

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878



LumiraDx HbA1c Test (24T) ML01

Version
1.0

Revision Date:
28.10.2024

Date of last issue: -
Date of first issue: 28.10.2024

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

1.1 Product identifier

Trade name : LumiraDx HbA1c Test (24T) ML01
Product code : 10418109001

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

Use of the Sub-
stance/Mixture : Laboratory chemicals, Refer to product literature for further
details.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
Sandhoferstrasse 116
68305 Mannheim
Deutschland
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH
Centre for detoxification: : Mainz +49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Additional Labelling

EUH210 Safety data sheet available on request.

EUH208 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.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9 613-167-00-5	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 2; H310 Skin Corr. 1C; H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH071 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 100 specific concentration limit Skin Corr. 1C; H314 >= 0,6 % Skin Irrit. 2; H315 0,06 - < 0,6 % Eye Irrit. 2; H319 0,06 - < 0,6 % Skin Sens. 1A; H317 >= 0,0015 % Eye Dam. 1; H318	>= 0,0002 - < 0,0015

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		>= 0,6 %	
		Acute toxicity estimate	
		Acute oral toxicity: 64 mg/kg	
		Acute inhalation toxicity (dust/mist): 0,33 mg/l	
		Acute dermal toxicity: 87,12 mg/kg	
		87,12 mg/kg	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Do not leave the victim unattended.
- Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : Wash off with soap and water.
- In case of eye contact : Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : General industrial hygiene practice.

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7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.
- Advice on common storage : No materials to be especially mentioned.
- Storage class (TRGS 510) : 12
- Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

- Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9	AGW (inhalable fraction)	0,2 mg/m ³	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			
	Further information: Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			
		MAK (inhalable fraction)	0,2 mg/m ³	DE DFG MAK
	Peak-limit: excursion factor (category): 2; I			
	Further information: Danger of sensitization of the skin, Damage to the embryo or foetus is unlikely when the MAK value or the BAT value is observed			

8.2 Exposure controls

Personal protective equipment

- Eye/face protection : Use eye protection according to EN 166.

Safety glasses

Hand protection

- In case of contact through splashing:
- Material : Nitrile rubber
- Break through time : > 30 min
- Glove thickness : > 0,11 mm
- In case of full contact:
- Material : butyl-rubber
- Break through time : > 480 min

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Glove thickness : > 0,4 mm

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us.

Skin and body protection : Protective suit

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/ range : No data available

Boiling point/boiling range : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 7,47 - 7,66
Concentration: 100 %

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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Solubility(ies)
Water solubility : No data available
Solubility in other solvents : No data available
Partition coefficient: n-
octanol/water : No data available
Vapour pressure : No data available
Relative density : No data available
Relative vapour density : No data available
Particle characteristics
Particle Size Distribution : Not applicable

9.2 Other information

Explosives : No data available
Oxidizing properties : No data available
Self-ignition : Not applicable
Evaporation rate : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : Not applicable

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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SECTION 11: Toxicological information

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

Acute toxicity

Not classified due to lack of data.

Components:

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Acute oral toxicity : LD50 Oral (Rat, male): 64 mg/kg

Acute inhalation toxicity : LC50 (Rat, male and female): 0,33 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 Dermal (Rabbit, male): 87,12 mg/kg

Acute toxicity estimate: 87,12 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified due to lack of data.

Components:

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Result : Corrosive after 1 to 4 hours of exposure

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Species : Rabbit
Result : Risk of serious damage to eyes.

Respiratory or skin sensitisation

Skin sensitisation

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Components:

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Test Type : Local lymph node assay (LLNA)

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Species : Mouse
Assessment : The product is a skin sensitizer, sub-category 1A.

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

Reproductive toxicity

Not classified due to lack of data.

STOT - single exposure

Not classified due to lack of data.

STOT - repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Product:

Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,19 mg/l
Exposure time: 96 h
Test Type: flow-through test

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0,16 mg/l
aquatic invertebrates : Exposure time: 48 h
Test Type: flow-through test

Toxicity to algae/aquatic : ErC50 (Skeletonema costatum (marine diatom)): 0,0063 mg/l
plants : Exposure time: 72 h

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Test Type: static test
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : NOEC: 0,02 mg/l
Exposure time: 38 d
Species: Cyprinodon sp. (minnow)
Test Type: semi-static test
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,1 mg/l
Exposure time: 21 d
Species: Daphnia (water flea)
GLP: yes

M-Factor (Chronic aquatic toxicity) : 100

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

Components:

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Biodegradability : Result: Inherently biodegradable.
Remarks: The 10 day time window criterion is not fulfilled.

Result: Not readily biodegradable.
Method: OECD Test Guideline 301B
GLP: yes

12.3 Bioaccumulative potential

Components:

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Temperature: 20 °C
Concentration: ca. 0,01 mg/l
Bioconcentration factor (BCF): 54

Partition coefficient: n-octanol/water : log Pow: 0,75

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12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Product:

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number or ID number

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

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ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,
IMDG-Code, ICAO/IATA-DGR

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European : Not applicable

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Parliament and of the Council
on the control of major-
accident hazards involving
dangerous substances.

- Water hazard class (Germany) : WGK 1 slightly hazardous to water
Classification according to AwSV §6(4)
- TA Luft List (Germany) : 5.2.1: Total dust:
Not applicable
5.2.2: Inorganic substances in powdered form:
Not applicable
5.2.4: Inorganic substances in gaseous form:
Not applicable
5.2.5: Organic Substances:
Class 1: < 0,01 % reaction mass of 5-chloro-2-methyl-2H-
isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
5.2.7.1.1: Carcinogenic substance:
Not applicable
5.2.7.1.1: Quartz fine dust PM4:
Not applicable
5.2.7.1.1: Formaldehyde:
Not applicable
5.2.7.1.1: fibres:
Not applicable
5.2.7.1.2: Germ cell mutagens:
Not applicable
5.2.7.1.3: Substances toxic to reproduction:
Not applicable
5.2.7.2: Poorly degradable, easily enrichable and highly toxic
organic substances:
Not applicable
- Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial
emissions (integrated pollution prevention and control)
Not applicable

The components of this product are reported in the following inventories:

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not
on the Canadian DSL nor NDSL.
Specific Placeholder for Lysis Buffer - LumiraDx HbA1c Test
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory

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KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

SECTION 16: Other information

Full text of H-Statements

H301	:	Toxic if swallowed.
H310	:	Fatal in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H330	:	Fatal if inhaled.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
EUH071	:	Corrosive to the respiratory tract.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation
DE DFG MAK	:	Germany. MAK BAT Annex IIa
DE TRGS 900	:	Germany. TRGS 900 - Occupational exposure limit values.
DE DFG MAK / MAK	:	MAK value
DE TRGS 900 / AGW	:	Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China;

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IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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