

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## LumiraDx NT-proBNP strip

Revision date: 16.05.2022

Product code:

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

#### 1.1. Product identifier

LumiraDx NT-proBNP strip

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

##### Use of the substance/mixture

in vitro diagnostic medical devices

##### 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<br>Chemieberatung GmbH<br>Otto-Hahn-Str. 36<br>D-48161 Münster | e-mail: info@tge-consult.de<br>Tel.: +49(0)2534 6441185<br>www.tge-consult.de |

#### 1.4. Emergency telephone number:

00800 58647239 - This number is serviced during office hours.

### 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 (>0,1%) 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. 2020/878, Annex II, Part A, 3.1/3.2. that must be mentioned in Chapter 3.

##### Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

##### 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

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### 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 (CO<sub>2</sub>). 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 (CO<sub>2</sub>).

### 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

#### General advice

Safe handling: see section 7

#### For non-emergency personnel

Wear personal protection equipment (refer to section 8).

#### For emergency responders

No special measures are necessary.

### 6.2. Environmental precautions

Discharge into the environment must be avoided.

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

#### For containment

Take up mechanically.

Treat the recovered material as prescribed in the section on waste disposal.

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### For cleaning up

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.

#### Advice on general occupational hygiene

Always close containers tightly after the removal of product. Do not eat, drink, smoke or sneeze at the workplace. Wash hands before breaks and after work.

#### 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

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

#### 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

Technical measures and the application of suitable work processes have priority over personal protection equipment.

Provide adequate ventilation.

#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN 166

##### Hand protection

In case of prolonged or frequently repeated skin contact:

Wear suitable gloves.

Suitable material:

FKM (fluororubber). - Thickness of glove material: 0,4 mm

Breakthrough time  $\geq$  8 h

Butyl rubber. - Thickness of glove material: 0,5 mm

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Breakthrough time  $\geq$  8 h

CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm

Breakthrough time  $\geq$  8 h

NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm

Breakthrough time  $\geq$  8 h

PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm

Breakthrough time  $\geq$  8 h

The selected protective gloves have to satisfy the specifications of EU Directive EC/2016/425 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**

Suitable protective clothing: Lab apron.

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.

**Thermal hazards**

No special precautionary measures are necessary.

**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      |

**Changes in the physical state**

|   |                |
|---|----------------|
| Melting point/freezing point:                             | not determined |
| Boiling point or initial boiling point and boiling range: | not determined |
| Sublimation point:  | not determined |
| Softening point:  | not determined |
| Pour point:   | not determined |
| Flash point:  | not determined |

**Explosive properties**

none

|                            |                |
|----------------------------|----------------|
| Lower explosion limits:    | not determined |
| Upper explosion limits:    | not determined |
| Auto-ignition temperature: | not determined |

**Self-ignition temperature**

Gas:

|                            |                |
|----------------------------|----------------|
| Decomposition temperature: | not determined |
| pH-Value:                  | not determined |
| Viscosity / dynamic:       | not determined |
| Viscosity / kinematic:     | not determined |
| Flow time:                 | not determined |
| Water solubility:          | not determined |

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**Solubility in other solvents**

not determined

Partition coefficient n-octanol/water:

SECTION 12: Ecological information

Vapour pressure:

not determined

Density:

not determined

Relative vapour density:

not determined

**9.2. Other information****Information with regard to physical hazard classes**

Sustaining combustion:

Not sustaining combustion

Oxidizing properties

none

**Other safety characteristics**

Solvent separation test:

not determined

Solvent content:

not determined

Solid content:

not determined

Evaporation rate:

not determined

**Further Information**

No information available.

**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**

No hazardous reaction when handled and stored according to provisions.

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**

Does not decompose when used for intended uses.

Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO<sub>2</sub>).**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Toxicocinetics, 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**

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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.

## **11.2. Information on other hazards**

### **Endocrine disrupting properties**

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.

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII.

### **12.6. Endocrine disrupting properties**

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

### **12.7. 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**

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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 or ID 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 or ID 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 or ID 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 or ID 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 chapter 6-8

### 14.7. Maritime transport in bulk according to IMO instruments

not relevant

## SECTION 15: Regulatory information

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

#### EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

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

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878)

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

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

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**National regulatory information**

Water hazard class (D):

**Additional information**

\*No information available.

**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: 16.05.2022

**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

PNEC: predicted no effect concentration

PBT: Persistent bioaccumulative toxic

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail )

REACH: Registration, Evaluation, Authorisation of Chemicals

SVHC: substance of very high concern

TRGS: Technische Regeln für Gefahrstoffe

UN: United Nations

VOC: Volatile Organic Compounds

**Further Information**

Classification according EC regulation 1272/2008 (CLP): - Classification procedure:



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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.

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