

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 S Plus CH100PLA / CH101PLA / CH102PLA / CH103PLA / CH110PLA.05 / CH111PLA.05 / CH112PLA.05 / CH113PLA.05 / CH114A.05 / CH115A.05 / CH116A.05 CH110CRP.05 / CH111CRP.05 / CH112CRP.05 / CH100CRP / CH101CRP / CH102CRP / CH103CRP / CH110MCRP.05 / CH100MCRP
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
		Co. 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
SEC	TION 2: HAZARDS IDENTIFICATION	
2.1	Classification of the substance or mixture	
	Regulation (EC) No. 1272/2008 (CLP)	Not classified as dangerous for supply/use.
	Directive 67/548/EEC & Directive 1999/45/EC	Not classified as dangerous for supply/use.
		3
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	
0.2	Description:	In vitro diagnostic reagent. Aqueous solution. Stabilised

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

 Dangerous components:
 The product does not contain reportable quantities of dangerous components.

 3.3
 Additional Information

 Each donor unit used in the preparation of this material was 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.



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

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 the immediate medical attention and special treatment needed	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	Do not allow to enter drains, sewers or watercourses.
6.3	Methods and material for containment and cleaning up	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

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

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
- 7.3 Specific end use(s)

Store frozen.

Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters
- 8.1.1 Occupational Exposure Limits

The 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
- 8.2.2 Personal protection equipment Eye/face protection

Not relevant for this material.

Disposable gloves. (EN374).

Safety glasses recommended. (EN166).

Hand protection



Material of gloves: Penetration time of glove material:

Body protection Respiratory protection Latex / natural rubber, Nitrile rubber. Gloves resistance is not critical when the product is handled according to the instructions for use.

Laboratory coat. Not normally required.

Environmental Exposure Controls 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 Liquid. Colour Odour Odour Threshold (ppm) pH (Value) Melting Point (°C) / Freezing Point (°C) Boiling point/boiling range (°C): Flash Point (°C) Evaporation rate (BA = 1)Flammability (solid, gas) Explosive limit ranges Vapour Pressure (mm Hg) Vapour Density (Air=1) Density (g/ml) ~ 1 Solubility (Water) Solubility (Other) Partition Coefficient (n-Octanol/water)

Liquid. Amber. Light. Not determined. 7.6 – 8.0. Similar to water, approximately 0°C. Similar to water, approximately 100°C. Not applicable. Not determined. Not applicable. Similar to water, approximately 23 hPa. Not determined. ~ 1 Completely miscible with water. Not determined. Not determined. Not determined. Not determined.



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

Auto Ignition Temperature (°C) Decomposition Temperature (°C) Viscosity (mPa.s) Explosive properties Oxidising properties Other information Not determined. Not determined. Not determined. Not explosive. Not oxidising Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

9.2

- 10.2 Chemical stability
- 10.3 Possibility of hazardous reactions
- 10.4 Conditions to avoid
- 10.5 Incompatible materials
- 10.6 Hazardous Decomposition Product(s)

None known.

The product is stable in accordance with the recommended storage conditions. Hazardous polymerisation will not occur. None. None known. 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.



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

SECTION 12: ECOLOGICAL INFORMATION

- 12.1 Toxicity
- 12.2 Persistence and degradability
- 12.3 Bioaccumulative potential
- 12.4 Mobility in soil
- 12.5 Results of PBT and vPvB assessment
- 12.6 Other adverse effects

The product does not contain significant quantities of ingredients that are environmentally toxic. The product is readily biodegradable. None anticipated. The product is predicted to have high mobility in soil. Not applicable. 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:

Packaging:

18 01 03.

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 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
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



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

STOT Specific Target Organ Toxicity

References:

Raw material safety data sheets.

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.