



1 PRODUCT IDENTIFICATION

TRADE NAME: Tumor Marker Control In-vitro Diagnostic Test Kit

PRODUCT CODE: TMCO

MANUFACTURER/SUPPLIER: EURO/DPC Limited, Glyn Rhonwy, Llanberis, Caernarfon, Gwynedd LL55 4EL, United Kingdom

Phone Number: 44-1-286-871-871 Fax Number: 44-1-286-871-802

Phone Number in U.S.: (800) 372-1782 Emergency Phone Number in U.S.: (800) 372-1782

PRODUCT COMPONENTS & CATALOG NUMBERS: Control Module TMCO1-3

PRODUCT FORMAL NAME Diagnostic Reagent

PRODUCT CHEMICAL NAME: Aqueous Solution

2 HAZARDOUS INGREDIENTS

Kit Component(s): TMCO1-3

Hazardous Component	Percent	CAS Number	EEC Classification	Symbol	Index #
TMCO1-3:					
Human Serum	--	--	--	--	--
Sodium Azide	<0.1%w/w	26628-22-8	--	--	--

3 HAZARD IDENTIFICATION

Human Serum (or its components) used in the manufacture of components was found non-reactive for HIV-1 antibody, non-reactive for HbsAg, and non-reactive for HCV when tested with licensed reagents. However, no known test method can offer absolute assurance that products derived from human serum will not be infectious. **Handle as if capable of transmitting disease.**

Sodium Azide is a toxic substance. Avoid contact with components, which contain sodium azide, and do not ingest. An accumulation of sodium azide may result in a reaction with lead or copper plumbing to form an explosive metal azide complex. If drain disposed, dilute and flush with a copious amount of running water to prevent azide build-up. Dangerous when in contact with acid.

4 FIRST AID MEASURES

EYE CONTACT: Flush with copious amounts of fresh water for at least 15 minutes.

SKIN CONTACT: Wash well with mild soap and copious amounts of fresh water. Remove any contaminated clothing. Flush skin surface with additional water.

INGESTION: Flush mouth with copious amounts of water. Do not swallow rinse water.

INHALATION: Remove victim to fresh air. If breathing is labored, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

If warranted, seek medical attention. If possible, save sample of material that caused reaction for use in determination of appropriate treatment.

5 FIRE EXTINGUISHING MEASURES

Use extinguishing media appropriate to surrounding fire. No special equipment or procedures are required.

6 ACCIDENTAL RELEASE MEASURES

Absorb spills of reagents and patient samples with absorbent paper, taking care not to spread the material. Clean spill area with a freshly made 0.5% sodium hypochlorite (bleach) solution. Discard all materials used to absorb spill and disinfect area into biohazard waste collection for proper disposal.

7 HANDLING AND STORAGE

HANDLING: Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipet patient samples or reagents by mouth. Avoid splashing or aerosol formation. Use all reagents in accordance with the relevant package insert. Avoid high temperatures and keep from freezing during transport.

STORAGE: Store all reagents as directed in the relevant package insert.

8 EXPOSURE CONTROL/PERSONAL PROTECTION

Wear appropriate personal protective equipment when working with reagents or patient specimens, including lab coats, disposable gloves and eye protection. Avoid hand/mouth contact. Wash hands as soon as possible after handling reagents or patient specimens.

Control Parameters of Hazardous Ingredients:

Sodium Azide: CAS # 26628-22-8, RTECS # VY805000, TLV-Ceiling=0.3mg/m, NIOSH (the concentration of sodium azide in this product is well below the TLV shown above). Threshold limit value 1.0 ppm, TDLo (oral) 710mcg/kg, female 3mg/kg, LDLo (oral) 29mg male, LDLo (oral) 786 mg female.



9 PHYSICAL & CHEMICAL PROPERTIES

Physical State: Liquid	Color: Clear	Odor: None	pH: N/A
Boiling Point: 100°C	Melting Point: 0°C	Flash Point: N/A	Inflammability: N/A
Autoinflammability: N/A	Explosiveness: N/A	Oxidizing Properties: N/A	
Vapor Pressure: N/A	Relative Density: N/A	Solubility in water: Complete	

10 STABILITY & REACTIVITY

The reagents in the kit are stable under the storage conditions described in the package insert. Hazardous decomposition will not occur. There are no known strong incompatibilities.

11 TOXICOLOGICAL INFORMATION

Not Applicable

12 ECOLOGICAL INFORMATION

Not applicable

13 DISPOSAL

Dispose in accordance with applicable laws. If drain disposed, dilute and flush with a copious amount of running water to prevent azide build-up (See Section 3).

14 TRANSPORT INFORMATION

Proper Shipping Name: In vitro diagnostic reagents
Hazard Class: None
Identification Number: None

15 REGULATORY INFORMATION

Pursuant to U.S. OSHA regulations and the EEC Directive Number 88/379, the only hazardous ingredients associated with this product are those listed in Section 2 above.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The user should determine the suitability of this information for the intended use of the product and adopt appropriate safety precautions. DPC shall not be held liable for any damage resulting from handling or from contact with the above product. Contact DPC for further information.

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Prepared By: B. Gonzalez

Sections Revised: 1, 3, 5, 14, 15