



## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

Product identifier used on the label:

**Product Name:** C-Peptide Chemiluminescence ELISA Kit  
**Product Code:** 80-CPTHU-CH01  
**SDS Manufacturer Number:** 232820

Other means of identification:

**Synonyms:** None.

Recommended use of the chemical and restrictions on use:

**Product Use/Restriction:** For research or in vitro diagnostic use only. Avoid contact with Stop Solution.

Chemical manufacturer address and telephone number:

**Manufacturer Name:** ALPCO  
**Address:** 26 Keewaydin Drive  
Unit G  
Salem, New Hampshire 03079  
USA  
**General Phone Number:** 800-592-5726  
**General Fax Number:** 603-898-6854

Emergency phone number:

**Emergency Phone Number:** ChemTrec 24 hours: 800-424-9300 or 703-527-3887

### SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

**GHS Pictograms:**



**Signal Word:** WARNING.

**GHS Class:** Skin Sensitization. Category 1.

**Hazard Statements:** H317 - May cause an allergic skin reaction.

**Precautionary Statements:** P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
P272 - Contaminated work clothing should not be allowed out of the workplace.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P321 - P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P501 - Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Hazards not otherwise classified that have been identified during the classification process:

**Route of Exposure:** Inhalation Ingestion Eye contact Skin Absorption. Injection.

**Potential Health Effects:** Potential Biohazard  
Standards and Controls are formulated with a buffer base and animal or human serum. The kit components that are made with human serum are tested by a United States Food and Drug Administration (USFDA) licensed method and found to be non-reactive for HIV-1, HIV-2, Hepatitis B surface antigen, and HCV. Because no test method can offer absolute assurance that these agents are absent, reagents should be handled at Biosafety Level 2 as recommended for any potentially infectious human blood product in the United States Center for Disease Control (USCDC) and National Institute of Health (NIH) manual Biosafety in Microbiological Laboratories, 1988. Standards and Controls are formulated with a buffer base and animal or human serum.

**Eye:** Contact with eyes may cause irritation.

**Skin:** Causes skin irritation. May cause allergic skin reaction.

**Inhalation:** May cause irritation of respiratory tract.

**Ingestion:** Harmful if swallowed.

**Aggravation of Pre-Existing Conditions:** Prolonged or repeated exposure may cause an allergic reaction in certain sensitive individuals.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures:

| Chemical Name        | CAS#       | Ingredient Percent | EC Num.   |
|----------------------|------------|--------------------|-----------|
| Amphotericin B       | 1397-89-3  | < 0.1 by weight    | 215-742-2 |
| Blood components     | No Data    | < 5 by weight      |           |
| Gentatmicin sulfate  | 1405-41-0  | < 0.1 by weight    | 215-778-9 |
| Maleic acid          | 110-16-7   | < 1 by weight      | 203-742-5 |
| ProClin 300          | No Data    | < 0.1 by weight    |           |
| Tetramethylbenzidine | 54827-17-7 | < 0.1 by weight    | 259-364-6 |

## SECTION 4 : FIRST AID MEASURES

### Description of necessary measures:

|                      |   |
|----------------------|---|
| <b>Eye Contact:</b>  | Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.  |
| <b>Skin Contact:</b> | Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.   |
| <b>Inhalation:</b>   | If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.   |
| <b>Ingestion:</b>    | If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. |

## SECTION 5 : FIRE FIGHTING MEASURES

### Suitable and unsuitable extinguishing media:

|  |  |
|--|--|
| <b>Suitable Extinguishing Media:</b>   | Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| <b>Unsuitable extinguishing media:</b> | Not determined.  |

### Specific hazards arising from the chemical:

|   |  |
|---|--|
| <b>Hazardous Combustion Byproducts:</b> | Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion. |
|---|--|

### Special protective equipment and precautions for fire-fighters:

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|------------------------------------|---|
| <b>Protective Equipment:</b>       | As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.   |
| <b>Fire Fighting Instructions:</b> | Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water. |

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures:

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|------------------------------|---|
| <b>Personal Precautions:</b> | Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8. |
|------------------------------|---|

### Environmental precautions:

|                                   |   |
|-----------------------------------|---|
| <b>Environmental Precautions:</b> | Avoid runoff into storm sewers, ditches, and waterways. |
|-----------------------------------|---|

### Methods and materials for containment and cleaning up:

|                                 |   |
|---------------------------------|---|
| <b>Methods for containment:</b> | Contain spills with an inert absorbent material such as soil, sand or oil dry.  |
| <b>Methods for cleanup:</b>     | Take care not to contaminate the body. Neutralize a Stop Solution spill with a dilute base, then clean the area with disposable towels. Soak a standard or control spill area with a 10% bleach solution, then clean the area with disposable towels. Dispose of all contaminated trash in accordance with local regulations. |

## SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

**Handling:** When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

**Hygiene Practices:** Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

Conditions for safe storage, including any incompatibilities:

**Storage:** Store kit reagents at 2-8°C in refrigerators designated and labeled to contain human blood products.

Specific end use(s):

**Work Practices:** Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Appropriate engineering controls:

**Engineering Controls:** General ventilation is sufficient if this product is being used in a controlled laboratory setting. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Individual protection measures:

**Eye/Face Protection:** Chemical splash goggles. Wear a face shield also when splash hazard exist.

**Skin Protection Description:** Protective laboratory coat, apron, or disposable garment recommended.

**Hand Protection Description:** Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

**Respiratory Protection:** No personal respiratory protective equipment is normally required. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/npptl/topics/respirators/>) for a list of respirator types and approved suppliers.

**Other Protective:** Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

**General Hygiene Considerations:** Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

**Physical State:** Liquid, except for lyophilized Standards and Controls, Levels 1 and 2.

**Color:** Blue for Conjugate Buffer and yellow for Standards.

**Odor:** Odorless.

**Odor Threshold:** Not determined.

**Boiling Point:** Not determined.

**Melting Point:** Not determined.

**Specific Gravity:** Not determined.

**Solubility:** 100% soluble.

**Vapor Density:** Not determined.

**Vapor Pressure:** Not determined.

**Percent Volatile:** Not determined.

**Evaporation Rate:** Not determined.

**pH:** 6.2 – 7.5 for all reagents, except TMB Substrate at > 3.5 and Stop Solution at < 2.

**Viscosity:** Not determined.

**Flash Point:** Not established.

**Flash Point Method:** Not established.

**Lower Flammable/Explosive Limit:** Not established.

**Upper Flammable/Explosive Limit:** Not established.

**Auto Ignition Temperature:** Not established.

**VOC Content:** Not determined.

## SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

**Chemical Stability:** Stable under normal temperatures and pressures.

**Possibility of hazardous reactions:**

**Hazardous Polymerization:** Not reported.

**Conditions To Avoid:**

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:**

**Incompatible Materials:** Strong oxidizing agents.

## SECTION 11 : TOXICOLOGICAL INFORMATION

### TOXICOLOGICAL INFORMATION:

#### **Amphotericin B :**

**Ingestion:** Oral - Rat LD50 - Lethal dose, 50 percent kill: >5 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

#### **Gentamicin sulfate :**

**Ingestion:** Oral - Rat LD50 - Lethal dose, 50 percent kill: >5 gm/kg [Behavioral - Somnolence (general depressed activity) Skin and Appendages - Hair] (RTECS)

#### **Maleic acid :**

**Eye:** Administration into the eye - Rabbit Standard Draize test: 1 %/2M [Severe] (RTECS)

## SECTION 12 : ECOLOGICAL INFORMATION

### Ecotoxicity:

**Ecotoxicity:** No ecotoxicity data was found for the product.

**Environmental Stability:** No environmental information found for this product.

## SECTION 13 : DISPOSAL CONSIDERATIONS

### Description of waste:

**Waste Disposal:** Dispose of in accordance with Local, State, Federal and Provincial regulations. Refer to Section 8 for information on personal protection equipment.

## SECTION 14 : TRANSPORT INFORMATION

**DOT Shipping Name:** Not Regulated.

**DOT UN Number:** Not Regulated.

## SECTION 15 : REGULATORY INFORMATION

### Safety, health and environmental regulations specific for the product:

#### **Amphotericin B :**

**EC Number:** 215-742-2

#### **Gentamicin sulfate :**

**EC Number:** 215-778-9

#### **Maleic acid :**

**TSCA Inventory Status:** Listed

**Canada DSL:** Listed

**EC Number:** 203-742-5

#### **Tetramethylbenzidine :**

**TSCA Inventory Status:** Listed

**Canada DSL:** Listed

**EC Number:** 259-364-6

## SECTION 16 : ADDITIONAL INFORMATION

### HMIS Ratings:

HMIS Health Hazard: 1  
HMIS Fire Hazard: 1  
HMIS Reactivity: 1  
HMIS Personal Protection: X

|                     |   |
|---------------------|---|
| Health Hazard       | 1 |
| Fire Hazard         | 1 |
| Reactivity          | 1 |
| Personal Protection | X |

SDS Creation Date: December 28, 2015

SDS Revision Date: December 28, 2015

**Disclaimer:** The information contained herein is believed to be correct as of the date of issue but is provided without warranty of any kind. The recipient is responsible for observing any applicable laws and guidelines. Use the product according to the package insert.

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