

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

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

1.1 Product identifier

1.3

Trade Name Multichem IA Speciality

Reference No. BP300X, BP301X, BP302X, BP303X,

BP300A, BP301A, BP302A, BP303A, BP300MX

In vitro diagnostic reagent. For professional use only.

1.2 Relevant identified uses of the substance or

mixture and uses advised against

Identified Use(s)

Details of the supplier of the safety data sheet

Company Identification Techno-path Manufacturing Ltd

Fort Henry Business Park

qcsupport@technopathcd.com

Ballina

**County Tipperary** 

Ireland

Telephone +353 (0) 61 525700

E-Mail (competent person)

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 hazardous.

2.2 Label elements Safety data sheet available on request.

2.3 Other hazards Contains materials of human origin.

## ▶ SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Mixtures

Description: In vitro diagnostic reagent. Aqueous solution.

Dangerous components:

EC Classification No. 1272/2008

Hazardous Ingredient(s)	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard Statement(s)	%W/W
Ethanol	64-17-5	200-578-6	Not available	Flam. Liq. 2; H225 Eye Irrit. 2; H319	1.0

**3.2** Additional Information For full text of H Statements see section 16.

Contains materials of human origin.

Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis using FDA approved methods and were found to

be nonreactive.

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



4.1 Description of first aid measures

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.

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

complaint.

4.2 Most important symptoms and effects, both

acute and delayed

None.

4.3 Indication of any immediate medical attention

and special treatment needed

None.

### **SECTION 5: FIREFIGHTING 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 Isola and emergency procedures Refe

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 co

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.

8, 13

## 6.4 Reference to other sections

## **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 /inactivation 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.

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Wash hands before breaks and after work.

Clean work areas with hypochlorite or other disinfecting

7.2 Conditions for safe storage, including any Store frozen.

incompatibilities 7.3

Specific end use(s)

CSF analythical control.

## ► SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Control parameters 8.1

8.1.1 **Occupational Exposure Limits**  Irl OELV / UK WEL

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note
Ethanol	64-17-5	-	-	1,000	-	Irl OELV
Ethanol	64-17-5	1,000	1,920	-	-	UK WEL

Sk - Can be absorbed through skin.

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.

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

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

#### 9.1 Information on basic physical and chemical

properties

Appearance Clear liquid. Colour. Yellow-Brown. Odour Slight.

Odour Threshold (ppm) Not determined.

pH (Value) 7.0.

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) Not applicable. Evaporation rate (BA = 1)Not determined. Flammability (solid, gas) Not applicable. **Explosive Limit Ranges** Not applicable.

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

Vapour Density (Air=1) Not determined.

Density (g/ml) ~ 1

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Solubility (Water) Completely miscible with water.

Solubility (Other) Not determined. Partition Coefficient (n-Octanol/water) Not determined. Auto Ignition Point (°C) Not determined. Decomposition Temperature (°C) Not determined. 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 Concentrated acids, heavy metals, metallic salts.

10.6 Hazardous decomposition products 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.

Skin corrosion/irritation Based upon the available data, the classification criteria are

not met.

Serious eye damage/irritation Based upon the available data, the classification criteria are

not met.

Respiratory/skin sensitization Based upon the available data, the classification criteria are

not met.

Germ cell mutagenicity Based upon the available data, the classification criteria are

not met.

Carcinogenicity Based upon the available data, the classification criteria are

not met.

Reproductive toxicity 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

Eye Contact

Ingestion

No significant harmful effects anticipated.

No significant harmful effects anticipated.

No significant harmful effects anticipated.

**11.2 Other information** Not applicable.



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### SECTION 12: ECOLOGICAL INFORMATION

Toxicity 12.1 The product does not contain significant quantities of

ingredients that are environmentally toxic.

Persistence and degradability The product is readily biodegradable. 12.2

None anticipated. 12.3 **Bioaccumulative potential** 

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

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

## **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.

18 01 03. European waste catalogue:

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 Not applicable 14.2 UN proper shipping name

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

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

Transport in bulk according to Annex II of 14.7

Not applicable Marpol and the IBC Code

## **SECTION 15: REGULATORY INFORMATION**

15.1 Safety, health and environmental In Vitro diagnostics medical devices directive 98/79/EC.

regulations/legislation specific for the substance or mixture

15.2 **Chemical Safety Assessment** Not applicable.

## ► SECTION 16: OTHER INFORMATION

### **LEGEND**

STOT Specific Target Organ Toxicity **STEL** Short Term Exposure Limit

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LTEL Long Term Exposure limit
TWA Time Weighted Average
TLV Threshold Limit Value

Classification code:

Flam. Liq. 2 Flammable Liquid, Category 2
Eye Irrit. 2 Serious eye irritation: Category 2

Hazard Statement(s)

H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation.

References:

Raw material safety data sheets.

**Additional Information** 

Reason for update:: SECTION 3: SECTION 8: SECTION 10: SECTION 16:

▶ Indicates altered section

Supersedes: Version: 3

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