CHARLES RIVER ENDOSAFE

1023 Wappoo Rd., Suite 43-B

Telephone: 803-766-7575 Charleston, SC 29407 Fax: 803-766-7576

November 1995

MATERIAL SAFETY DATA SHEET

PRODUCT: ENDOTOXIN INDICATOR for dry-heat oven validation. Endosafe Catalog No(s): EVV2K, EVV10K,

EVV100K, EVV1M, EVV2.5M, EVV10M

CSE, LPS, Lipopolysaccharide, Lipid A **Synonyms:**

Source: Escherichia coli 055:B5

FOR IN VITRO LABORATORY PURPOSES ONLY. NOT FOR HUMAN USE

TOXICITY/HEALTH HAZARD DATA:

TOXICITY DATA: Endotoxin is pyrogenic by parenteral administration; however this product is not for human use.

I.V. Rabbit - PD50 = 1.0 ng/kg (threshold for pyrogenic reaction)

Oral - Not Toxic

No reported/known cases of toxic or harmful reactions.

Reactivity Data: Stable; contains no hazardous combustion or decomposition products.

PHYSICAL DATA:

APPEARANCE AND ODOR: The indicator vial appears empty since the air-dried endotoxin contains no fillers or stabilizers. No odor.

CONTENTS: Each vial contains a specified amount of endotoxin as determined by a LAL method using a specific lot of Limulus Amebocyte Lysate (LAL). The vial is rehydrated with LAL Reagent Water prior to use.

BIOLOGICAL ACTIVITY IN ENDOTOXIN UNITS (EU)

CATALOG NO.	OF LIPOPOLYSACCHARIDE	ENDOTOXIN CONTENT
EVV2K	2,000 EU per vial	200 ng
EVV10K	10,000 EU per vial	1000 ng
EVV100K	100,000 EU per vial	10,000 ng
EVV1M	1 Million EU per vial	100,000 ng
EVV2.5M	2.5 Million EU per vial	250,000 ng
EVV10M	10 Million EU ner vial	1,000,000 ng

CAUTION - USE PROPER HANDLING: Good laboratory technique should be used in handling product:

Avoid mouth pipetting; work in well ventilated area; avoid contact with open wounds;

If hypodermic syringes are used, extreme care should be employed to avoid accidental injection.

Reminder: Product is for laboratory use only and IS NOT for human use.

FIRE AND EXPLOSIVE DATA: Contains no flammable materials and is soluble in water.

HANDLING - SPILLS: If rehydrated material is spilled, absorb with sponge or towel and dispose of towel in closed plastic bag/container. Wear rubber gloves during clean-up.

Avoid contact with skin and eyes. In case of skin contact, immediately flush with plenty of water.

THE ABOVE INFORMATION IS NOT REPRESENTED TO BE ALL INCLUSIVE AND SHOULD BE USED ONLY AS A GUIDE. If, after delivery and inspection, you determine that the product does not conform to your specifications and is not acceptable, please contact Charles River Endosafe immediately to determine whether a replacement or credit is due. It is reasonable to believe that proper use of this product does not constitute actionable risk. Charles River Endosafe will not be liable for any causes of action or damages arising out of the use of this product.

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Reactivity Data: Stable; contains no hazardous combustion or decomposition products.

PHYSICAL DATA:

APPEARANCE AND ODOR: The indicator vial appears empty since the air-dried endotoxin contains no fillers or stabilizers. No odor.

CONTENTS: Each vial contains a specified amount of endotoxin as determined by a quantitative method using a specific lot of Limulus Amebocyte Lysate (LAL) certified for KTA (Kinetic-turbidimetric analysis). The vial is rehydrated with LAL Reagent Water prior to use.

BIOLOGICAL ACTIVITY IN ENDOTOXIN UNITS (EU)

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