a doctor.
Skin Contact	Wash skin with soap and water. If symptoms persist, call a doctor.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a doctor.
Ingestion	Clean mouth with water and drink afterwards plenty of water. If symptoms persist, call a doctor.
Self-protection of the first aider	Use personal protective equipment as required.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing agent suitable for type of surrounding fire.
Unsuitable Extinguishing Media	None

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	None under normal use conditions.
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5.3. Advice for firefighters

Special protective equipment for fire-fighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Use personal protective equipment as required.
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6.2. Environmental precautions

Environmental precautions	See Section 12 for additional Ecological Information.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Cover with absorbent or contain.
Methods for cleaning up	Soak up with inert absorbent material. Dispose of contents/containers in accordance with local regulations.

6.4. Reference to other sections

Reference to other sections	See Section 12: ECOLOGICAL INFORMATION.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Wash hands thoroughly after handling. Use personal protection recommended in Section 8.

General Hygiene Considerations Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with local regulations. Use appropriate containment to avoid environmental contamination.

7.3. Specific end use(s)

Specific use(s) In vitro diagnostic

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Component name	European Union	United Kingdom	France	Spain	Germany
Lauryl Sulfate Lithium Salt 2044-56-6					TWA: 0.2 mg/m ³ Ceiling / Peak: 0.2 mg/m ³

Derived No Effect Level (DNEL) No information available

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Controls Showers. Eyewash stations. Provide adequate ventilation.

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).
Hand Protection Wear protective gloves.
Skin and body protection Wear suitable protective clothing.
Respiratory protection Not applicable.

Environmental exposure controls Use appropriate containment to avoid environmental contamination.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Appearance No information available
Colour Colourless

Odour No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	~ 6.7	
Melting point/freezing point		No information available
Boiling point / boiling range		No information available
Flash point		No information available
Evaporation rate		No information available
Flammability (solid, gas)		No information available
Flammability Limits in Air		
Upper flammability limits		No information available
Lower flammability limit		No information available
Vapour pressure		No information available
Vapour density		No information available

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Specific Gravity	1.003	
Water solubility		No information available
Solubility(ies)		No information available
Partition coefficient		No information available
Autoignition temperature		No information available
Decomposition temperature		No information available
Kinematic viscosity		No information available
Dynamic viscosity		No information available

9.2. Other information

Molecular weight	No information available
density	No information available
Bulk density	No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	None under normal use conditions
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10.2. Chemical stability

Stability	Stable under normal conditions.
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Explosion data

Sensitivity to Mechanical Impact	None
Sensitivity to Static Discharge	None

10.3. Possibility of hazardous reactions

Possibility of Hazardous Reactions	None under normal use conditions.
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10.4. Conditions to avoid

Conditions to avoid	None under normal use conditions.
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10.5. Incompatible materials

Incompatible materials	None under normal use conditions.
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10.6. Hazardous decomposition products

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	Product does not present an acute toxicity hazard based on known or supplied information.
Irritation	None under normal use conditions

Skin corrosion/irritation	Not applicable
Serious eye damage/eye irritation	Not applicable
Sensitisation	Not applicable
Germ cell mutagenicity	Not applicable
Carcinogenicity	Not applicable

Reproductive toxicity	Not applicable
STOT - single exposure	Not applicable
STOT - repeated exposure	Not applicable
Aspiration hazard	Not applicable

SECTION 12: Ecological information

12.1. Toxicity

3.49% of the mixture consists of component(s) of unknown hazards to the aquatic environment

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

This preparation contains no substance considered to be persistent, bio-accumulating nor toxic (PBT). This preparation contains no substance considered to be very persistent nor very bio-accumulating (vPvB).

12.6. Other adverse effects

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Dispose of in accordance with federal, state and local regulations.

SECTION 14: Transport information

IMDG

14.1 UN/ID no	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing group	Not regulated
14.5 Marine pollutant	Not applicable
14.6 Special Provisions	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1 UN/ID no	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental Hazard	Not applicable
14.6 Special Provisions	None

ADR

14.1 UN/ID no	Not regulated
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14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental Hazard	Not applicable
14.6 Special Provisions	None

ICAO (air)

14.1 UN/ID no	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental Hazard	Not applicable
14.6 Special Provisions	None

IATA

14.1 UN/ID no	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3 Hazard Class	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental Hazard	Not applicable
14.6 Special Provisions	None

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****SVHC**

This product contains one or more candidate substance(s) of very high concern (Regulation (EC) No. 1907/2006 (REACH), Article 59)

Water hazard class (WGK)	Not determined
TA Luft (German Air Pollution Control Regulation)	Not determined

International Inventories

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Water 7732-18-5	Present	X	X	X
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	-
Sodium Phosphate, Monobasic, Monohydrate 10049-21-5	-	-	-	X
Sodium Phosphate Dibasic 7558-79-4	Present	X	X	X
EDTA Disodium Dihydrate 6381-92-6	-	-	X	X
EGTA Free Acid 67-42-5	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	Present	X	X	Present
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	Present
Sodium Phosphate, Monobasic, Monohydrate 10049-21-5	-	X	X	-
Sodium Phosphate Dibasic 7558-79-4	Present	X	X	Present
EDTA Disodium Dihydrate 6381-92-6	-	X	X	-
EGTA Free Acid 67-42-5	-	X	X	-

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Legend

X - Present

- Not Listed

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report

No information available

SECTION 16: Other information

Revision Date

17-Sep-2021

Version

2

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet