Safety Data Sheet LumiraDx D-Dimer Quality Control Kit

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| **Product Code** | **Description** |
| L005080101003 | LumiraDx D-Dimer Quality Control Kit |
| L005080101006 |

|  |  |
| --- | --- |
| **Component Code** | **Description** |
| CQ5051 | LumiraDx D-Dimer Quality Control Level 1 |
| CQ5053 | LumiraDx D-Dimer Quality Control Level 2 |

**Safety data sheet**

According to EC Directive 1907/2006/EC

# IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

## Identification of the substance or preparation

Product Name : LumiraDx D-Dimer Quality Control Level 1 and 2

Product Number : QC Level 1- CQ5051

 QC Level 2- CQ5053

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.

## 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 Strip

## 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

## Emergency telephone

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

# HAZARDS IDENTIFICATION

## Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

## 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.

## Other hazards

 Biohazard

The product contains material of human origin. This material has been tested for the HIV (Human Immunodeficiency Virus) Antibody, HBs Ag and HCV and found to be non-reactive at the donor stage. This product, as with all human based specimens, should be treated as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

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.

This control contains sodium azide (<0.1%). Avoid ingestion or contact with skin or mucous membranes. Sodium azide reacts with lead or copper plumbing to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

# COMPOSITION/INFORMATION ON INGREDIENTS

## Chemical characterisation: Mixtures

Mixture of the substances listed below with non-hazardous addition

Synonym : Human serum

 : Sodium Azide, Formula: NaN3, CAS-No: 26628-22-8

|  |  |  |
| --- | --- | --- |
| **Component** | **Classification** | **Concentration** |
| Sodium Azide CAS-No. 26628-22-8EC-No 247-852-1Index-No 011-004-00-7Registration number 01-2119457019-37-XXXXX | EUH032; Acute Tox. 2; Acute Tox. 1; STOT RE 2; Aquatic Acute 1;Aquatic Chronic 1; H300,H310, H373, H400, H410M-Factor - Aquatic Acute: 1 | <0.1% |

Each bottle contains 3mL of liquid mixture.

**Additional information:**

Contains human sourced potentially infectious components

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

# FIRST AID MEASURES

## Description of first-aid measures.

**General Information:** No special measures required

**After inhalation:** Supply fresh air, consult doctor in case of complaints

**After skin contact:** Immediately wash with water and soap and rinse thoroughly.

**After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

## Most important symptoms and effects, both and acute and delayed:

May cause irritation to skin eyes, may be irritating to the mucous membranes and upper respiratory tract. Avoid contact with skin, inhalation and ingestion.

## Indication of any immediate medical attention and special treatment needed:

Call an internal person trained in First Aid if available, or contact a physician.

# FIRE-FIGHTING MEASURES

## Suitable extinguishing agents

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

## Special hazards arising from the substance or mixture

May emit toxic fumes under fire conditions.

## Advice for firefighters

**Protective equipment:** Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes if necessary.

# ACCIDENTAL RELEASE MEASURES

## Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation. For personal protection see section 8.

Precaution - Handle as potentially infectious

## Environmental precautions:

Keep contaminated washing water and dispose of appropriately.

Do not allow to enter sewers/ surface or ground water

## Methods and material for containment and cleaning up:

Absorb liquid components with liquid-binding material.

Pick up mechanically.

Clean the affected area carefully; disinfectant is a suitable cleaning agent.

Discard as biohazard waste according to local guidelines.

## Reference to other sections

See Section 13 for disposal information.

# HANDLING AND STORAGE

## Handling

Wear personal protective equipment (see section 8). Avoid contact with eyes, skin and clothing. Wash and dry hands thoroughly after handling.

**Information about protection against explosions and fires:** No special measures required.

## Storage

Keep container tightly closed.

Recommended storage temperature 2 - 8°C.

## Specific use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

# EXPOSURE CONTROLS/PERSONAL PROTECTION

## Exposure limit values

**Components with limit values that require monitoring at the workplace:** The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

## Exposure controls

**Appropriate engineering controls:**

Ensure adequate ventilation

**General protective and hygienic measures:**

Follow usual biosafety practices for handling potentially infectious materials.

The usual precautionary measures should be adhered to when handling chemicals.

 **Personal protective equipment:**

**Eye/face protection:**

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin protection:**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands thoroughly.

The selected protective gloves should satisfy the specifications of relevant standards for handling this material.

**Penetration time of glove material**

The exact break through time of the protective gloves determined by the manufacturer should be observed.

**Body Protection**

Protective work clothing.

**Respiratory protection**

Respiratory protection is not required.

**Environmental exposure controls:**

Do not let product enter the drains

# PHYSICAL AND CHEMICAL PROPERTIES

## General information

Appearance

Form : Liquid

Colour : Light yellow

Odour : Mild odour

## Important health, safety and environmental information

pH : No data available

Melting point/freezing point : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Flammability (solid, gas) : No data available

Explosive properties : No data available

Oxidising properties : No data available

Vapour pressure : No data available

Relative density : No data available

Solubility : Not applicable

Water solubility : Not applicable

Partition coefficient: n-octanol/water : No data available

Viscosity : No data available

Vapour density : No data available

Evaporation rate : No data available

## Other safety information

No further relevant information available.

# STABILITY AND REACTIVITY

## Reactivity

No data available

## Chemical stability

Stable under recommended storage conditions

## Possibility of hazardous reactions

No dangerous reactions known

## Conditions to avoid

No further relevant information available.

## Materials to avoid

Strong oxidising agents and acids.

## Hazardous decomposition products

No dangerous decomposition products known

#  TOXICOLOGICAL INFORMATION

Description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

This may include the following:

## Information on toxicological effects

**Acute toxicity :** No data available

**Skin corrosion/irritation :** No data available

**Serious eye damage/eye irritation :** No data available

**Respiratory or skin sensitisation :** No data available

**Germ cell mutagenicity :** No data available

**Carcinogenicity:**

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

**Reproductive toxicity :** No data available

**Specific target organ toxicity – :** No data available

**single exposure**

**Specific target organ toxicity – :** No data available

**repeated exposure**

**Aspiration hazard :** No data available

**Additional Information :** RTECS: Not available

## Additional toxicological information

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

## Other adverse effects

No data available.

# Ecological information

## Toxicity

No data available

## Persistence and Degradability

No data available

## Bioaccumulative Potential

No data available

## Mobility in Soil

No data available

## Results of PBT and vPvB 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.

## Other Adverse Effects

No data available

# DISPOSAL CONSIDERATIONS

**Waste treatment methods:**

**Recommendation:** Dispose of waste in accordance to applicable national, regional, or local regulations.

**Uncleaned packaging:**

**Recommendation:** Disposal must be made according to official regulations.

**Recommended cleansing agent:** Water, if necessary, with cleansing agents.

# TRANSPORT INFORMATION

## UN number

**ADR, ADN, IMDG, IATA:** Void

## UN proper shipping name

**ADR/RID:** Not dangerous goods

**IMDG:** Not dangerous goods

**IATA:** Not dangerous goods

## Transport hazard class(es)

**ADR/RID: Void IMDG: Void IATA: Void**

## Packaging group

**ADR/RID: Void IMDG: Void IATA: Void**

## Environmental hazards

**ADR/RID**: no **IMDG Marine pollutant**: no **IATA:** no– class,

## Special precautions for user

Not applicable.

## Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Not applicable

# REGULATORY INFORMATION

## 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 : Neither banned nor restricted

dangerous substances and preparations

Regulation (EC) No 649/2012 of the European : Neither banned nor restricted

Parliament and the Council concerning the export

and import of dangerous chemicals

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

Authorisation

## European labelling in accordance with EC Directives Hazard Symbols: The D-Dimer Quality Controls pack insert contains the following symbol  which indicates that potential biological risks are associated with the Quality Control material.

## Risk Phrases: The pack insert contains the following risk phrases:

## The serum control contains human source material that was tested and found nonreactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be treated as potentially infectious and handled with proper laboratory safety procedures to minimize the risk of transmission of infectious disease.

## All components of this kit can be discarded as Biohazard waste according to the local guidelines.

## Additional information: Consult country codes for specific requirements.

## Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

# OTHER INFORMATION

## Full text of H-Statements referred to under section 3.

EUH032 – Contact with acids liberates very toxic gas.

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

## 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

## Additional advice: None.

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 D-Dimer Quality Controls is subject to referenced and limitations included in the product specifications.

LumiraDx UK (company number: 09206123)

**End of safety data sheet.**