MICROGEN BIOPRODUCTS	**Type:**	**Safety Data Sheet**
	Title:	**M121** **Microgen IM Kit**

DATE OF ISSUE: May 2015

ISSUED TO MEET THE REQUIREMENTS OF REGULATION (EC) 1907/2006:
ARTICLE 31

SECTION 1: Identification of the substance and of the company/undertaking

Product Identifier: M121 CE		**Microgen IM Kit**			
Product Use: The Microgen IM Kit is intended for the in vitro laboratory detection of heterophile ntibodies associated with infectious mononucleosis in human serum or plasma samples.					
Manufacturer's Name: Microgen Bioproducts Limited					
Manufacturer's Address: 1 Admiralty Way, Camberley, Surrey, England					
Postal Code	GU 15 3DT	**Emergency Telephone**	+44(0)1276 600081	**Fax:** +44 (0) 1276600151	
Hours of Operation:	09:00 -17:00 GMT	**Email**	customerservices@microgenbioproducts.com		

SECTION: 2 Hazards Identification

2.1 Classification of the substance or mixture

1) Phenol 2)Sodium Azide

Classification according to Regulation (EC) No 1272/2008: Phenol
Acute Tox. 3 (Oral), H301
Acute Tox. 3 (Dermal), H311
Acute Tox. 2 (Inhalation), H330
Skin Corr. 1B, H314
Muta. 2, H341
STOT RE 2, H373
Aquatic Acute 2, H401
Aquatic Chronic 2, H411

Classification according to Directive 67/548/EEC or Directive 1999/45/EC:
Toxic, Corrosive

RISK PHRASES:
R-24/25 Toxic in contact with skin and if swallowed.
R-34 Causes burns.
SAFETY PHR ASES:
S-26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S-45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S-36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S-28C After contact with skin, wash immediately with plenty of soap and water.

Classification according to Regulation (EC) No 1272/2008: Sodium Azide

Acute Tox. 2	H300 Fatal if swallowed.
Aquatic Acute 1	H400 Very toxic to aquatic life.
Aquatic Chronic 1	H410 Very toxic to aquatic life with long lasting effects.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC:

T+; Very toxic
R28: Very toxic if swallowed.

N; Dangerous for the environment

R50/53: Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.
R32: Contact with acids liberates very toxic gas.

Information concerning particular hazards for human and environment: Not applicable
Other hazards that do not result in classification: No information known

2.2 Labelling according to Regulation (EC) No 1272/2008:

The substance is not classified and labelled as hazardous as the concentration of sodium azide is present in minute quantities.

SECTION 3: Composition/Information on Ingredients

Components	CAS Number/ EC Number	Concentration
M121A Guinea Pig Kidney suspension M121B Ox Cell Reagent The above reagents contain Phenol	108-95-2/ 203-632-7	0.5 %

M121C Horse Cell Reagent M121D Positive Control The above two reagents contain: Sodium Azide	26628-22-8/ 247-852-1	0.099% in all of these components

SECTION 4: First aid measures

- **Eye contact** – Wash out eyes with plenty of water. Assure adequate flushing by separating eyelids with fingers.
- **Inhalation**: Supply with fresh air or oxygen. Consult doctor if discomfort persists.
- **Skin contact** – Wash skin immediately with soap and water
- **Ingestion –** If chemical has been swallowed, wash out mouth with water. Do not swallow mouthwash. Seek medical advice.
- **Equipment to be available at the workplace for specific and immediate treatment:** Eye –washing and skin-washing facilities

SECTION 5: Fire-fighting measures

5.1 Extinguishing media
Suitable extinguishing agents: Use whatever is required for the surrounding area.

5.2 Special hazards arising from the substance or mixture
If the product is involved in a fire, the following can be released:
Carbon monoxide and carbon dioxide
Nitrogen oxides
Hydrogen chloride
Avoid inhalation of fumes

5.3. Advice for firefighters

- **Protective equipment**: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

1) Wear disposable vinyl/nitrile gloves
2) Absorb with dry earth, sand or other non-combustible material. Hold in a bag for waste disposal.

6.2. Environmental precautions:

Dispose of any contaminated material in biohazardous disposal units and in accordance with established safety procedures.

6.3. Methods and material for containment and cleaning up:

Wipe up spills with absorbent paper, then clean area with a concentrated chlorine solution.

SECTION 7: Handling and storage

7.1. Handling

For in vitro diagnostic use only. Read the Instructions for Use. Always follow Good Laboratory Practice when using this product.

7.2. Storage

Store at 2-8°C. Keep all containers tightly closed until ready to use. Under these conditions reagents will retain their activity until the expiry date shown on the label on outer carton.

SECTION 8: Exposure controls/personal protection

8.1. Exposure Limit Values Only very small quantities involved

8.2. Exposure Controls

8.2.1. Occupational

Respiratory	Respiratory protection is not required under normal and intended conditions of use.
Hands	Disposable vinyl or nitrile gloves
Eyes	Safety glasses with side shields recommended
Body	Laboratory coat

SECTION 9: Physical and Chemical Properities

9.1. Appearance:

M121A Guinea Pig Kidney	Homogenised guinea pig kidney suspended in 0.5% Reagent phenol saline solution. Being liquid suspension.
M121B Ox Cell Reagent	Lysed ox cell stroma suspended in 0.5% phenol saline Solution. Red brown liquid solution.
M121C Horse Cell Reagent	Suspension of Horse Red Blood Cells in a stabiliser solution containing antibiotics and preserved in 0.099% sodium azide. Red brown liquid suspension.
M121D Positive Control	Human Positive Control Serum diluted in buffered saline solution preserved with 0.099% sodium azide clear solution.

10. Stability and Reactivity

10.1. Stability: Stable under recommended storage conditions. Do not use after stated expiry date. S t o r e at 2-8°C.

10.2. Materials/Conditions to avoid: Avoid contact with lead or copper plumbing

10.3. Hazardous decomposition products: Combustion will generate carbon oxides and Nitrogen oxides.

SECTION 11: Toxicological Information

11.1. Acute toxicity: Low order of acute toxicity

11.2. Sensitisation – skin: Possibility of allergic sensation should be considered

SECTION 12: Ecological Information:

- Persistence and degradability: No further relevant information available.
- Bio accumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- Other adverse effects :No further relevant information available

SECTION 13: Disposal Considerations

Dispose of according to any local, national or regional regulations.

SECTION 14: Transport Information

This material is not considered dangerous or hazardous for transportation

SECTION 15: Regulatory Information

Health, safety or environmental information is not required on the label (according to Regulation (EC) No 1272/2008)

SECTION 16: Other Information

16.1. Recommended restrictions on use:

This product is intended to be used for invitro diagnostic use only by technical staff trained in microbiological techniques. Classification and labelling have been performed according to CLP Regulations.

Read the Instructions for Use for further information on limitations of use.

16.2. Sources of information used to compile this sheet

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH): Article 31: Requirements for safety data sheets, and Annex II: Guide to the compilation of safety data sheets, OJL, 136, 29.5.2007, pp 35-36 and pp 84-89.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 (in short CLP).

Commission Decision 2000/532/EC establishing a list of wastes pursuant to Article 1 (a) of Directive 75/442/EEC on Waste and Article 1 (4) of Directive 91/689/EEC on Hazardous Waste. CONSLEG: 2000D0532-01/01/2002, Office for Official Publications of the European Communities.

Approved Supply List (8th edition), Information provided for the classification and labelling of substances and preparations for supply, United Kingdom Health and Safety Commission, 2005 (based on Annex I of 67/548/EEC).

Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices, Annex I, Essential Requirements, OJ L, 331, 7.12.98, p 20.

List of approved workplace exposure limits, Table 1 of EH40/2005, United Kingdom Health and Safety Commission, 2ND edition published 2011, implementing the European Commission's Indicative Occupational Exposure Limit Values Directive 2009/161/EU.

16.3. Changes from previous version

Replaces previous MSDS for M121 CE, Microgen IM Kit, December 2014.

All sections: updated format and details according to REACH GUIDELINES Annex-II and CLP.

The above information is based on data available and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determinations of the effects, properties and protections which pertain to their particular conditions.

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QA/RA Department: Sajana	Date: 29 May '15