MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION
1.1. Identification of the product
Product Name: electra Anti-CCP
Chemiluminescence Assay for the quantitative measurement of Anti-Cyclic Citrullinated Peptides (CCP) present in human serum.
Product Classification: In-vitro diagnostics (IVD)

1.2. Manufacturer identification
Company Name: ZEPHYR BIOMEDICALS - A Division of Tulip Diagnostics (P) Ltd.
Tel.: +91 (0832) 6682000 / 6624502
Fax: +91 (0832) 6680156
E-mail: zephyr@tulipgroup.com

2. HAZARDS IDENTIFICATION
2.1. Potential biohazard:
The standards and Controls are formulated with a buffer base, animal serum, and human serum. The human serums are tested by a 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 the Bio-safety Level 2, as recommended for any potentially infectious human blood product.

2.2. Chemical hazard:
Chemiluminescent substrate A with enhanced Luminol solution:
Eye: Causes eye irritation.
Skin: Causes skin irritation.
Ingestion: May cause gastrointestinal irritation with nausea, vomiting and diarrhea.
Inhalation: Causes respiratory tract irritation.

Chemiluminescent substrate B with stabilized peroxide solution:
May cause fire or explosion, strong oxidizer
Causes severe skin burns and eye damage
Harmful if swallowed or if inhaled.

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3. COMPOSITION OF THE KIT COMPONENTS
   Coated Microwells: Microwells coated with Cyclical citrullinated peptides
   Anti-CCP Enzyme Conjugate
   Anti-CCP Sample Diluent
   Anti-CCP Negative Control
   Anti-CCP Positive Control
   Substrate A: Chemiluminescent substrate containing enhanced luminol solution.
   Substrate B: Chemiluminescent substrate containing stabilized peroxide solution.
   Anti-CCP Standard set of 5 standards labeled as A to F in liquid form
   Wash Buffer Concentrate (20X)

4. FIRST-AID MEASURES
   4.1. Skin contact: Remove contaminated clothing and wash the exposed skin area thoroughly with soap and water.
   4.2. Eye contact: Flush with copious amounts of water for at least 15 minutes. Seek medical attention.
   4.3. Inhalation: Remove to fresh air, give oxygen if breathing becomes difficult and seek medical attention.
   4.4. Ingestion: Flush mouth with copious amounts of water, provided that the person is conscious and seek medical attention.

5. FIRE-FIGHTING MEASURES
   5.1. Suitable extinguishing media: Chemical or water fire extinguisher.
   5.2. Extinguishing media not to be used: None known.
   5.3. Special fire-fighting procedures: None known.
   5.4. Unusual fire and explosion hazards: Not available
   5.5. NFPA rating: Health: 2, Flammability: 0, Reactivity: 1

6. ACCIDENTAL RELEASE MEASURES
   6.2. Environmental precautions: Contain the spill to the smallest area possible.
   6.3. Cleaning measures: Take care not to contaminate body. Absorb the material with disposable towels. Soak area with 2% Sodium Hypochlorite solution and wipe up with disposable towels. Dispose of all contaminated trash in accordance with local regulations.

7. HANDLING AND STORAGE
   7.1. Handling: Wear suitable personal protective equipment. Take care not to splash spill or splatter reagents. Do not eat, drink, smoke or apply cosmetics in laboratory areas. Do not pipette samples or reagents by mouth.
   7.2. Storage: Store the test kits in 2°C - 8°C refrigerators designated and labeled to contain human blood products.

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Zephyr Biomedicals
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION
8.2. Respiratory protection: In case of fire, wear self-contained breathing apparatus.
8.3. Hand protection: Wear non-permeable rubber, neoprene, latex or nitrile disposable gloves. Change gloves when they become contaminated.
8.4. Eye protection: Wear safety glasses or goggles when a splash hazard exists.

9. PHYSICAL AND CHEMICAL PROPERTIES
9.1. Physical state (at 20°C): Microwell plate is in solid form. All other reagents are in liquid form.
9.2. Odor: Odorless
9.3. pH value: All reagents 6.8 ~ 8.0
9.4. Melting point/freezing Point: Not determined
9.5. Boiling point: Not determined
9.6. Evaporation rate: Not determined
9.7. Flammability (solid, gas): Not flammable
9.8. Upper/lower flammability or explosive limits: Not applicable
9.9. Vapor pressure: Not determined
9.10. Vapor density: Not determined
9.11. Relative density: Not determined
9.13. Auto-ignition temperature: Not applicable
9.15. Viscosity: Not determined
9.16. Explosive properties: None
9.17. Oxidizing properties: Not determined

10. STABILITY AND REACTIVITY
10.1. Stability
   Stable under recommended storage conditions.
10.2. Reactivity
   No known reactivity hazards associated with product.
10.3. Possibility of hazardous reactions
   No hazardous polymerization
10.4. Conditions to avoid
   Excessive heat and light
10.5. Incompatible materials
   Acids
11. TOXICOLOGICAL INFORMATION
11.1. Acute toxicity: Not determined
11.2. Skin corrosion/irritation: In case of contact, flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical aid if irritation develops and persists. Wash clothing before reuse.
11.3. Serious eye damage/irritation: Not determined
11.4. Respiratory or skin sensitization: Not determined
11.5. Germ cell mutagenicity: Not determined
11.6. Carcinogenicity: None known
11.7. Reproductive toxicity: Not determined
11.8. STOT - single exposure: Not determined
11.9. STOT - repeated exposure: Not determined
11.10. Aspiration hazard: Not determined

12. ECOLOGICAL INFORMATION: None known.

13. DISPOSAL CONSIDERATIONS
13.1. Disposal of reagents: Dispose according to current regional and national regulations.
13.2. Contaminated containers: Dispose following current regional and national regulations.

14. TRANSPORT INFORMATION
14.1. UN number: Not available
14.2. UN proper shipping name: Not available
14.3. Transport hazard class(es): Not available
14.4. Packing group: Not available
14.5. Environmental hazards:
14.6. Overland transport (ADR/RID): None
Water transport (ADN/IMDG): None
Air transport (ICAO/IATA): None
14.7. Special precautions for user: None

15. REGULATORY INFORMATION
15.1. Classification: This preparation is classified and labeled in accordance with applicable national and international regulations.
15.2. Symbols of danger: N/A
15.3. "R" phrases indicating specific risks: Irritant R36/37/38, Irritating to the eyes, respiratory system and skin.
15.4. "S" phrases indicating caution: S26, In case of contact with any reagents rinse with copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention. S36, Wear suitable protective clothing.
16. OTHER INFORMATION

Recommended Use: For In Vitro Diagnostic Use only.
Not for use on or in human and animals. Information contained in this MSDS relies upon our best knowledge of the product upon issue of this document to describe the use, storage, transport and disposal under safe and secure measures. Such information is not a guarantee of the characteristics and specific quality of the product. This MSDS concerns the stated preparation and cannot apply to the product if used with other materials or in a process other than those specifically stated.