LumiraDx SARS-COV-2 Ag (Antigen Test Strip)

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

1.1. Product identifier
LumiraDx SARS-COV-2 Ag (Antigen Test Strip)

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/mixture
in vitro diagnosis.

Uses advised against
Any non-intended use.

1.3. Details of the supplier of the safety data sheet
Company name: LumiraDx UK Ltd
Street: Dumyat Business Park
Place: GB-FK10 2PB Alloa
Telephone: 00800 58647239
e-mail: customerservices@lumiradx.com
Responsible Department: Dr. Gans-Eichler
e-mail: info@tge-consult.de
Chemieberatung GmbH
Otto-Hahn-Str. 36
D-48161 Münster

1.4. Emergency telephone number:
Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Regulation (EC) No. 1272/2008
This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements
Additional advice on labelling
Labelling according to Regulation (EC) No. 1272/2008 [CLP]: none

2.3. Other hazards
The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
No risks worthy of mention. Please observe the information on the safety data sheet at all times.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
Chemical characterization
The product does not contain dangerous substances according to REGULATION (EU) No. 2015/830, Annex II,
Part A, 3.2.2. that must be mentioned in Chapter 3.

Further Information
Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures
General information
In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
After inhalation
In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

After contact with skin
Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes
Rinse cautiously with water for several minutes. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion
Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed
No 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
Carbon dioxide (CO2). Dry extinguishing powder. alcohol resistant foam. Atomized water.

Unsuitable extinguishing media
High power water jet.

5.2. Special hazards arising from the substance or mixture
Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO2).

5.3. Advice for firefighters
In case of fire: Wear self-contained breathing apparatus.

Additional information
Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Safe handling: see section 7
Personal protection equipment: see section 8

6.2. Environmental precautions
Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up
Take up mechanically.
Treat the recovered material as prescribed in the section on waste disposal.
Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Advice on safe handling
Wear suitable protective clothing. (See section 8.)
Advice on protection against fire and explosion
Usual measures for fire prevention.

Further information on handling
General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep container tightly closed in a cool, well-ventilated place.

Hints on joint storage

Further information on storage conditions
Keep the packing dry and well sealed to prevent contamination and absorption of humidity.
Recommended storage temperature: 20°C
Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)
See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
Additional advice on limit values
To date, no national critical limit values exist.

8.2. Exposure controls
Appropriate engineering controls
No special measures are necessary.

Protective and hygiene measures
Always close containers tightly after the removal of product. When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work.

Eye/face protection
No special measures are necessary.

Hand protection
Suitable gloves type: Single-use gloves.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Before using check leak tightness / impermeability. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

Respiratory protection
With correct and proper use, and under normal conditions, breathing protection is not required.

Environmental exposure controls
No special precautionary measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state: solid
Colour: not determined
### Odour:
- Odourless

### pH-Value:
- not determined

### Changes in the physical state

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point</td>
<td>not determined</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>not determined</td>
</tr>
<tr>
<td>Sublimation point</td>
<td>not determined</td>
</tr>
<tr>
<td>Softening point</td>
<td>not determined</td>
</tr>
<tr>
<td>Pour point</td>
<td>not determined</td>
</tr>
<tr>
<td>Flash point</td>
<td>not determined</td>
</tr>
<tr>
<td>Sustaining combustion</td>
<td>Not sustaining combustion</td>
</tr>
</tbody>
</table>

### Explosive properties
- none

### Lower explosion limits:
- not determined

### Upper explosion limits:
- not determined

### Ignition temperature:
- not determined

### Auto-ignition temperature
- Gas: not determined

### Decomposition temperature:
- not determined

### Oxidizing properties
- none

### Vapour pressure:
- not determined

### Density:
- not determined

### Water solubility:
- not determined

### Solubility in other solvents
- not determined

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partition coefficient:</td>
<td>not determined</td>
</tr>
<tr>
<td>Viscosity / dynamic:</td>
<td>not determined</td>
</tr>
<tr>
<td>Viscosity / kinematic:</td>
<td>not determined</td>
</tr>
<tr>
<td>Flow time:</td>
<td>not determined</td>
</tr>
<tr>
<td>Vapour density:</td>
<td>not determined</td>
</tr>
<tr>
<td>Evaporation rate:</td>
<td>not determined</td>
</tr>
<tr>
<td>Solvent separation test:</td>
<td>not determined</td>
</tr>
<tr>
<td>Solvent content:</td>
<td>not determined</td>
</tr>
</tbody>
</table>

### Solid content:
- not determined

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity
- No information available.

#### 10.2. Chemical stability
- The product is chemically stable under recommended conditions of storage, use and temperature.

#### 10.3. Possibility of hazardous reactions
- Refer to chapter 10.5.
10.4. Conditions to avoid
Protect against: UV-radiation/sunlight, heat.

10.5. Incompatible materials
Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

10.6. Hazardous decomposition products
Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO2).

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Toxicokinetics, metabolism and distribution
No data available.

Acute toxicity
Based on available data, the classification criteria are not met.

Irritation and corrosivity
Based on available data, the classification criteria are not met.

Sensitising effects
Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction
Based on available data, the classification criteria are not met.

STOT-single exposure
Based on available data, the classification criteria are not met.

STOT-repeated exposure
Based on available data, the classification criteria are not met.

Aspiration hazard
Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal
No data available.

SECTION 12: Ecological information

12.1. Toxicity
The product has not been tested.

12.2. Persistence and degradability
The product has not been tested.

12.3. Bioaccumulative potential
No indication of bioaccumulation potential.

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Other adverse effects
No data available.

Further information
Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Disposal recommendations
Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.
Non-contaminated packages may be recycled.
According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.
Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products
200132  MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); medicines other than those mentioned in 20 01 31

List of Wastes Code - used product
200132  MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; separately collected fractions (except 15 01); medicines other than those mentioned in 20 01 31

List of Wastes Code - contaminated packaging
150106  WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging
Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)
14.1. UN number:  No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:  No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):  No dangerous good in sense of these transport regulations.
14.4. Packing group:  No dangerous good in sense of these transport regulations.

Inland waterways transport (ADN)
14.1. UN number:  No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:  No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):  No dangerous good in sense of these transport regulations.
14.4. Packing group:  No dangerous good in sense of these transport regulations.

Marine transport (IMDG)
14.1. UN number:  No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:  No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):  No dangerous good in sense of these transport regulations.

Air transport (ICAO-TI/IATA-DGR)
14.1. UN number:  No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:  No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):  No dangerous good in sense of these transport regulations.

14.5. Environmental hazards
ENVIRONMENTALLY HAZARDOUS:  no

14.6. Special precautions for user
Refer to section 6-8

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
not relevant
SECTION 15: Regulatory information

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

EU regulatory information

2010/75/EU (VOC): No information available.
2004/42/EC (VOC): No information available.
Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Additional information


The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

in vitro diagnosis. - 2017/746/EC

REACH 1907/2006 Appendix XVII, No (mixture): not relevant

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:

SECTION 16: Other information

Changes

Rev. 1.0; Initial release: 31.07.2020

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW: Arbeitsplatzgrenzwert
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging of substances and mixtures
DNEL: Derived No Effect Level
d: day(s)
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
ECHA: European Chemicals Agency
EWC: European Waste Catalogue
IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
h: hour
LOAEL: Lowest observed adverse effect level
LOAEC: Lowest observed adverse effect concentration
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOAEL: No observed adverse effect level
NOAEC: No observed adverse effect concentration
NLP: No-Longer Polymers
N/A: not applicable
OECD: Organisation for Economic Co-operation and Development
Further Information
Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:
Health hazards: Calculation method.
Environmental hazards: Calculation method.
Physical hazards: On basis of test data and / or calculated and / or estimated.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)