

Safety Data Sheet

according to Regulation (EC) No 1907/2006

LumiraDx HbA1c strip + Lysis Buffer

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**

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

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**Regulation (EC) No 1272/2008****Special labelling of certain mixtures**

Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Additional advice on labelling

Lysis Buffer:

Labelling according to Regulation (EC) No. 1272/2008 [CLP]: EUH 208

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****Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)			< 0.1 %
	-	613-167-00-5		

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Acute Tox. 2, Acute Tox. 2, Acute Tox. 3, Skin Corr. 1B, Eye Dam. 1, Skin Sens. 1A, Aquatic Acute 1, Aquatic Chronic 1; H330 H310 H301 H314 H318 H317 H400 H410 EUH071
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Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
55965-84-9	-	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	< 0.1 %
		inhalation: ATE = 0,5 mg/l (vapours); inhalation: ATE = 0,05 mg/l (dusts or mists); dermal: ATE = 50 mg/kg; oral: LD50 = 53 mg/kg Skin Corr. 1C; H314: >= 0,6 - 100 Skin Irrit. 2; H315: >= 0,06 - < 0,6 Eye Dam. 1; H318: >= 0,6 - 100 Eye Irrit. 2; H319: >= 0,06 - < 0,6 Skin Sens. 1A; H317: >= 0,0015 - 100 M acute; H400: M=100 M chron.; H410: M=100	

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.

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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.

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

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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

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.

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

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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: not determined

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: 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.

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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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
55965-84-9	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)				
	oral	LD50 53 mg/kg	Rat.	RTECS	
	dermal	ATE 50 mg/kg			
	inhalation vapour	ATE 0,5 mg/l			
	inhalation dust/mist	ATE 0,05 mg/l			

Irritation and corrosivity

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

Sensitising effects

Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

May cause sensitisation especially in sensitive humans.

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.

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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

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.

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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

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)

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

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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

Relevant H and EUH statements (number and full text)

Toxic if swallowed.
Fatal in contact with skin.
Causes severe skin burns and eye damage.
May cause an allergic skin reaction.
Causes serious eye damage.
Fatal if inhaled.
Very toxic to aquatic life.
Very toxic to aquatic life with long lasting effects.
Corrosive to the respiratory tract.
Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

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.

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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.)