

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

Reference No.

Multichem U 05P80-10 & 08P89-10

Relevant identified uses of the substance or 1.2 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

Abbott GmbH & Co.KG Max-Planck-Ring 2 65205 Wiesbaden

Germany

Telephone

(+49)-6122-58-0 E-Mail (competent person) qcsupport@technopathcd.com

Emergency telephone number 1.4

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. 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: The product does not contain reportable quantities of

dangerous components.

Additional Information 3.3 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



Version: 6 Date: 01/04/2019 Page: 1/6

Multichem U



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

Description of first aid measures 4.1

> Inhalation Supply fresh air; consult doctor in case of complaint. Skin Contact

Wash skin with soap and water. Remove contaminated

clothing.

Eye Contact 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 Ingestion

complaint.

Most important symptoms and effects, both 4.2

acute and delayed

None.

Indication of the immediate medical attention 4.3

and special treatment needed

None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media

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

spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or

mixture

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

(COx), nitrogen oxides (NOx).

5.3 Advice for fire-fighters 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

6.2 **Environmental precautions**

6.3 Methods and material for containment and

SECTION 7: HANDLING AND STORAGE

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

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.

Version: 6 Date: 01/04/2019 Page: 2/6



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

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 LimitsThe product does not contain any relevant quantities of

materials with critical values that have to be monitored at the

workplace.

8.2 Exposure controls

8.2.1 Appropriate engineering controls Not relevant for this material.

8.2.2 Personal protection equipment

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 ControlsNo 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. 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.

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)

Partition Coefficient (n-Octanol/water)

Auto Ignition Temperature (°C)

Decomposition Temperature (°C)

Viscosity (mPa.s)

Explosive properties

Oxidising properties

Not determined.

Not explosive.

Not oxidising

9.2 Other information Not available.

Version: 6 Page: 3/6 Date: 01/04/2019



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

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

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

not met.

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

not met.

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

not met.

Health Effects and Symptoms

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

11.2 Other information Not applicable.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity The product does not contain significant quantities of

ingredients that are environmentally toxic.

2.2 Persistence and degradability The product is readily biodegradable.

12.3 Bioaccumulative potential None anticipated.

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

Version: 6 Page: 4/6 Date: 01/04/2019



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

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

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

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 applicable14.2 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

14.7 Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental

regulations/legislation specific for the

substance or mixture

In Vitro diagnostics medical devices directive 98/79/EC.

15.2 Chemical Safety Assessment Not applicable.

SECTION 16: OTHER INFORMATION

LEGEND

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

Vial Labels contain Benzophenone

Version: 6 Page: 5/6 Date: 01/04/2019

Multichem U



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

Additional Information

Prepared by: Dr. J. J. Tobin, ChemHaz Solutions, Email: info@chemhazsolutions.com

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.

Version: 6 Page: 6/6 Date: 01/04/2019

Multichem U