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

1.1. Product identifier

Product form: Mixture
Product name: Lyra Direct SARS-CoV-2 EUA Assay
Product code: M124

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

1.2.1. Relevant identified uses

No additional information available

1.2.2. Uses advised against

Restrictions on use: Professional Use of Medical Devices

1.3. Details of the supplier of the safety data sheet

Manufacturer
Quidel Corporation
2005 East State Street, Suite 100
45701 Athens - USA
T 1.800.874.1517 - F 1.740.592.9820
qehs@quidel.com - quidel.com

1.4. Emergency telephone number

Emergency number: 1.866.519.4752

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

Adverse physicochemical, human health and environmental effects
To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

According to EC directives or the corresponding national regulations there is no labeling obligation for this product.

2.3. Other hazards

Other hazards not contributing to the classification: Follow Universal Precautions when handling this component.

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II.

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact: Wash skin with plenty of water.
First-aid measures after eye contact: Rinse eyes with water as a precaution.
First-aid measures after ingestion: Call a poison center/doctor/physician if you feel unwell.

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

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.
### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

**Suitable extinguishing media**: Water spray. Dry powder. Foam. Carbon dioxide.

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

**Hazardous decomposition products in case of fire**: Toxic fumes may be released.

#### 5.3. Advice for firefighters

**Protection during firefighting**: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### SECTION 6: Accidental release measures

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

##### 6.1.1. For non-emergency personnel

**Emergency procedures**: Ventilate spillage area.

##### 6.1.2. For emergency responders

**Protective equipment**: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

#### 6.2. Environmental precautions

Avoid release to the environment.

#### 6.3. Methods and material for containment and cleaning up

**Methods for cleaning up**: Take up liquid spill into absorbent material.

**Other information**: Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

**Precautions for safe handling**: Ensure good ventilation of the work station. Wear personal protective equipment.

**Hygiene measures**: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

**Storage conditions**: Store in a well-ventilated place. Keep cool.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

**Appropriate engineering controls**: Ensure good ventilation of the work station.

**Materials for protective clothing**:

- **Lab coat**

**Eye protection**:

- Safety glasses

**Skin and body protection**:

- Wear suitable protective clothing

**Respiratory protection**:

In case of insufficient ventilation, wear suitable respiratory equipment
### Personal protective equipment symbol(s):

- [ ]
- [ ]
- [ ]

### Environmental exposure controls:

Avoid release to the environment.

### Other information:

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

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Appearance</td>
<td>In vitro diagnostic medical test kit.</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>Lyra Direct SARS-CoV-2 Process Buffer, pH 3.3</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Pow)</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosion limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

#### 10.5. Incompatible materials

No additional information available
10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Serious eye damage/irritiation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td>Not classified</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>Not classified</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>Not classified</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

SECTION 12: Ecological information

12.1. Toxicity

<table>
<thead>
<tr>
<th>Effect</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecology - general</td>
<td>The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.</td>
</tr>
<tr>
<td>Hazardous to the aquatic environment, short-term (acute)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Hazardous to the aquatic environment, long-term (chronic)</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional legislation (waste)</td>
<td>Disposal must be done according to official regulations.</td>
</tr>
<tr>
<td>Waste treatment methods</td>
<td>Dispose of contents/container in accordance with licensed collector’s sorting instructions.</td>
</tr>
<tr>
<td>Sewage disposal recommendations</td>
<td>Disposal must be done according to official regulations.</td>
</tr>
<tr>
<td>Ecology - waste materials</td>
<td>Avoid release to the environment.</td>
</tr>
</tbody>
</table>

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

14.1. UN number

<table>
<thead>
<tr>
<th>Number</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN-No. (ADR)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>UN-No. (IMDG)</td>
<td>Not regulated</td>
</tr>
<tr>
<td>UN-No. (IATA)</td>
<td>Not regulated</td>
</tr>
</tbody>
</table>
14.2. UN proper shipping name
Proper Shipping Name (ADR) : Not regulated
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated

14.3. Transport hazard class(es)
ADR
Transport hazard class(es) (ADR) : Not regulated

IMDG
Transport hazard class(es) (IMDG) : Not regulated

IATA
Transport hazard class(es) (IATA) : Not regulated

14.4. Packing group
Packing group (ADR) : Not regulated
Packing group (IMDG) : Not regulated
Packing group (IATA) : Not regulated

14.5. Environmental hazards
Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user
Overland transport
Not regulated

Transport by sea
Not regulated

Air transport
Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable

SECTION 15: Regulatory information
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
15.1.1. EU-Regulations
Contains no REACH substances with Annex XVII restrictions
Contains no REACH candidate substance
Contains no REACH Annex XIV substances.

15.1.2. National regulations
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

Germany
Regulatory reference : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)
Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

15.2. Chemical safety assessment
No chemical safety assessment has been carried out
### SECTION 16: Other information

Other information: Please review product insert prior to using this product.

<table>
<thead>
<tr>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not classified</td>
</tr>
</tbody>
</table>

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.