

LumiraDx SARS-CoV-2 RNA STAR Complete Safety Data Sheet

Product numbers:

LumiraDx Reference Number	Component
L018180130096	LumiraDx SARS-CoV-2 RNA STAR Complete Kit
WI-30109	LumiraDx SARS-CoV-2 RNA STAR Complete Positive Control Media (Pos. Ctrl. Med.)
WI-30108	LumiraDx SARS-CoV-2 RNA STAR Complete Negative Control Media (Neg. Ctrl. Med.)
WI-30107	LumiraDx SARS-CoV-2 RNA STAR Complete Salt Mix
WI-30116	LumiraDx SARS-CoV-2 RNA STAR Complete Extraction Buffer
WI-30106	LumiraDx SARS-CoV-2 RNA STAR Complete Internal Control & Primer Mix (IC/P Mix)
WI-30105	LumiraDx SARS-CoV-2 RNA STAR Complete Master Mix
L018180130384	LumiraDx SARS-CoV-2 RNA STAR Complete Kit, 384
WI-30109	LumiraDx SARS-CoV-2 RNA STAR Complete Positive Control Media (Pos. Ctrl. Med.)
WI-30108	LumiraDx SARS-CoV-2 RNA STAR Complete Negative Control Media (Neg. Ctrl. Med.)
WI-30214	LumiraDx SARS-CoV-2 RNA STAR Complete Salt Mix
WI-30215	LumiraDx SARS-CoV-2 RNA STAR Complete Extraction Buffer
WI-30213	LumiraDx SARS-CoV-2 RNA STAR Complete Internal Control & Primer Mix (IC/P Mix)
WI-30212	LumiraDx SARS-CoV-2 RNA STAR Complete Master Mix

Date of revision: April 2022

Safety data sheet

According to OSHA Hazard Communication standard 29CFR 1910.1200

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance:

Product Name: LumiraDx SARS-CoV-2 RNA STAR Complete Positive Control Media (Pos. Ctrl. Med.)

Product Number: WI-30109

Use of the substance: For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

Company identification: LumiraDx UK Ltd,
Unit 50
Yorkshire Way
Doncaster
United Kingdom

Telephone number: 1-888-586-4721

Emergency telephone: USA National Response Center: (1) 800 424 8802

Customer Services Email: customerservices.US@lumiradx.com

Website: www.lumiradx.com

2. HAZARDS IDENTIFICATION

2.1. **Classification of the substance or mixture:** Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2. Label elements:

GHS label elements: Not Applicable.

Hazard pictograms: Not Applicable.

Signal word: Not Applicable.

Hazard statements: Not Applicable.

2.3. **Other hazards:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures.

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

Chemical	% Weight	CAS #	Classification according to GHS
Water	82.9%	7732-18-5	Not classified
Glycerol	15.0 %	56-81-5	Not classified
Tris	< 1.0%	77-86-1	Not classified
Ethylenediaminetetracetic acid	< 1.0 %	60-00-4	Eye Irrit. 2A, H319 Aquatic Acute 3, H402
Gentamicin sulfate	0.05%	1405-41-0	Skin Sens. 1, H317
Sodium Azide	0.05%	26628-22-8	Acute Tox. 2 (Oral), H300 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Inactivated virus	<0.01%	Not applicable	Not applicable

4. FIRST AID MEASURES

4.1. Description of first-aid measures

General information: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

Skin contact: Immediately wash with water and soap and rinse thoroughly.

Ingestion: If swallowed, seek medical attention.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Inhalation: Supply fresh air. If you feel unwell, seek medical advice.

4.2. **Most important symptoms and effects, both and acute and delayed:** No further relevant information available.

4.3. **Indication of any immediate medical attention and special treatment needed:** No further relevant information available.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or `alcohol` foam.

Special firefighting procedure: No special measures required.

Special hazards arising from the substance or mixture: No further relevant information available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Ensure suitable personal protection during removal of spillages. Avoid breathing vapors, mist, or gas. Avoid prolonged contact with eyes, skin, and clothing. For personal protection see section 8.

Environmental precautions: Keep contaminated washing water and dispose of appropriately. Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. Pick up mechanically. Clean the affected area carefully; suitable cleaners are: disinfectant.

Reference to other sections: See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling: Use personal protective equipment as required. No special handling advices are necessary.

Information about protection against explosions and fires: No special measures required.

Precautions to be taken in handling and storage: Store in secure area. Keep out of reach of children.

Storage conditions: Keep container tightly closed. Recommended storage temperature is $\leq 8^{\circ}\text{C}$.

Specific use(s): For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values:

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls:

Appropriate engineering controls: No data available.

General protective and hygienic measures: Follow usual biosafety practices for handling potentially infectious materials. The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material: The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body protection: Protective work clothing.

Respiratory protection: Respiratory protection is not required.

Environmental exposure controls: Do not let product enter the drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form: Liquid.

Color: Colorless.

Odor: No data.

9.2. Important health, safety and environmental information

pH: No data available.

Melting point/freezing point: No data available.

Boiling point/boiling range: No data available.

Flash point: No data available.

Flammability (solid, gas): No data available.

Explosive properties: No data available.

Oxidizing properties: No data available.

Vapor pressure: No data available.

Relative density: No data available.

Solubility: Soluble in water.

Water solubility: Soluble.

Partition coefficient: *n*-octanol/water: No data available.

Viscosity: No data available.

Vapor density: No data available.

Evaporation rate: No data available.

9.3. Other safety information: No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.

Materials to avoid: Strong oxidizing agents, acids and bases.

Hazardous decomposition products: Carbon oxides, nitrogen oxides. No decomposition if stored and applied as directed.

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

11.1. Information on toxicological effects

Acute toxicity: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory or skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: Based on the available data, the classification criteria are not met.

Reproductive toxicity: No data available.

Specific target organ toxicity – single exposure: No data available.

Specific target organ toxicity – repeated exposure: No data available.

Aspiration hazard: No data available.

Additional information: RTECS: Not available.

The toxicological risks are not classified due to the low concentration of hazardous ingredients. The following toxicological information is for the hazardous ingredient in pure form.

Glycerol (56-81-5)

LD₅₀ Oral Rat: 23000 mg/kg

LD₅₀ Dermal Rabbit: >10 g/kg

LC₅₀ Inhalation: >570 mg/m³

Gentamicin, sulfate salt (1405-41-0)

LD₅₀ Oral Rat: >5 g/kg

TRIS (77-86-1)

LD₅₀ Oral Rat: >5000 mg/kg

LD₅₀ Dermal Rabbit: >5000 g/kg

Sodium Azide (26628-22-8)

LD₅₀ Oral Rat 27 mg/kg

Ethylenediaminetetraacetic acid (60-00-4)

LD₅₀ Oral Rat: >2000 mg/kg

11.2. Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects: No data available.

Glycerol (56-81-5)	
LC ₅₀ Fish1	54000 (51000-57000) mg/l (Exposure time: 96h – Species: <i>Oncorhynchus mykiss</i> (static))
Sodium azide (26628-22-8)	
LC ₅₀ Fish 1:	0.8 mg/L (Exposure time: 96h – Species: <i>Oncorhynchus mykiss</i>)
LC ₅₀ Fish 2:	0.7 mg/L (Exposure time: 96h – Species: <i>Lepomis macrochirus</i>)
ErC ₅₀ (algae)	0.348 mg/l
Ethylenediaminetetraacetic acid (60-00-4)	
LC ₅₀ fish 1	34 – 62 mg/l (Exposure time: 96h – Species: <i>Lepomis macrochirus</i>)
EC ₅₀ Daphnia 1	113 mg/l (Exposure time: 48h – Species: <i>Daphnia magna</i> (static))
LC ₅₀ fish 2	44.2 – 76.5 mg/l (Exposure time: 96h – Species: <i>Pimephales promelas</i> (static))
NOEC chronic fish	>/= 25.7 mg/l (Duration: 35d – Species: <i>Brachydanio rerio</i> (Flow-through))
NOEC chronic crustacea	25 mg/l (Duration: 21d – Species: <i>Daphnia magna</i> (Semi-static))
Persistence/Degradability:	Not established
Mobility in Environmental Media:	Not Available
Bioaccumulation/ Accumulation:	
Glycerol (56-81-5)	
BCF fish 1	No accumulation
Log Pow	-1.76

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

IATA/DOT/IMDG/ADR

UN-Number: Not regulated in the meaning of transport regulations.

UN proper shipping name: Not regulated.

Transport hazard class: Not regulated.

Packaging group: Not regulated.

Environmental hazards: Not regulated.

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": Not regulated.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Glycerol (56-81-5)

Listed on the US TSCA inventory

EPA TSCA Regulatory Flag Y2 – Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

TRIS (77-86-1)

Listed on the US TSCA inventory

Ethylenediaminetetraacetic acid (60-00-4)

Listed on the US TSCA inventory

Sodium azide (26628-22-8)

Listed on the US TSCA inventory

Listed on US SARA 302

Subject to report requirements of US SARA 313

SARA Section 302 500 (this material is reactive solid. (The TPQ does not default

Threshold Planning to 10000 pounds for non-powder, non-molten, non-solution

Quantity form)

SARA 313 Emission 1%

Reporting

State Regulations

Sodium azide (26628-22-8)

US – Massachusetts – Right To Know list

US – New Jersey - Right To Know Hazardous Substance List

US Pennsylvania - Right To Know Environmental Hazard List

California Proposition 65:

This product contains the following Proposition 65 chemicals	This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.
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State Right to Know Act

Chemical Name:	Glycerol	Sodium azide	Ethylenediaminetetra acetic acid
Massachusetts:	Listed	Listed	Listed
New Jersey:	RTK Haz. Substance List	RTK Haz. Substance List	RTK Haz. Substance List
Pennsylvania:	Not Listed	RTK Enviro. List	RTK Environ. List
Pennsylvania:	Not Listed	Right To Know list	Right To Know list
New York:	Not Listed	Not Listed	Not listed
Rhode Island:	Not Listed	Not Listed	Not listed

International Inventories

Chemical Name	Glycerol	Sodium azide	Ethylenediaminetetra acetic acid
TSCA:	Listed	Listed	Listed
DSL:	Listed	Listed	Listed
NDSL:	Not Listed	Not Available	Not Listed
EINECS:	Listed	Listed	Listed
CHINA:	Listed	Listed	Listed
KECL:	Listed	Listed	Listed
JAPAN:	Listed	Listed	Listed
AICS:	Listed	Listed	Listed

15.2. [Chemical safety assessment](#): For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

GHS full text phrases:

Acute Tox. 2 (Oral) Acute toxicity (oral), Category 2
 Aquatic Acute 1 Hazardous to the aquatic environment — Acute Hazard, Category 1
 Aquatic Chronic 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1
 Aquatic Chronic 3 Hazardous to the aquatic environment — Chronic Hazard, Category 3
 Eye Irrit. 2 Serious eye damage/eye irritation, Category 2
 Resp. Sens. 1 Sensitization — Respiratory, Category 1
 Skin Irrit. 2 Skin corrosion/irritation, Category 2
 Skin Sens. 1 Sensitization — Skin, Category 1
 STOT SE 3 Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
 H300 Fatal if swallowed
 H315 Causes skin irritation
 H317 May cause an allergic skin reaction
 H319 Causes serious eye irritation
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
 H335 May cause respiratory irritation
 H400 Very toxic to aquatic life
 H410 Very toxic to aquatic life with long lasting effects
 H412 Harmful to aquatic life with long lasting effects

Abbreviations and acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists
CAS: Chemical Abstracts Service (division of the American Chemical Society)DOT: US Department of Transportation
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
HMIS: Hazardous Materials Identification System (USA)
IATA: International Air Transport Association
IMDG: International Maritime Code for Dangerous Goods
LC₅₀: Lethal concentration, 50 percent
LD₅₀: Lethal dose, 50 percent
NFPA: National Fire Protection Association (USA)
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
PBT: Persistent, Bioaccumulative and Toxic
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
TLV: Threshold Limit Value
vPvB: very Persistent and very Bioaccumulative

Information contained herein are based on reasonable investigation and research. However, LumiraDx UK or its affiliates do not warrant the accuracy of this information. All materials may present unknown hazards and should be used with caution. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this product by a properly trained person using this product. In no case shall LumiraDx be liable for incidental or consequential damages. Use of **LumiraDx SARS-CoV-2 RNA STAR Complete** Positive Control Media (Pos. Ctrl. Med.) and/or **LumiraDx SARS-CoV-2 RNA STAR Complete** Kit is subject to referenced and limitations included the product specifications.

END OF SAFETY DATA SHEET

Safety data sheet

According to OSHA Hazard Communication standard 29CFR 1910.1200

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance:

Product Name: LumiraDx SARS-CoV-2 RNA STAR Complete Negative Control Media (Neg. Ctrl. Med.)

Product Number: WI-30108

Use of the substance: For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

Company identification: LumiraDx UK Ltd,
Unit 50
Yorkshire Way
Doncaster
United Kingdom

Telephone number: 1-888-586-4721

Emergency telephone: USA National Response Center: (1) 800 424 8802

Customer Services Email: customerservices.US@lumiradx.com

Website: www.lumiradx.com

2. HAZARDS IDENTIFICATION

2.1. **Classification of the substance or mixture:** Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2. Label elements:

GHS label elements: Not Applicable.

Hazard pictograms: Not Applicable.

Signal word: Not Applicable.

Hazard statements: Not Applicable.

2.3. **Other hazards:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures.

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

Additional information: No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. Description of first-aid measures

General information: No special measures required.

Skin contact: Immediately wash with water and soap and rinse thoroughly.

Ingestion: If swallowed, seek medical attention.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Inhalation: Supply fresh air. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed: No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or `alcohol` foam.

Special firefighting procedure: No special measures required.

Special hazards arising from the substance or mixture: No further relevant information available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

Environmental precautions: Keep contaminated washing water and dispose of appropriately. Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. Pick up mechanically. Clean the affected area carefully; suitable cleaners are: disinfectant.

Reference to other sections: See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling: Use personal protective equipment as required. No special handling advices are necessary.

Information about protection against explosions and fires: No special measures required.

Precautions to be taken in handling and storage: Store in secure area. Keep out of reach of children.

Storage conditions: Keep container tightly closed. Recommended storage temperature -25°C to -15°C.

Specific use(s): For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values:

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls:

Appropriate engineering controls: No data available.

General protective and hygienic measures: Follow usual biosafety practices for handling potentially infectious materials. The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material: The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body protection: Protective work clothing.

Respiratory protection: Respiratory protection is not required.

Environmental exposure controls: Do not let product enter the drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form: Liquid.

Color: Colorless.

Odor: Odorless.

9.2. Important health, safety and environmental information

pH: No data available.

Melting point/freezing point: No data available.

Boiling point/boiling range: No data available.

Flash point: No data available.

Flammability (solid, gas): No data available.

Explosive properties: No data available.

Oxidizing properties: No data available.

Vapor pressure: No data available.

Relative density: No data available.

Solubility: Soluble in water.

Water solubility: Soluble.

Partition coefficient: *n*-octanol/water: No data available.

Viscosity: No data available.

Vapor density: No data available.

Evaporation rate: No data available.

9.3. Other safety information: No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Materials to avoid: No further relevant information available.

Hazardous decomposition products: No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

11.1. Information on toxicological effects

Acute toxicity: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory or skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: Based on the available data, the classification criteria are not met.

Reproductive toxicity: No data available.

Specific target organ toxicity – single exposure: No data available.

Specific target organ toxicity – repeated exposure: No data available.

Aspiration hazard: No data available.

Additional information: RTECS: Not available.

Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

IATA/DOT/IMDG/ADR

UN-Number: Not regulated in the meaning of transport regulations.

UN proper shipping name: Not regulated.

Transport hazard class: Not regulated.

Packaging group: Not regulated.

Environmental hazards: Not regulated.

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": Not regulated.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

Section 355 (extremely hazardous substances): None of the ingredients is listed.

Section 313 (Specific toxic chemical listings): None of the ingredients is listed.

TSCA (Toxic Substances Control Act): All components have the value ACTIVE.

Hazardous Air Pollutants: None of the ingredients is listed.

Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed.

Chemicals known to cause developmental toxicity: None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency): None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH): None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health): None of the ingredients is listed.

GHS label elements: None.

Hazard pictograms: None.

Signal word: None.

Hazard statements: None.

15.2. Chemical safety assessment: For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

Abbreviations and acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society) DOT: US Department of Transportation

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HMIS: Hazardous Materials Identification System (USA)

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

LC₅₀: Lethal concentration, 50 percent

LD₅₀: Lethal dose, 50 percent

NFPA: National Fire Protection Association (USA)

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

PBT: Persistent, Bioaccumulative and Toxic

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

TLV: Threshold Limit Value

vPvB: very Persistent and very Bioaccumulative

Information contained herein are based on reasonable investigation and research. However, LumiraDx UK or its affiliates do not warrant the accuracy of this information. All materials may present unknown hazards and should be used with caution. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this product by a properly trained person using this product. In no case shall LumiraDx be liable for incidental or consequential damages. Use of **LumiraDx SARS-CoV-2 RNA STAR Complete** Negative Control Media (Neg. Ctrl. Med.) and/or **LumiraDx SARS-CoV-2 RNA STAR Complete** Kit is subject to referenced and limitations included the product specifications.

END OF SAFETY DATA SHEET

Safety data sheet

According to OSHA Hazard Communication standard 29CFR 1910.1200

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance:

Product Name: LumiraDx SARS-CoV-2 RNA STAR Complete Salt Mix

Product Number: WI-30107, WI-30214

Use of the substance: For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

Company identification: LumiraDx UK Ltd,
Unit 50
Yorkshire Way
Doncaster
United Kingdom

Telephone number: 1-888-586-4721

Emergency telephone: USA National Response Center: (1) 800 424 8802

Customer Services Email: customerservices.US@lumiradx.com

Website: www.lumiradx.com

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture: Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2. Label elements:

GHS label elements: Not Applicable.

Hazard pictograms: Not Applicable.

Signal word: Not Applicable.

Hazard statements: Not Applicable.

2.3. Other hazards: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures.

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

Additional information: No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. Description of first-aid measures

General information: No special measures required.

Skin contact: Immediately wash with water and soap and rinse thoroughly.

Ingestion: If swallowed, seek medical attention.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Inhalation: Supply fresh air. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed: No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or `alcohol` foam.

Special firefighting procedure: No special measures required.

Special hazards arising from the substance or mixture: No further relevant information available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

Environmental precautions: Keep contaminated washing water and dispose of appropriately. Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. Pick up mechanically. Clean the affected area carefully; suitable cleaners are: disinfectant.

Reference to other sections: See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling: Use personal protective equipment as required. No special handling advices are necessary.

Information about protection against explosions and fires: No special measures required.

Precautions to be taken in handling and storage: Store in secure area. Keep out of reach of children.

Storage conditions: Keep container tightly closed. Recommended storage temperature -25°C to -15°C.

Specific use(s): For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values:

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls:

Appropriate engineering controls: No data available.

General protective and hygienic measures: Follow usual biosafety practices for handling potentially infectious materials. The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material: The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body protection: Protective work clothing.

Respiratory protection: Respiratory protection is not required.

Environmental exposure controls: Do not let product enter the drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form: Liquid.

Color: Colorless.

Odor: No data.

9.2. Important health, safety and environmental information

pH: No data available.

Melting point/freezing point: No data available.

Boiling point/boiling range: No data available.

Flash point: No data available.

Flammability (solid, gas): No data available.

Explosive properties: No data available.

Oxidizing properties: No data available.

Vapor pressure: No data available.

Relative density: No data available.

Solubility: Soluble in water.

Water solubility: Soluble.

Partition coefficient: *n*-octanol/water: No data available.

Viscosity: No data available.

Vapor density: No data available.

Evaporation rate: No data available.

9.3. Other safety information: No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Materials to avoid: No further relevant information available.

Hazardous decomposition products: No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

11.1. Information on toxicological effects

Acute toxicity: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory or skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: Based on the available data, the classification criteria are not met.

Reproductive toxicity: No data available.

Specific target organ toxicity – single exposure: No data available.

Specific target organ toxicity – repeated exposure: No data available.

Aspiration hazard: No data available.

Additional information: RTECS: Not available.

Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

IATA/DOT/IMDG/ADR

UN-Number: Not regulated in the meaning of transport regulations.

UN proper shipping name: Not regulated.

Transport hazard class: Not regulated.

Packaging group: Not regulated.

Environmental hazards: Not regulated.

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": Not regulated.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

Section 355 (extremely hazardous substances): None of the ingredients is listed.

Section 313 (Specific toxic chemical listings): None of the ingredients is listed.

TSCA (Toxic Substances Control Act): All components have the value ACTIVE.

Hazardous Air Pollutants: None of the ingredients is listed.

Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed.

Chemicals known to cause developmental toxicity: None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency): None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH): None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health): None of the ingredients is listed.

GHS label elements: None.

Hazard pictograms: None.

Signal word: None.

Hazard statements: None.

15.2. Chemical safety assessment: For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

Abbreviations and acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society) DOT: US Department of Transportation

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HMIS: Hazardous Materials Identification System (USA)

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

LC₅₀: Lethal concentration, 50 percent

LD₅₀: Lethal dose, 50 percent

NFPA: National Fire Protection Association (USA)

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

PBT: Persistent, Bioaccumulative and Toxic

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

TLV: Threshold Limit Value

vPvB: very Persistent and very Bioaccumulative

Information contained herein are based on reasonable investigation and research. However, LumiraDx UK or its affiliates do not warrant the accuracy of this information. All materials may present unknown hazards and should be used with caution. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this product by a properly trained person using this product. In no case shall LumiraDx be liable for incidental or consequential damages. Use of **LumiraDx SARS-CoV-2 RNA STAR Complete Salt Mix** and/or **LumiraDx SARS-CoV-2 RNA STAR Complete Kit** is subject to referenced and limitations included the product specifications.

END OF SAFETY DATA SHEET

Safety data sheet

According to OSHA Hazard Communication standard 29CFR 1910.1200

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance:

Product Name: LumiraDx SARS-CoV-2 RNA STAR Complete Extraction Buffer

Product Number: WI-30116, WI-30215

Use of the substance: For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

Company identification: LumiraDx UK Ltd,
Unit 50
Yorkshire Way
Doncaster
United Kingdom

Telephone number: 1-888-586-4721

Emergency telephone: USA National Response Center: (1) 800 424 8802

Customer Services Email: customerservices.US@lumiradx.com

Website: www.lumiradx.com

2. HAZARDS IDENTIFICATION

2.1. **Classification of the substance or mixture:** Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2. Label elements:

GHS label elements: Not Applicable.

Hazard pictograms: Not Applicable.

Signal word: Not Applicable.

Hazard statements: Not Applicable.

2.3. **Other hazards:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures.

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

Additional information: No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. Description of first-aid measures

General information: No special measures required.

Skin contact: Immediately wash with water and soap and rinse thoroughly.

Ingestion: If swallowed, seek medical attention.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Inhalation: Supply fresh air. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed: No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or `alcohol` foam.

Special firefighting procedure: No special measures required.

Special hazards arising from the substance or mixture: No further relevant information available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

Environmental precautions: Keep contaminated washing water and dispose of appropriately. Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. Pick up mechanically. Clean the affected area carefully; suitable cleaners are: disinfectant.

Reference to other sections: See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling: Use personal protective equipment as required. No special handling advices are necessary.

Information about protection against explosions and fires: No special measures required.

Precautions to be taken in handling and storage: Store in secure area. Keep out of reach of children.

Storage conditions: Keep container tightly closed. Recommended storage temperature -25°C to -15°C.

Specific use(s): For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values:

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls:

Appropriate engineering controls: No data available.

General protective and hygienic measures: Follow usual biosafety practices for handling potentially infectious materials. The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material: The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body protection: Protective work clothing.

Respiratory protection: Respiratory protection is not required.

Environmental exposure controls: Do not let product enter the drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form: Liquid.

Color: Colorless.

Odor: No data.

9.2. Important health, safety and environmental information

pH: No data available.

Melting point/freezing point: No data available.

Boiling point/boiling range: No data available.

Flash point: No data available.

Flammability (solid, gas): No data available.

Explosive properties: No data available.

Oxidizing properties: No data available.

Vapor pressure: No data available.

Relative density: No data available.

Solubility: Soluble in water.

Water solubility: Soluble.

Partition coefficient: *n*-octanol/water: No data available.

Viscosity: No data available.

Vapor density: No data available.

Evaporation rate: No data available.

9.3. Other safety information: No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Materials to avoid: No further relevant information available.

Hazardous decomposition products: No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

11.1. Information on toxicological effects

Acute toxicity: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory or skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: Based on the available data, the classification criteria are not met.

Reproductive toxicity: No data available.

Specific target organ toxicity – single exposure: No data available.

Specific target organ toxicity – repeated exposure: No data available.

Aspiration hazard: No data available.

Additional information: RTECS: Not available.

Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

IATA/DOT/IMDG/ADR

UN-Number: Not regulated in the meaning of transport regulations.

UN proper shipping name: Not regulated.

Transport hazard class: Not regulated.

Packaging group: Not regulated.

Environmental hazards: Not regulated.

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": Not regulated.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

Section 355 (extremely hazardous substances): None of the ingredients is listed.

Section 313 (Specific toxic chemical listings): None of the ingredients is listed.

TSCA (Toxic Substances Control Act): All components have the value ACTIVE.

Hazardous Air Pollutants: None of the ingredients is listed.

Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed.

Chemicals known to cause developmental toxicity: None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency): None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH): None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health): None of the ingredients is listed.

GHS label elements: None.

Hazard pictograms: None.

Signal word: None.

Hazard statements: None.

15.2. Chemical safety assessment: For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

Abbreviations and acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society) DOT: US Department of Transportation

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HMIS: Hazardous Materials Identification System (USA)

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

LC₅₀: Lethal concentration, 50 percent

LD₅₀: Lethal dose, 50 percent

NFPA: National Fire Protection Association (USA)

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

PBT: Persistent, Bioaccumulative and Toxic

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

TLV: Threshold Limit Value

vPvB: very Persistent and very Bioaccumulative

Information contained herein are based on reasonable investigation and research. However, LumiraDx UK or its affiliates do not warrant the accuracy of this information. All materials may present unknown hazards and should be used with caution. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this product by a properly trained person using this product. In no case shall LumiraDx be liable for incidental or consequential damages. Use of **LumiraDx SARS-CoV-2 RNA STAR Complete** Extraction Buffer and/or **LumiraDx SARS-CoV-2 RNA STAR Complete** Kit is subject to referenced and limitations included the product specifications.

END OF SAFETY DATA SHEET

Safety data sheet

According to OSHA Hazard Communication standard 29CFR 1910.1200

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance:

Product Name: LumiraDx SARS-CoV-2 RNA STAR Complete Internal Control & Primer Mix (IC/P Mix)

Product Number: WI-30106, WI-30213

Use of the substance: For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

Company identification: LumiraDx UK Ltd,
Unit 50
Yorkshire Way
Doncaster
United Kingdom

Telephone number: 1-888-586-4721

Emergency telephone: USA National Response Center: (1) 800 424 8802

Customer Services Email: customerservices.US@lumiradx.com

Website: www.lumiradx.com

2. HAZARDS IDENTIFICATION

2.1. **Classification of the substance or mixture:** Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2. Label elements:

GHS label elements: Not Applicable.

Hazard pictograms: Not Applicable.

Signal word: Not Applicable.

Hazard statements: Not Applicable.

2.3. **Other hazards:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures.

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

Additional information: No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. Description of first-aid measures

General information: No special measures required.

Skin contact: Immediately wash with water and soap and rinse thoroughly.

Ingestion: If swallowed, seek medical attention.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Inhalation: Supply fresh air. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed: No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or `alcohol` foam.

Special firefighting procedure: No special measures required.

Special hazards arising from the substance or mixture: No further relevant information available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

Environmental precautions: Keep contaminated washing water and dispose of appropriately. Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. Pick up mechanically. Clean the affected area carefully; suitable cleaners are: disinfectant.

Reference to other sections: See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling: Use personal protective equipment as required. No special handling advices are necessary.

Information about protection against explosions and fires: No special measures required.

Precautions to be taken in handling and storage: Store in secure area. Keep out of reach of children.

Storage conditions: Keep container tightly closed. Recommended storage temperature -25°C to -15°C.

Specific use(s): For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values:

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls:

Appropriate engineering controls: No data available.

General protective and hygienic measures: Follow usual biosafety practices for handling potentially infectious materials. The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material: The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body protection: Protective work clothing.

Respiratory protection: Respiratory protection is not required.

Environmental exposure controls: Do not let product enter the drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form: Liquid.

Color: Light purple.

Odor: No data.

9.2. Important health, safety and environmental information

pH: No data available.

Melting point/freezing point: No data available.

Boiling point/boiling range: No data available.

Flash point: No data available.

Flammability (solid, gas): No data available.

Explosive properties: No data available.

Oxidizing properties: No data available.

Vapor pressure: No data available.

Relative density: No data available.

Solubility: Soluble in water.

Water solubility: Soluble.

Partition coefficient: *n*-octanol/water: No data available.

Viscosity: No data available.

Vapor density: No data available.

Evaporation rate: No data available.

9.3. Other safety information: No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Materials to avoid: No further relevant information available.

Hazardous decomposition products: No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

11.1. Information on toxicological effects

Acute toxicity: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory or skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: Based on the available data, the classification criteria are not met.

Reproductive toxicity: No data available.

Specific target organ toxicity – single exposure: No data available.

Specific target organ toxicity – repeated exposure: No data available.

Aspiration hazard: No data available.

Additional information: RTECS: Not available.

Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

IATA/DOT/IMDG/ADR

UN-Number: Not regulated in the meaning of transport regulations.

UN proper shipping name: Not regulated.

Transport hazard class: Not regulated.

Packaging group: Not regulated.

Environmental hazards: Not regulated.

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": Not regulated.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

Section 355 (extremely hazardous substances): None of the ingredients is listed.

Section 313 (Specific toxic chemical listings): None of the ingredients is listed.

TSCA (Toxic Substances Control Act): All components have the value ACTIVE.

Hazardous Air Pollutants: None of the ingredients is listed.

Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed.

Chemicals known to cause developmental toxicity: None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency): None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH): None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health): None of the ingredients is listed.

GHS label elements: None.

Hazard pictograms: None.

Signal word: None.

Hazard statements: None.

15.2. Chemical safety assessment: For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

Abbreviations and acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society) DOT: US Department of Transportation

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HMIS: Hazardous Materials Identification System (USA)

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

LC₅₀: Lethal concentration, 50 percent

LD₅₀: Lethal dose, 50 percent

NFPA: National Fire Protection Association (USA)

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

PBT: Persistent, Bioaccumulative and Toxic

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

TLV: Threshold Limit Value

vPvB: very Persistent and very Bioaccumulative

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END OF SAFETY DATA SHEET

Safety data sheet

According to OSHA Hazard Communication standard 29CFR 1910.1200

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance:

Product Name: LumiraDx SARS-CoV-2 RNA STAR Complete Master Mix

Product Number: WI-30105, WI-30212

Use of the substance: For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

Company identification: LumiraDx UK Ltd,
Unit 50
Yorkshire Way
Doncaster
United Kingdom

Telephone number: 1-888-586-4721

Emergency telephone: USA National Response Center: (1) 800 424 8802

Customer Services Email: customerservices.US@lumiradx.com

Website: www.lumiradx.com

2. HAZARDS IDENTIFICATION

2.1. **Classification of the substance or mixture:** Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).

2.2. Label elements:

GHS label elements: Not Applicable.

Hazard pictograms: Not Applicable.

Signal word: Not Applicable.

Hazard statements: Not Applicable.

2.3. **Other hazards:** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures.

The product contains no substances which at their given concentration, are considered to be hazardous to health. We recommend handling all chemicals with caution.

Additional information: No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. Description of first-aid measures

General information: No special measures required.

Skin contact: Immediately wash with water and soap and rinse thoroughly.

Ingestion: If swallowed, seek medical attention.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Inhalation: Supply fresh air. If you feel unwell, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed: No further relevant information available.

4.3. Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or `alcohol` foam.

Special firefighting procedure: No special measures required.

Special hazards arising from the substance or mixture: No further relevant information available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

Environmental precautions: Keep contaminated washing water and dispose of appropriately. Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material. Pick up mechanically. Clean the affected area carefully; suitable cleaners are: disinfectant.

Reference to other sections: See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling: Use personal protective equipment as required. No special handling advices are necessary.

Information about protection against explosions and fires: No special measures required.

Precautions to be taken in handling and storage: Store in secure area. Keep out of reach of children.

Storage conditions: Keep container tightly closed. Recommended storage temperature -25°C to -15°C.

Specific use(s): For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values:

Components with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2. Exposure controls:

Appropriate engineering controls: No data available.

General protective and hygienic measures: Follow usual biosafety practices for handling potentially infectious materials. The usual precautionary measures should be adhered to when handling chemicals.

Personal protective equipment:

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

Penetration time of glove material: The exact break through time of the protective gloves determined by the manufacturer should be observed.

Body protection: Protective work clothing.

Respiratory protection: Respiratory protection is not required.

Environmental exposure controls: Do not let product enter the drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Form: Liquid.

Color: Colorless.

Odor: No data.

9.2. Important health, safety and environmental information

pH: No data available.

Melting point/freezing point: No data available.

Boiling point/boiling range: No data available.

Flash point: No data available.

Flammability (solid, gas): No data available.

Explosive properties: No data available.

Oxidizing properties: No data available.

Vapor pressure: No data available.

Relative density: No data available.

Solubility: Soluble in water.

Water solubility: Soluble.

Partition coefficient: *n*-octanol/water: No data available.

Viscosity: No data available.

Vapor density: No data available.

Evaporation rate: No data available.

9.3. Other safety information: No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid: No further relevant information available.

Materials to avoid: No further relevant information available.

Hazardous decomposition products: No dangerous decomposition products known.

11. TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

11.1. Information on toxicological effects

Acute toxicity: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory or skin sensitization: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: Based on the available data, the classification criteria are not met.

Reproductive toxicity: No data available.

Specific target organ toxicity – single exposure: No data available.

Specific target organ toxicity – repeated exposure: No data available.

Aspiration hazard: No data available.

Additional information: RTECS: Not available.

Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. ECOLOGICAL INFORMATION

Toxicity: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation: Dispose of waste in accordance to applicable national, regional, or local regulations.

Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14. TRANSPORT INFORMATION

IATA/DOT/IMDG/ADR

UN-Number: Not regulated in the meaning of transport regulations.

UN proper shipping name: Not regulated.

Transport hazard class: Not regulated.

Packaging group: Not regulated.

Environmental hazards: Not regulated.

Special precautions for user: Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": Not regulated.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)

Section 355 (extremely hazardous substances): None of the ingredients is listed.

Section 313 (Specific toxic chemical listings): None of the ingredients is listed.

TSCA (Toxic Substances Control Act): All components have the value ACTIVE.

Hazardous Air Pollutants: None of the ingredients is listed.

Proposition 65

Chemicals known to cause cancer: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for females: None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males: None of the ingredients is listed.

Chemicals known to cause developmental toxicity: None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency): None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH): None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health): None of the ingredients is listed.

GHS label elements: None.

Hazard pictograms: None.

Signal word: None.

Hazard statements: None.

15.2. Chemical safety assessment: For this product a chemical safety assessment was not carried out.

16. OTHER INFORMATION

Abbreviations and acronyms:

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society) DOT: US Department of Transportation

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HMIS: Hazardous Materials Identification System (USA)

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

LC₅₀: Lethal concentration, 50 percent

LD₅₀: Lethal dose, 50 percent

NFPA: National Fire Protection Association (USA)

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

PBT: Persistent, Bioaccumulative and Toxic

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

TLV: Threshold Limit Value

vPvB: very Persistent and very Bioaccumulative

Information contained herein are based on reasonable investigation and research. However, LumiraDx UK or its affiliates do not warrant the accuracy of this information. All materials may present unknown hazards and should be used with caution. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this product by a properly trained person using this product. In no case shall LumiraDx be liable for incidental or consequential damages. Use of **LumiraDx SARS-CoV-2 RNA STAR Complete** Master Mix and/or **LumiraDx SARS-CoV-2 RNA STAR Complete** Kit is subject to referenced and limitations included the product specifications.

END OF SAFETY DATA SHEET