

Safety Data Sheet

according to Regulation (EC) No 1907/2006

LumiraDx NT-proBNP Quality Control

Revision date: 28.09.2022

Product code: L023080101002

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

1.1. Product identifier

LumiraDx NT-proBNP Quality Control

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

Use of the substance/mixture

Quality control reagent, 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 Chemieberatung GmbH Otto-Hahn-Str. 36 D-48161 Münster	e-mail: info@tge-consult.de Tel.: +49(0)2534 6441185 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 (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

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

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). 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.
Recommended cleaning agent: 0,5% Sodium Hypochlorite

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

Occupational exposure limits

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
128-37-0	2,6-Ditertiary-butyl-para-cresol	-	2		TWA (8 h)	
64-17-5	Ethanol	1000	-		STEL (15 min)	
7647-01-0	Hydrogen chloride	5	8		TWA (8 h)	
		10	15		STEL (15 min)	
67-56-1	Methanol	200	260		TWA (8 h)	
143-33-9	Sodium cyanide (as cyanide)	-	1		TWA (8 h)	
		-	5		STEL (15 min)	
1310-73-2	Sodium hydroxide	-	2		STEL (15 min)	

Biological limit values

CAS No	Substance	Parameter	Value	Test material	Sampling time
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67-56-1	Methanol	Methanol	15 mg/L	Urine	End of shift
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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

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:	liquid
Colour:	light yellow
Odour:	characteristic

Test method

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

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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:

not determined

Decomposition temperature: not determined

pH-Value: 7.2 - 7.4

Viscosity / dynamic: not determined

Viscosity / kinematic: not determined

Flow time: not determined

Water solubility: not determined

Solubility in other solvents

not determined

Partition coefficient n-octanol/water: SECTION 12: Ecological information

Vapour pressure: not determined

Density: 1 g/cm³ estimated

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.

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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 (CO₂).

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicokinetics, metabolism and distribution

No data available.

Acute toxicity

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

ATEmix calculated

ATE (oral) 10001,0 mg/kg; ATE (dermal) 30003,0 mg/kg; ATE (inhalation vapour) 300,03 mg/l; ATE (inhalation dust/mist) 50,005 mg/l

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.

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

12.6. Endocrine disrupting properties

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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

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.

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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 69, 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

National regulatory information

Water hazard class (D): 2 - obviously 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: 28.09.2022

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)

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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: Reglement 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:

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.)