



MATERIAL SAFETY DATA SHEET FOR IMMULITE 2000 / IMMULITE 2500 UNCONJUGATED ESTRIOL L2KEF / L5KEF

1 PRODUCT IDENTIFICATION

TRADE NAME: IMMULITE 2000 / IMMULITE 2500 Unconjugated Estriol In-vitro Diagnostic Test Kit PRODUCT CODE: L2KEF2, 6 / L5KEF2, 6

MANUFACTURER/SUPPLIER: Diagnostic Products Corporation 5700 W. 96th St., Los Angeles CA 90045
Emergency Phone Number: (800) 372-1782 Phone Number: (800) 372-1782 Fax Number: (310) 645-9999

PRODUCT COMPONENTS & CATALOG NUMBERS: Unconjugated Estriol Bead Pack L2EF12; Reagent Wedge L2EFA2; Adjustors LEFL & LEFH

PRODUCT FORMAL NAME: Diagnostic Reagent PRODUCT CHEMICAL NAME: Aqueous Solution

2 HAZARDOUS INGREDIENTS

Kit Component(s): L2EFA2, LEFL, LEFH

Hazardous Component	Percent	CAS Number	EEC Classification	Symbol	Index #
L2EFA2, LEFL, LEFH: Human Serum	--	--	--	--	--
LEFL, LEFH: Sodium Azide (NaN ₃)	<0.1% w/w	26628-22-8	--	--	--
L2EFA2: Theelin (C ₁₈ H ₂₂ O ₂)	<0.01%w/w	53-16-7	--	--	--

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.

Theelin is a known carcinogen. May cause eye and skin irritation, as well as gastrointestinal complications. May cause reproductive damage and can present a danger to a developing fetus.

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.



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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, TDL_o (oral) 710mcg/kg, female 3mg/kg, LDLo (oral) 29mg male, LDLo (oral) 786 mg female.

Theelin: CAS # 53-16-7, RTECS # KG8575000, **Chronic Exposure Carcinogen** Result: There is sufficient evidence for the carcinogenicity of theelin in experimental animals. In the absence of adequate data in humans, it is reasonable for practical purposes to regard theelin as if it presented a carcinogenic risk to humans. Studies in humans strongly suggest that the administration of estrogens is casually related to an increased incidence of endometrial carcinoma; there is no evidence that theelin is different from other estrogens in this respect. IARC Monograph, volume 2, page 357, 1979

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

WARNING: This product contains Theelin, a chemical known to the State of California (Proposition 65) to cause cancer and birth defects or other reproductive harm.

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.

Date MSDS first initiated: August 22, 2000

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Sections Revised: Header, Footer, 1