

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

# SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name Multichem U

Reference No. UC201A.10 / UC202A.10 / UC201X / UC20BX /

UC202X

09339868190 / 09339876190

1.2 Relevant identified uses of the substance or

mixture and uses advised against

Identified use(s)

In vitro diagnostic reagent. For professional use only.

1.3 Details of the supplier of the safety data sheet

Company Identification Techno-path Manufacturing Ltd

Fort Henry Business Park

Ballina

**County Tipperary** 

Ireland

Telephone +353 (0) 61 525700

E-Mail (competent person) qcsupport@technopathcd.com

1.4 Emergency telephone number

Emergency Phone No. +353 (0) 61 525700

### ► SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP) Not classified as dangerous for supply/use.

**2.2** Label elements No measures required.

**2.3** Other hazards Contains materials of human origin.

#### ▶ SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Description: In vitro diagnostic reagent. Aqueous solution. Stabilised human urine with adjusted levels of defined analytes.

Dangerous components:

Hazardous Ingredient(s)	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard Statement(s)	%W/W
Sodium azide*	26628-22-8	247-852-1	Not available	Acute Tox. 2; H300 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	< 0.1

<sup>\*</sup> Substance with a community exposure limit.

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#### 3.3 Additional Information

For full text of H Statements see section 16. The serum from each donor contributing urine for this material has been tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and non-reactive for HBsAg

#### **SECTION 4: FIRST AID MEASURES**



4.3

4.1 Description of first aid measures

Inhalation

Skin Contact

Eye Contact

Ingestion

4.2 Most important symptoms and effects, both acute and delayed

Indication of the immediate medical attention and special treatment needed

Supply fresh air; consult doctor in case of complaint. Wash skin with soap and water. Remove contaminated

clothing.

Rinse cautiously with water for several minutes. Consult a

doctor in case of complaint.

Wash out mouth with water. Consult a doctor in case of

complaint. None.

None.

#### **SECTION 5: FIRE-FIGHTING MEASURES**

5.1 Extinguishing media

Suitable Extinguishing Media

5.2 Special hazards arising from the substance or mixture

5.3 Advice for fire-fighters

CO2, powder or water spray. Fight larger fires with water

spray or alcohol resistant foam.

In case of fire, the following can be released: Carbon oxides

(COx), nitrogen oxides (NOx).

Use fire-extinguishing methods suitable to surrounding

conditions.

Wear full protective suit and self-contained breathing aparatus (SCBA) when extinguishing fires.

#### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

6.1 Personal precautions, protective equipment and emergency procedures Isolate spillage and clean up immediately.

Refer to Section 8 for protective measures when handling the spillage.

6.2 Environmental precautions

6.3 Methods and material for containment and cleaning up

Do not allow to enter drains, sewers or watercourses.

Absorb with liquid-binding material (paper towelling, sand,

diatomite, acid binders, universal binders, sawdust). Dispose of contaminated material as waste according to Section 13. Swab down area with Chloros or other disinfecting agent.

6.4 Reference to other sections

8, 13

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#### **SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling** This product should be handled as a potentially infectious

material, as no known test method procedure can offer complete assurance that products derived from materials of

human origin will not transmit infectious agents.

Refer to Directive 2000/54/EC for information on handling

biohazardous materials.

Avoid contact with the eyes, skin and mucous membranes.

Keep out of reach of children.

Wash hands before breaks and after work.

Clean work areas with hypochlorite or other disinfecting

agent.

7.2 Conditions for safe storage, including any

incompatibilities

Store in the original container at 2 to 8°C.

7.3 Specific end use(s)

Use as per instructions for use.

#### ▶ SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits EU IOELV / UK EH40

SUBSTANCE.	CAS No.	LTEL (8 hr	LTEL (8 hr	STEL	STEL	Note
		TWA ppm)	TWA	(ppm)	(mg/m³)	
			mg/m³)			
Sodium azide	26628-22-8		0.1		0.3	Sk

Sk - Can be absorbed through skin.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

8.2.2 Personal protection equipment

Not relevant for this material.

Eye/face protection Safety glasses recommended. (EN166).

Hand protection Disposable gloves. (EN374).



Material of gloves: Latex / natural rubber, Nitrile rubber.

Penetration time of glove material: Gloves resistance is not critical when the product is handled

according to the instructions for use.

Body protection Laboratory coat.

Respiratory protection Not normally required.

**8.2.3 Environmental Exposure Controls**No special measures are required.

### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

9.1 Information on basic physical and chemical

properties

Appearance Liquid.
Colour Amber.
Odour Light.

Odour Threshold (ppm) Not determined.

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pH (Value) 5.8 – 6.2.

Melting Point (°C) / Freezing Point (°C) Similar to water, approximately 0°C.

Boiling point/boiling range (°C): Similar to water, approximately 100°C.

Flash Point (°C)

Evaporation rate (BA = 1)

Flammability (solid, gas)

Explosive limit ranges

Not applicable.

Not applicable.

Vapour Pressure (mm Hg) Similar to water, approximately 23 hPa.

Vapour Density (Air=1) Not determined.

Density (g/ml) ~ 1

Solubility (Water) Completely miscible with water.

Solubility (Other) Not determined. Partition Coefficient (n-Octanol/water) Not determined. Auto Ignition Temperature (°C) Not determined. Not determined. Decomposition Temperature (°C) Viscosity (mPa.s) Not determined. Explosive properties Not explosive. Oxidising properties Not oxidising Other information Not available.

#### **SECTION 10: STABILITY AND REACTIVITY**

**10.1 Reactivity** None known.

**10.2** Chemical stability The product is stable in accordance with the recommended

storage conditions.

**10.3** Possibility of hazardous reactions Hazardous polymerisation will not occur.

**10.4 Conditions to avoid** None.

10.5 Incompatible materials None known.
 10.6 Hazardous Decomposition Product(s) None known.

### **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1 Information on toxicological effects

#### 11.1.2 Mixtures

9.2

Acute toxicity
 Based upon the available data, the classification criteria are

not met. ATE > 2,000 mg/kg

Irritation Based upon the available data, the classification criteria are

not met.

Corrosivity Based upon the available data, the classification criteria are

not met.

Sensitisation Based upon the available data, the classification criteria are

not met.

Repeated dose toxicity Based upon the available data, the classification criteria are

not met.

Carcinogenicity Based upon the available data, the classification criteria are

not met.

Mutagenicity Based upon the available data, the classification criteria are

not met.

Toxicity for reproduction Based upon the available data, the classification criteria are

not met.

STOT-single exposure Based upon the available data, the classification criteria are

not met.

STOT-repeated exposure Based upon the available data, the classification criteria are

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not met.

Aspiration hazard Based upon the available data, the classification criteria are

**Health Effects and Symptoms** 

Skin Contact No significant harmful effects anticipated. Eye Contact No significant harmful effects anticipated. Ingestion No significant harmful effects anticipated.

Other information Not applicable.

#### **SECTION 12: ECOLOGICAL INFORMATION**

12.1 **Toxicity** The product does not contain significant quantities of

ingredients that are environmentally toxic.

12.2 Persistence and degradability The product is readily biodegradable.

Bioaccumulative potential 12.3 None anticipated.

Mobility in soil The product is predicted to have high mobility in soil. 12.4

12.5 Results of PBT and vPvB assessment Not applicable. Other adverse effects 12.6 Not applicable.

#### SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

> Product: Dispose of as potentially biohazardous waste and in

> > compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved

waste-disposal company for information.

European waste catalogue: 18 01 03.

Disposal should be in accordance with local, state or Packaging:

national legislation.

Contaminated packaging must be disposed of in the same

manner as the product.

Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

### **SECTION 14: TRANSPORT INFORMATION**

14.1 **UN** number Not applicable 14.2 **UN Proper Shipping Name** Not applicable

14.3 Transport hazard class(es) Not classified as dangerous for transport.

14.4 **Packing Group** Not applicable 14.5 **Environmental hazards** Not applicable 14.6 Special precautions for user Not applicable

Transport in bulk according to Annex II of 14.7

Not applicable MARPOL73/78 and the IBC Code

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### **SECTION 15: REGULATORY INFORMATION**

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

In Vitro diagnostics medical devices directive 98/79/EC. In Vitro Diagnostic Medical Device Regulation EU/2017/746

Regulation (EC) No. 1272/2008 (CLP) Regulation (EC) No. 1907/2006 (REACH)

15.2 **Chemical Safety Assessment**  Not applicable.

#### ► SECTION 16: OTHER INFORMATION

#### **LEGEND**

STOT Specific Target Organ Toxicity

Short Term Exposure Limit STEL I TFI Long Term Exposure limit Time Weighted Average TWA Threshold Limit Value TLV Acute toxicity estimate ATE

#### Classification code:

Acute Tox. 1 Acute toxicity, Category 1 Acute Tox. 2 Acute toxicity: Category 2

STOT RE 2 Specific target organ toxicity — repeated exposure: Category 2 Aquatic Acute 1 Hazardous to the aquatic environment - Acute: Category 1 Aquatic Chronic 1 Hazardous to the aquatic environment - Chronic: Category 1

#### Hazard Statement(s)

H300: Fatal if swallowed.

H310: Fatal in contact with skin.

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

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects. EUH032: Contact with acids liberates very toxic gas.

#### References:

Raw material safety data sheets.

#### **Additional Information**

Reason for update: SECTION 2: SECTION 3: SECTION 8: SECTION 11:

SECTION 16:

► Indicates altered section

Supersedes: Version: 4

#### **Additional Information**

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To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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