

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

Product Numbers:

LumiraDx Reference Number	Component
L018180030096	<b>LumiraDx SARS-CoV-2 RNA STAR Kit</b>
SPEC-30092	<b>LumiraDx SARS-CoV-2 RNA STAR Master Mix</b>
SPEC-30093	<b>LumiraDx SARS-CoV-2 RNA STAR 50X Internal Control &amp; Primer Mix (50X IC/P Mix)</b>
SPEC-30094	<b>LumiraDx SARS-CoV-2 RNA STAR 10X Salt Mix</b>
SPEC-30095	<b>LumiraDx SARS-CoV-2 RNA STAR Positive Extraction Control (Pos. Ext. Ctrl.)</b>
SPEC-30096	<b>LumiraDx SARS-CoV-2 RNA STAR Negative Extraction Control (Neg. Ext. Ctrl.)</b>

## 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 or preparation

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

Product Number : SPEC-30092

## 1.2. Use of the substance/preparation

Identified Uses : For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

## 1.3. Company/undertaking identification

Company Address : LumiraDx UK Ltd.  
3 More London Riverside  
London  
SE1 2AQ  
United Kingdom

Telephone Number : 1-888-586-4721

Email : customerservices.US@lumiradx.com

## 1.4. Emergency telephone

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

# 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

**After inhalation:** Supply fresh air, consult doctor in case of complaints

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

#### 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

#### 5.1. Suitable extinguishing agents

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

#### 5.2. Special hazards arising from the substance or mixture

No further relevant information available.

#### 5.3. Advice for firefighters

**Protective equipment:** No special measures required.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

## 6.2. Environmental precautions:

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water.

## 6.3. 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

## 6.4. Reference to other sections

See Section 13 for disposal information.

# 7. HANDLING AND STORAGE

## 7.1. Handling

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

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

## 7.2. Storage

Keep container tightly closed.

Recommended storage temperature -25°C to -15°C.

## 7.3. 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

### 10.1. Reactivity

No data available

### 10.2. Chemical stability

Stable under recommended storage conditions

### 10.3. Possibility of hazardous reactions

No dangerous reactions known

### 10.4. Conditions to avoid

No further relevant information available.

### 10.5. Materials to avoid

No further relevant information available.

### 10.6. 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.

This may include the following:

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	: No data available
<b>Skin corrosion/irritation</b>	: No data available
<b>Serious eye damage/eye irritation</b>	: No data available
<b>Respiratory or skin sensitization</b>	: No data available
<b>Germ cell mutagenicity</b>	: No data available

#### **Carcinogenicity:**

Based on the available data, the classification criteria are not met

<b>Reproductive toxicity</b>	: No data available
<b>Specific target organ toxicity – single exposure</b>	: No data available
<b>Specific target organ toxicity – repeated exposure</b>	: No data available
<b>Aspiration hazard</b>	: No data available
<b>Additional Information</b>	: RTECS: Not available

## 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

### 12.1. Toxicity

No data available

### 12.2. Persistence and Degradability

No data available

### 12.3. Bioaccumulative Potential

No data available

### 12.4. Mobility in Soil

No data available

### 12.5. 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.

### 12.6. 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

### 14.1. UN number

**DOT, ADR, IMDG, IATA:** Not regulated in the meaning of transport regulations

### 14.2. UN proper shipping name

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.3. Transport hazard class(es)

**DOT, ADR, ADN, IMDG, IATA:** Not regulated

### 14.4. Packaging group

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

### 14.8. 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**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### **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

## 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 or preparation

Product Name : LumiraDx SARS-CoV-2 RNA STAR 50X Internal Control & Primer Mix  
(50X IC/P Mix)

Product Number : SPEC-30093

## 1.2. Use of the substance/preparation

Identified Uses : For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

## 1.3. Company/undertaking identification

Company Address : LumiraDx UK Ltd.  
3 More London Riverside  
London  
SE1 2AQ  
United Kingdom

Telephone Number : 1-888-586-4721

Email : customerservices.US@lumiradx.com

## 1.4. Emergency telephone

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

# 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

**After inhalation:** Supply fresh air, consult doctor in case of complaints

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

#### 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

#### 5.1. Suitable extinguishing agents

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

#### 5.2. Special hazards arising from the substance or mixture

No further relevant information available.

#### 5.3. Advice for firefighters

**Protective equipment:** No special measures required.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

## 6.2. Environmental precautions:

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water.

## 6.3. 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

## 6.4. Reference to other sections

See Section 13 for disposal information.

# 7. HANDLING AND STORAGE

## 7.1. Handling

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

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

## 7.2. Storage

Keep container tightly closed.

Recommended storage temperature -25°C to -15°C

## 7.3. 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

### 10.1. Reactivity

No data available

### 10.2. Chemical stability

Stable under recommended storage conditions

### 10.3. Possibility of hazardous reactions

No dangerous reactions known

### 10.4. Conditions to avoid

No further relevant information available.

### 10.5. Materials to avoid

No further relevant information available.

### 10.6. 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.

This may include the following:

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	: No data available
<b>Skin corrosion/irritation</b>	: No data available
<b>Serious eye damage/eye irritation</b>	: No data available
<b>Respiratory or skin sensitization</b>	: No data available
<b>Germ cell mutagenicity</b>	: No data available

#### **Carcinogenicity:**

Based on the available data, the classification criteria are not met

<b>Reproductive toxicity</b>	: No data available
<b>Specific target organ toxicity – single exposure</b>	: No data available
<b>Specific target organ toxicity – repeated exposure</b>	: No data available
<b>Aspiration hazard</b>	: No data available
<b>Additional Information</b>	: RTECS: Not available

## 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

### 12.1. Toxicity

No data available

### 12.2. Persistence and Degradability

No data available

### 12.3. Bioaccumulative Potential

No data available

### 12.4. Mobility in Soil

No data available

### 12.5. 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.

### 12.6. 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

### 14.1. UN number

**DOT, ADR, IMDG, IATA:** Not regulated in the meaning of transport regulations

### 14.2. UN proper shipping name

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.3. Transport hazard class(es)

**DOT, ADR, ADN, IMDG, IATA:** Not regulated

### 14.4. Packaging group

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

### 14.8. 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**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### **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

## 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 or preparation

Product Name : LumiraDx SARS-CoV-2 RNA STAR 10X Salt Mix  
Product Number : SPEC-30094

## 1.2. Use of the substance/preparation

Identified Uses : For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

## 1.3. Company/undertaking identification

Company Address : LumiraDx UK Ltd.  
3 More London Riverside  
London  
SE1 2AQ  
United Kingdom  
Telephone Number : 1-888-586-4721  
Email : customerservices.US@lumiradx.com

## 1.4. Emergency telephone

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

# 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

**After inhalation:** Supply fresh air, consult doctor in case of complaints

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

#### 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

#### 5.1. Suitable extinguishing agents

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

#### 5.2. Special hazards arising from the substance or mixture

No further relevant information available.

#### 5.3. Advice for firefighters

**Protective equipment:** No special measures required.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

## 6.2. Environmental precautions:

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water.

## 6.3. 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

## 6.4. Reference to other sections

See Section 13 for disposal information.

# 7. HANDLING AND STORAGE

## 7.1. Handling

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

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

## 7.2. Storage

Keep container tightly closed.

Recommended storage temperature -25°C to -15°C

## 7.3. 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

### 10.1. Reactivity

No data available

### 10.2. Chemical stability

Stable under recommended storage conditions

### 10.3. Possibility of hazardous reactions

No dangerous reactions known

### 10.4. Conditions to avoid

No further relevant information available.

### 10.5. Materials to avoid

No further relevant information available.

### 10.6. 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.

This may include the following:

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	: No data available
<b>Skin corrosion/irritation</b>	: No data available
<b>Serious eye damage/eye irritation</b>	: No data available
<b>Respiratory or skin sensitization</b>	: No data available
<b>Germ cell mutagenicity</b>	: No data available

#### **Carcinogenicity:**

Based on the available data, the classification criteria are not met

<b>Reproductive toxicity</b>	: No data available
<b>Specific target organ toxicity – single exposure</b>	: No data available
<b>Specific target organ toxicity – repeated exposure</b>	: No data available
<b>Aspiration hazard</b>	: No data available
<b>Additional Information</b>	: RTECS: Not available

## 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

### 12.1. Toxicity

No data available

### 12.2. Persistence and Degradability

No data available

### 12.3. Bioaccumulative Potential

No data available

### 12.4. Mobility in Soil

No data available

### 12.5. 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.

### 12.6. 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

### 14.1. UN number

**DOT, ADR, IMDG, IATA:** Not regulated in the meaning of transport regulations

### 14.2. UN proper shipping name

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.3. Transport hazard class(es)

**DOT, ADR, ADN, IMDG, IATA:** Not regulated

### 14.4. Packaging group

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

### 14.8. 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

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### 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

### 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 or preparation

Product Name : LumiraDx SARS-CoV-2 RNA STAR Positive Extraction Control  
(Pos. Ext. Ctrl.)

Product Number : SPEC-30095

### 1.2. Use of the substance/preparation

Identified Uses : For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

### 1.3. Company/undertaking identification

Company Address : LumiraDx UK Ltd.  
3 More London Riverside  
London  
SE1 2AQ  
United Kingdom

Telephone Number : 1-888-586-4721

Email : customerservices.US@lumiradx.com

### 1.4. Emergency telephone

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

## 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).

**After inhalation:** Supply fresh air, consult doctor in case of complaints

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

#### 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

### 5.1. Suitable extinguishing agents

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

### 5.2. Special hazards arising from the substance or mixture

No further relevant information available.

### 5.3. Advice for firefighters

**Protective equipment:** No special measures required.

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1. 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.

### 6.2. Environmental precautions:

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water.

### 6.3. 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

### 6.4. Reference to other sections

See Section 13 for disposal information.

## 7. HANDLING AND STORAGE

### 7.1. Handling

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

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

### 7.2. Storage

Keep container tightly closed.

Recommended storage temperature 2 - 8°C.

### 7.3. 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

## 10.1. Reactivity

No data available

## 10.2. Chemical stability

Stable under recommended storage conditions

## 10.3. Possibility of hazardous reactions

No dangerous reactions known

## 10.4. Conditions to avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials

## 10.5. Materials to avoid

Strong oxidizing agents, acids and bases

## 10.6. 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.

This may include the following:

### 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/m<sup>3</sup>

#### **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

### 12.1. Toxicity

No data available

### 12.2. Persistence and Degradability

No data available

### 12.3. Bioaccumulative Potential

No data available

### 12.4. Mobility in Soil

No data available

### 12.5. 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.

### 12.6. Other Adverse Effects

No data available

<b>Glycerol (56-81-5)</b>	
LC <sub>50</sub> Fish1	54000 (51000-57000) mg/l (Exposure time: 96h – Species: <i>Oncorhynchus mykiss</i> (static))
<b>Sodium azide (26628-22-8)</b>	
LC <sub>50</sub> Fish 1:	0.8 mg/L (Exposure time: 96h – Species: <i>Oncorhynchus mykiss</i> )
LC <sub>50</sub> Fish 2:	0.7 mg/L (Exposure time: 96h – Species: <i>Lepomis macrochirus</i> )
ErC <sub>50</sub> (algae)	0.348 mg/l
<b>Ethylenediaminetetraacetic acid (60-00-4)</b>	
LC50 fish 1	34 – 62 mg/l (Exposure time: 96h – Species: <i>Lepomis macrochirus</i> )
EC50 Daphnia 1	113 mg/l (Exposure time: 48h – Species: <i>Daphnia magna</i> (static))
LC50 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:	
Glycerin (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

#### 14.1. UN number

**DOT, ADR, IMDG, IATA:** Not regulated in the meaning of transport regulations

#### 14.2. UN proper shipping name

**DOT, ADR, IMDG, IATA:** Not regulated

#### 14.3. Transport hazard class(es)

**DOT, ADR, ADN, IMDG, IATA:** Not regulated

#### 14.4. Packaging group

**DOT, ADR, IMDG, IATA:** Not regulated

#### 14.5. Environmental hazards

Not applicable

#### 14.6. Special precautions for user

Not applicable

#### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

#### 14.8. 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 to 10000 pounds for non-powder, non-molten, non-solution form)  
 Threshold Planning Quantity  
 SARA 313 Emission Reporting 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.

#### **State Right to Know Act**

Chemical Name:	<b>Glycerol</b>	<b>Sodium azide</b>	<b>Ethylenediaminetetraacetic acid</b>
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	<b>Glycerol</b>	<b>Sodium azide</b>	<b>Ethylenediaminetetraacetic acid</b>
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

**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

### 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

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### 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

## 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 or preparation

Product Name : LumiraDx SARS-CoV-2 RNA STAR Negative Extraction Control  
(Neg. Ext. Ctrl.)

Product Number : SPEC-30096

## 1.2. Use of the substance/preparation

Identified Uses : For Emergency Use Authorization (EUA) Only. For *In Vitro* Diagnostic (IVD) Use. Rx Use Only.

## 1.3. Company/undertaking identification

Company Address : LumiraDx UK Ltd.  
3 More London Riverside  
London  
SE1 2AQ  
United Kingdom

Telephone Number : 1-888-586-4721

Email : customerservices.US@lumiradx.com

## 1.4. Emergency telephone

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

# 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

**After inhalation:** Supply fresh air, consult doctor in case of complaints

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

#### 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

#### 5.1. Suitable extinguishing agents

CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

#### 5.2. Special hazards arising from the substance or mixture

No further relevant information available.

#### 5.3. Advice for firefighters

**Protective equipment:** No special measures required.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. For personal protection see section 8.

## 6.2. Environmental precautions:

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water.

## 6.3. 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

## 6.4. Reference to other sections

See Section 13 for disposal information.

# 7. HANDLING AND STORAGE

## 7.1. Handling

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

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

## 7.2. Storage

Keep container tightly closed.

Recommended storage temperature -25°C to -15°C

## 7.3. 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

### 10.1. Reactivity

No data available

### 10.2. Chemical stability

Stable under recommended storage conditions

### 10.3. Possibility of hazardous reactions

No dangerous reactions known

### 10.4. Conditions to avoid

No further relevant information available.

### 10.5. Materials to avoid

No further relevant information available.

### 10.6. 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.

This may include the following:

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	: No data available
<b>Skin corrosion/irritation</b>	: No data available
<b>Serious eye damage/eye irritation</b>	: No data available
<b>Respiratory or skin sensitization</b>	: No data available
<b>Germ cell mutagenicity</b>	: No data available

#### **Carcinogenicity:**

Based on the available data, the classification criteria are not met

<b>Reproductive toxicity</b>	: No data available
<b>Specific target organ toxicity – single exposure</b>	: No data available
<b>Specific target organ toxicity – repeated exposure</b>	: No data available
<b>Aspiration hazard</b>	: No data available
<b>Additional Information</b>	: RTECS: Not available

## 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

### 12.1. Toxicity

No data available

### 12.2. Persistence and Degradability

No data available

### 12.3. Bioaccumulative Potential

No data available

### 12.4. Mobility in Soil

No data available

### 12.5. 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.

### 12.6. 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

### 14.1. UN number

**DOT, ADR, IMDG, IATA:** Not regulated in the meaning of transport regulations

### 14.2. UN proper shipping name

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.3. Transport hazard class(es)

**DOT, ADR, ADN, IMDG, IATA:** Not regulated

### 14.4. Packaging group

**DOT, ADR, IMDG, IATA:** Not regulated

### 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable

### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

### 14.8. 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

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**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