

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

1.1 Product identifier

Product form	Mixture (Solid)
Trade name	TB-HIRA Assay - RUO
Product code	Q04-019-R01

1.2 Relevant identified uses of the substance/mixture

Main use category	For professional users only.
Use of the substance/mixture	Research use only. Not for clinical use.
Users advised against	No additional information available.

1.3 Details of the supplier of the safety data sheet

QuantuMDx Group Ltd
Lugano Building 57 Melbourne Street
Newcastle upon Tyne
NE12JQ
United Kingdom
<u>quality@quantumdx.com</u>

1.4 Emergency Telephone Number

Tel: +44 (0)870 803 1234 (Mon-Fri, 9am-5:30pm)

Section 2: Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physiochemical, human health and environmental effects:

No additional information available

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2.2 Label elements

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

No labelling applicable

2.3 Other hazards

No additional information available

Section 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Comments

Non-hazardous ingredients are the remainder and add up to 100%

Section 4: First Aid Measures

4.1 Description of first aid measures

First-aid measures general	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	Remove from exposure. Allow affected person to breathe fresh air.
First-aid measures after skin contact	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if persistent signs of discomfort.
First-aid measures after eye contact	Rinse immediately with plenty of water. Obtain medical attention if persistent signs of discomfort.
First-aid measures after ingestion	Rinse mouth. Do NOT induce vomiting. Seek medical attention if feeling unwell.



4.2 Most importance symptoms and effects, both acute and delayed

Symptoms/effects	Not expected to present a significant hazard under
	anticipated conditions of normal use.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Section 5: Fire Fighting Measures

5.1 Extinguishing Media

Suitable extinguishing media	Foam Dry powder
	Carbon dioxide
	Water
	Spray Sand
Unsuitable extinguishing media	Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

Fire hazard	Not expected to be a fire/explosion hazard under normal conditions of use.
Reactivity in case of fire	None known.
Hazardous decomposition products in case of fire	No hazardous decomposition products known.

5.3 Advice for firefighters

Firefighting instructions	Use water spray or fog for cooling exposed containers.
	Exercise caution when fighting any chemical fire.
	Prevent firefighting water from entering the environment.
Protective equipment for firefighters	Do not enter fire area without proper protective equipment, including respiratory protection.



Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Emergency procedures	Evacuate unnecessary personnel.
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For emergency responders

Protective equipment	Equip clean-up crew with proper protection.
Emergency procedures	Ventilate area.

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3 Methods and material for containment and cleaning up:

In case of large spillages: Contain large spills to maximise product recovery or disposal. For small spills, wipe up with damp cloth. Larger spills can be diluted with water and mopped up. Ensure adequate ventilation and avoid ignition sources. On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away fromother materials.

6.4 Reference to other sections

See Section 8: Expose controls/personal protection.

Section 7: Handling and Storage

7.1 Procedures for safe handling

Precautions for safe handling	Wash hands and other exposed areas with mild soap and waterbefore eating, drinking, or smoking and when leaving work.

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7.2 Conditions for safe storage, including any incompatibilities

Technical measures	Comply with applicable regulations.
Storage conditions	Keep only in the original container in a cool, well-ventilated
	place away from: Heat sources and light.
	Keep container closed when not in use.
Incompatible products	Strong bases. Strong acids.
Incompatible materials	Sources of ignition. Direct sunlight.
Storage temperature	5 – 25 °C

7.3 Specific end use(s)

Refer to Section 1.

Section 8: Expose controls/personal protection

8.1 Control Parameters

National occupational exposure and biological limit values

No additional information available.

Recommended monitoring procedures

Monitoring methods

A specific exposure sample method is not available.

Air contaminants formed

No additional information available.

DNEL and PNEC

No additional information available.

Control banding

No additional information available.

8.2 Exposure Controls

Appropriate engineering controls

No additional information available.

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Personal protection equipment

Avoid all unnecessary exposure.

Eye and face protection	Safety glasses equipped with side shields are recommended as minimum protection in industrial settings. Wear approved safety goggles. Chemical goggles should be consistent with EN166 or equivalent.
Skin protection	Wear suitable protective clothing. Chemical resistant protective apron / clothing (tested to EN 14605 or equivalent).
Hand protection	It is a good industrial hygiene practice to minimise skin contact. Neoprene gloves are recommended with breakthrough times of approx. 25 minutes according to EN 374 (0.1 mm thickness); changing gloves after 20 minutes is recommended.
Respiratory protection	No additional information available.
Thermal hazards	No additional information available.

Environmental exposure controls

Other information	Do not eat or drink during use. Avoid release to drains or
	surface water.



Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid.
Colour	White.
Appearance	Solid (lyophilised).
Odour	None.
Melting point/Freezing point	Not determined for this product.
Boiling point	Not determined for this product.
Flammability	Non-flammable.
Lower explosive limit (LEL)	Not applicable; not considered potentially explosive.
Upper explosive limit (UEL)	Not applicable; not considered potentially explosive.
Flash point	Not determined for this product.
Auto-ignition temperature	Not determined for this product.
Decomposition temperature	Not determined for this product.
рН	Not determined for this product.
Viscosity, kinematic	Not applicable for solid.
Solubility	Soluble in water.
Partition coefficient n-octanol/water (LogKow)	Not applicable for solid.
Vapour pressure	Not applicable for solid.
Density	Not determined for this product.
Relative density	Not determined for this product.
Relative vapour density at 20 °C	Not determined for this product.
Particle characteristics	Not determined for this product.

9.2 Other information

Information regarding physical hazard classes

No additional information available.

Other safety characteristics

Re	elative evaporation rate (butyl acetate = 1)	Not determined for this product.

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Section 10: Stability and Reactivity

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage, and transport.

Thermal decomposition generates

Not established.

10.2 Chemical Stability

The product is stable under recommended handling and storage conditions.

10.3 Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4 Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5 Incompatible materials

Strong Acids, Strong Bases.

10.6 Hazardous decomposition products

May form oxides of carbon, phosphorus or nitrogen.

Section 11: Toxicological Information

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

a)	Acute toxicity	Based on available data, the classification criteria are not met.
b)	Skin corrosion/irritation	Based on available data, the classification criteria are not met.
c)	Serious eye damage/irritation	Based on available data, the classification criteria are not met.
d)	Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.
e)	Germ cell mutagenicity	Based on available data, the classification criteria are not met.
f)	Carcinogenicity	Based on available data, the classification criteria are not met.
g)	Reproductive toxicity	Based on available data, the classification criteria are not met.
h)	STOT-single exposure	Based on available data, the classification criteria are not met.
i)	STOT-repeated exposure	Based on available data, the classification criteria are not met.
j)	Aspiration hazard	Based on available data, the classification criteria are not met.

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11.2 Information on other hazards

Endocrine disrupting properties

Based on available data, the classification criteria are not met

Other information

No other health hazards

Section 12: Ecological Information

12.1 Toxicity

Not established.

12.2 Persistence and degradability

Not established.

12.3 Bioaccumulative potential

Not established.

12.4 Mobility in Soil

Not established.

12.5 Results of PBT, vPvB, PMT or vPvP assessment

Not established.

12.6 Endocrine disrupting properties

None of the components are currently considered to be potentially damaging to the endocrine system.

12.7 Other adverse effects

No other known adverse effects.

Section 13: Disposal Considerations

13.1 Waste treatment methods

Dispose of as hazardous waste. No specific precautions.

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Section 14: Transport Information

14.1 UN number or ID number

Not regulated

14.2 UN proper shipping name

Not regulated

14.3 Transport hazard class(es)

Not regulated

14.4 Packing group

Not regulated

14.5 Environmental hazards

Not regulated

14.6 Special precautions for user

Not regulated

14.7 Maritime transport in bulk according to IMO instruments

Not regulated

Section 15: Regulatory Information

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

EU-Regulations

Contains no substance on the REACH candidate list \geq 0.1 % / SCL.

Contains no REACH Annex XIV substances in concentration \geq to the Annex XIV limit values.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.

National regulations

No additional information available.

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15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this product.

Section 16: Other Information

16.1 Sources of key data:

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. ECHA (European Chemical Agency). Supplier information. CLP inventory. The REACH etc. (Amendment etc.; EU Exit) Regulations 2020 (UK REACH).

European Chemical Agency, https://echa.europa.eu/

16.2 Method used for classification of mixtures:

Ingredient based approach

*** This health and safety information is correct to the best of our knowledge and belief at the date of its publication, but we cannot accept liability for any loss, injury or damage that may result from its use.

The information given in this Safety Data Sheet is designed only as guidance for safe handling, storage and use of the product named. It is not a specification nor does it guarantee any specific properties. All chemicals should be handled only by competent personnel within a controlled environment.***

16.3 Version History

- V1 First issue
- V2 Updated trade name
- V3 Change from liquid to solid mixture Updated document template