

LumiraDx Multi Quality Control Safety Data Sheet

Safety data sheet

According to EC Directive 1907/2006/EC

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance or preparation

Product Name : LumiraDx Multi Quality Control

Reach No : A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration.

1.2. Use of the substance/preparation

Identified Uses : In-vitro laboratory reagent or component, liquid quality control testing performed on the LumiraDx Instrument when used with the LumiraDx D-Dimer test or LumiraDx CRP test

1.3. Company/undertaking identification

Company Address : LumiraDx UK Ltd,
Dumyat Business Park,
Alloa
FK10 2PB
United Kingdom

Telephone Number : 00800 58647239

Email : customerservices@lumiradx.com

Website : www.lumiradx.com

1.4. Emergency telephone

Emergency Phone # : 00800 58647239, open 09:00 -17:00

2. HAZARDS IDENTIFICATION

2.1. Hazardous Classification

Product does not present a physical, health or environmental hazard according to EC Regulation No. 1272/2008.


2.2. Label elements

Not a hazardous substance or mixture according to Regulation (EC) No.1272/2008. The product does not need to be labelled in accordance with the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

2.3. Other hazards

Biohazard

The product contains material of human and animal origin. No known test method can offer complete assurance that products derived from human or animal origin will not transmit infectious agents. Consider all human and animal source derivatives potentially infectious.

The LumiraDx Multi Quality Control+ pack insert contains the following symbol  which indicates that potential biological risks are associated with the Quality Control material.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterisation: Mixture

Mixture of the substances listed below:

Component	Identification	Concentration
Human Sourced Material	CAS #: N/A EC#: N/A	50-55%
Methanol	CAS #: 67-56-1 EC#: 200-659-6	<0.1%
Sodium Cyanide	CAS #: 143-33-9 EC#: 205-599-4	<0.1%
Hydrochloric Acid, 6.0N, solution	CAS #: 7647-01-0 EC#: 231-595-7	<0.5%
Sodium Azide	CAS #: 26628-22-8 EC#: 247-852-1	≤0.09%
Ethanol	CAS #: 64-17-5 EC#: 200-578-6	<1%
Streptomycin Sulfate	CAS #: 3810-74-0 EC#: 223-286-0	<0.1%
Chloramphenicol	CAS #: 56-75-7 EC#: 200-287-4	<0.1%
Proprietary neutral non-hazardous buffer/solution/water	CAS #: N/A EC#: N/A	44-49%

Exposure Limits: None known

Additional information:

Contains human and animal sourced potentially infectious components

No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. Description of first-aid measures.

General Information: In case of doubt or if symptoms persist, always call a doctor. Never induce swallowing in an unconscious person.

Eye contact: Rinse immediately with plenty of water for several minutes and seek medical attention if symptoms occur.

Ingestion: Seek medical attention immediately and show the label.

Inhalation: Supply fresh air immediately. Seek medical attention if breathing difficulty occurs.

Skin contact: Seek medical attention if symptoms of skin irritation appear.

Protection of First-Aid Providers: Wear suitable gloves and eye/face protection.

5. FIRE-FIGHTING MEASURES

5.1. Suitable extinguishing agents

Use an extinguishing media suitable for the surrounding fire.

5.2. Unsuitable Method of Extinguishing

None known

5.3. Special Protective Equipment for Firefighters

Self-contained breathing apparatus and protective suit.

5.4. Specific Hazards

No information available

5.5. Hazardous Combustion Products

None known

5.6. Explosion Limits

Lower: Unknown

Upper: Unknown

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions

Ensure adequate ventilation. Handle as potentially infectious.

6.2. Environmental precautions

Waste disposal must be in accordance with appropriate national, regional, or local regulations. Dilute with plenty of water.

6.3. Methods for Clean Up

Wipe up with absorbent material. Place in suitable container for prompt disposal. Label the contained as to the potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g. a fresh 1:10 dilution of common household bleach.

7. HANDLING AND STORAGE

7.1. Handling

Technical Measures/Precautions: wear protective safety glasses, gloves and clothing. Wear disposable gloves while handling reagent. Thoroughly wash hands afterwards.

7.2. Storage

Technical Measures/Storage Conditions: Store according to labelling.

Incompatible Products: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values

Occupational Exposure Limits: None known.

8.2. Exposure controls

Personal Protection Measures:

Use personal protective equipment that is clean and has been properly maintained.

Personal protective equipment:

Eye/face protection:

Wear safety glasses

Hand protection:

Wear disposable gloves. Thoroughly wash hands

Skin and Body Protection

Wear suitable protective clothing, gloves and eye/face protection.

Respiratory protection

None required.

Other General Precautions:

None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Appearance

Physical State: Liquid

Colour: Straw coloured

Odour/Odour Threshold: Mild to none

pH: 7.3 ± 0.1

Melting Point/Freezing Point : Undetermined/Undetermined

Initial Boiling Point and Boiling Range: Undetermined/Undetermined

Flash point: Not relevant

Evaporation Rate: Not determined

Upper/Lower Flammability or Explosive Limits: Not determined

Vapour pressure: Not relevant

Vapour density: Not determined

Relative density: Not determined

Solubility(ies): Not determined

Auto-Ignition: Product is not self-igniting

Decomposition Temperature: Not determined

Viscosity: No data available

Other(s): No other standard characteristics applicable to the identification or hazards of the products are known.

10. STABILITY AND REACTIVITY

10.1. Reactivity

No data is available

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Conditions to avoid

Keep away from heat and sources of ignition

10.4. Materials to avoid

No data is available

10.5. Hazardous polymerisation

No data available

10.6. Hazardous decomposition products

No dangerous decomposition products known

11. TOXICOLOGICAL INFORMATION

11.1. Acute Effects

Oral: No data is available

Eye Contact: No data is available

Skin Contact: No data is available

Inhalation: No data is available

Other: No data is available

11.2. Chronic Effects

Oral: No data is available

Inhalation: No data is available

Dermal: No data is available

Other: No data is available

11.3. Carcinogenicity Rating

Component(s)	CAS Number	NTP	IARC	California Proposition 65 List
Methanol	67-56-1	Not listed	Not rated	Listed
Streptomycin Sulfate	3810-74-0	Not listed	Not rated	Listed
Chloramphenicol	56-75-7	Not listed	2A	Not listed

Signs and Symptoms: None known

Medical Conditions Aggravated by Exposure: None known

12. Ecological information

12.1. Toxicity

Eco-Toxicity: This product has no know ecologically toxic effects

Aquatic Toxicity: No data is available

12.2. Mobility

No data is available

12.3. Persistence/Degradability

No data is available

12.4. Bioaccumulative Potential

No data is available

12.5. Degradation

No data is available

13. DISPOSAL CONSIDERATIONS

Waste from Residual/Unused Products: Waste disposal must be in accordance with applicable national, regional, or local regulations.

Contaminated packaging: Waste disposal must be in accordance with applicable national, regional, or local regulations.

Methods for Clean Up: Wipe up with absorbent material. Place in suitable container for prompt disposal. Label the container as to the potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g. a fresh 1:10 dilution of common household bleach.

14. TRANSPORT INFORMATION

Product not regulated by DOT, IATA/ICAO for air transport, IMO/IMDG for sea, ADR for road, RID for rail or TDG.

15. REGULATORY INFORMATION

Description	CAS#	SARA Title III, Section 302	SARA Title III, Section 313	SARA Title III, Section 311/312	Japan Poisonous and Deleterious Substances Control Law
Methanol	67-56-1			X	Deleterious Substance
Sodium Cyanide	143-33-9	X	X	X	Poisonous Substance
Sodium Azide	26628-22-8	X	X	X	Poisonous Substance
Hydrochloric Acid, 6 N, solution	7647-01-0	X	X	X	Deleterious Substance
Ethanol	64-17-5			X	
Streptomycin Sulfate	3810-74-0			X	
Chloramphenicol	56-75-7			X	

Immediate Health: No data is available

Delayed Health: No data is available

SVHC: No component of this product is identified as a substance of very high concern by SVHC

TSCA: No component of this product is present at levels identified by the Toxic Substance Control Act

OSHA: No component of this product is present at levels identified as a carcinogen or potential carcinogen by OSHA

WHMIS:

7 of 9	Document Name:	LumiraDx Multi Quality Control Safety Data Sheet		
	Document Number:	S-RA-MSDS-00297	Revision:	2

WHMIS Trade Secret: None known

WHMIS Hazard Class: None known

Canada DSL Inventory List: Not listed

NOTES:

- 1) This product has been classified in accordance with the hazards criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR

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


This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

International Chemical Weapons Convention (CWC) : Neither banned nor restricted
Schedules of Toxic Chemicals and Precursors

Restrictions on the marketing and use of certain dangerous substances and preparations : Neither banned nor restricted

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Neither banned nor restricted

Candidate List of Substances of Very High Concern for Authorisation : Neither banned nor restricted

European labelling in accordance with EC Directives Hazard Symbols: The LumiraDx Multi Quality Controls product insert contains the following symbol  which indicates that potential biological risks are associated with the Quality Control material.

16. OTHER INFORMATION

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)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EC: European Commission

NTP: National Toxicology Program

IARC: International Agency for Research on Cancer

DOT: Department of Transport

ICAO: International Civil Aviation Organisation

IMO: International Maritime Organisation

RID: Regulations concerning the Intl Transport of Dangerous Goods by Rail

TDG: Transportation of Dangerous Goods

CAS: Chemical Abstracts Service (division of the American Chemical Society)
SARA: Superfund Amendments and the Reauthorization Act
SVHC: Substance of Very High Concern
TSCA: Toxic Substance Control Act
WHMIS 2015: Canadian Workplace Hazardous Material Information System
CPR: Controlled Products Regulations
OSHA: Occupational Health and Safety
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

Additional advice: None known.

SDS Formats: North American Format (U.S. and Canada): This Safety Data Sheet was prepared in accordance with OSHA 29 CFR 1910.1200.

European Format: This Safety Data Sheet was prepared in accord with (EC) No. 1907/2006 (REACH) and its amendments.

Information contained herein are based on reasonable investigation and research. However, LumiraDx UK or its affiliates do not warrant the accuracy of this information. All materials may present unknown hazards and should be used with caution. This document is intended only as a guide to the appropriate precautionary handling of the materials contained in this product by a properly trained person using this product. In no case shall LumiraDx be liable for incidental or consequential damages. Use of LumiraDx Multi Quality Controls is subject to references and limitations included in the product specifications.

LumiraDx UK Ltd (company number: 09206123)