

**Works:**

Plot Nos. 88/89, Phase II C, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
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Date of issue: 5/12/23

Material Safety Data Sheet

SECTION 1: Information of the substance/mixture and of the company.

1.1 Product Name : electra 25-OH Vitamin D CLIA - Chemiluminensence Assay for Quantitative Determination of total 25-OH Vitamin D in Human Serum

1.2 Product Code : 410010096

1.3 Intended use : Electra 25-OH Vitamin D CLIA test is intended for the qualitative determination of total 25- hydroxy (25-OH) Vitamin D in human serum. The product is intended only for in-vitro diagnostic purpose.

1.4 Manufacturer : Qualpro Diagnostic-A division of Tulip Diagnostic (P) Ltd.
Plot No. 88/89, Phase IIC, verna Industrila Estate,
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SECTION 2: HAZARD IDENTIFICATION

The test kit should be handled only by qualified personnel duly trained in laboratory procedures. Specific precautions have been detailed in the product package insert but the absence of a specific warning should not be interpreted as an indication of safety. The following information is provided only for those hazardous product constituents that require regulatory control at the concentrations used in this product.

2.1 EMERGENCY OVERVIEW

Reagents: The kit reagents contain less than 1% and 0.1% hazardous and carcinogenic chemicals respectively and therefore are not considered to be hazardous.

Health Hazards: Possible skin/eye irritant can possibly cause mild skin and eye irritation

Flammability Hazards: Non-flammable solution.

Reactivity Hazards: None known.

Environmental Hazards: Not expected to have significant environmental effects

Emergency Considerations: Emergency responders must wear proper personal protective equipment. Appropriate fire-suppression equipment and response training suitable for the situation is recommended.



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Material Safety Data Sheet**SECTION 3: COMPOSITION INFORMATION OF INGREDIENTS:**

3.1 Electra 25-OH Vitamin D comprises of the below listed components and may be categorised as a mixture

3.2 MIXTURE

Component	Content
Coated microwells	Microwells are coated with monoclonal anti-25-OH Vitamin D antibody. Hazard classification: Not Classified; Hazard Phrases: None
Vitamin D Sample Diluent	Ready to use. Hazard classification: Not classified; Hazard Phrases: None
Vitamin D Enzyme Conjugate	Ready to use. Hazard classification: Not classified; Hazard Phrases: None
Chemi-HRP A	To be used in combination of Chemi-HRP B. Hazard classification: Not classified, Hazard Phrases: None
Chemi-HRP B	To be used in combination of Chemi HRP-A. Hazard classification: Not classified, Hazard Phrases: None
Two levels of controls	Control values are provided in the kit.
25-OH Vitamin D Calibrator set of 6 calibrators labeled A to F in liquid form.	For calibrator concentration refer vial label
Wash Buffer	Buffer containing surfactants (20x) Disodium Hydrogen phosphate (EC no.231-448-7), Potassium Dihydrogen phosphate (EC no.231-913-4), Sodium Chloride (EC no. 231-598-3), Potassium Chloride (EC no. 231-211-8), Proclin Kathon CG (EC no.247-500-7 & EC no. 220-239-6) Hazard classification: Irritant (Proclin), Hazard Phrases: H302,H314,H317,H332,H410 Precaution Phrases: P273,P2280,P305+P351+P338,P310, P501

3.3 RELATED PRODUCT INFORMATION:

Component contains silica quartz (CAS#14808-60-7 EC No. 238-87-4) which in dust form is classified as an ACGIH Class A2 (suspected human carcinogen) and 1ARC Group 1 (Carcinogenic to humans). To avoid the generation of dust the silica has been pelletized and sealed in a desiccant pouch and placed with the microwell pouch. As long as the pellets remain in a sealed dessiccant pouch they are unlikely to generate significant amount of dust and are therefore not typically considered a health hazard.

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Qualpro Diagnostics
A Division of Tulip Diagnostics (P) Ltd.

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Material Safety Data Sheet**3.4 EU LABELING AND CLASSIFICATION:****EU DANGEROUS PREPARATIONS DIRECTIVE (DPD) LABELING AND CLASSIFICATION:**

This product does not meet the definition of any hazard class as defined by the European Union Council Directives and subsequent Directives.

EU CLASSIFICATION:

Classification: [Xi] Irritant, [Xn] Harmful

Hazard Phrases:

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H332 Harmful if inhaled.
H410 Very toxic to aquatic life with long lasting effects.

Precaution Phrases:

P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and continue rinsing.
P310 Immediately call a doctor / Physician.
P501 Dispose of contents / container to an approved waste disposal plant
Hazard Symbol according to EC No. 1272/2008

**HEALTH HAZARDS OR RISKS FROM EXPOSURE:**

Acute: Prolonged contact with the liquid components may irritate the skin. Contact with eyes may cause irritation or redness. This product is to be used only in a laboratory environment. Individuals using this product should be wearing the proper personal protective equipment to prevent skin and eye contact.

Chronic: None known

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SECTION 4: FIRST AID MEASURES

First aid personnel should ensure self protection

4.1: DESCRIPTION OF FIRST- AID MEASURES

On acute exposure to hazardous chemicals, the individual must be provided medical attention if an adverse effect occurs.

Health effects: Symptoms of over exposure may include headache and dizziness.

Inhalation: Not a normal route of entry. However, if any chemical component is inhaled, remove the person from the area of exposure to fresh air. If breathing becomes laborious, use artificial respiration to support vital functions and seek immediately medical attention.

Skin Contact: Flush contact area in excess cold water and wash it with soap and water. Remove exposed/contaminated clothing, taking care not to contaminate eyes. Seek medical attention if irritation develops and persists.

Eye Contact: If a chemical component comes in contact with the eyes, flush the eyes with copious clean water for at least 15 minutes. Ensure adequate flushing by gently parting the eyelids. Remove contact lenses, if worn. Seek medical attention if irritation persists.

Ingestion: If component is swallowed, seek medical help. Do not induce vomiting. If the person is conscious rinse mouth thoroughly with water. Do not give water to someone who is unconscious or has convulsions. Victims of chemical exposure must be provided medical attention immediately.

4.2 RECOMMENDATIONS TO PHYSICIANS

Treat symptomatically and eliminate overexposure

SECTION 5 FIRE-FIGHTING MEASURES

5.1 FIRE EXTINGUISHING MEDIA: Use media appropriate for surrounding fire.

5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS

The product is a water-based mixture with no known fire or explosion hazards.

5.3 SPECIAL FIRE - FIGHTING PROCEDURES

Incipient fire responders should wear eye protection. Structural firefighters must use self-contained breathing apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if possible or cool with carefully applied water spray. Prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.



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5.4 ADDITIONAL INFORMATIONS

FLASH POINT: Non-flammable

AUTOIGNITION TEMPERATURE: Not applicable

FLAMMABLE LIMITS (in air by volume,%): Lower N/A Upper N/A

EXPLOSION SENSITIVITY TO MECHANICAL IMPACT : Not sensitive

EXPLOSION SENSITIVITY TO STATIC DISCHARGE: Not sensitive

SECTION 6: ACCIDENTAL RELEASE MEASURES

Spills: In the event of hazardous material spill, contain the spill. Safely remove contaminated clothing and flush exposure areas as necessary. Isolate the spill area and ventilate if appropriate.

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURE

SPILL AND LEAK RESPONSE: Avoid direct contact with skin, eyes and mucous membranes. Use appropriate laboratory clothing as recommended to avoid contact of chemical components with personal clothing. Personnel should be trained for spill response operations. Only trained personnel following planned procedures should handle non-incident releases.

6.2 ENVIRONMENTAL PRECAUTION

Avoid releasing the chemical components into the environment. Prevent possibly hazardous materials from entering sewage, storm drains, waterways, waterbodies or other environmentally sensitive areas. Ensure that undiluted hazardous products/chemicals do not percolate into the ground water.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Absorb spilled material using polypads or other suitable absorbent material. Place all spill residue in appropriate containers and seal. Decontaminate the area thoroughly. Do not mix with wastes from other materials. Dispose of in accordance with applicable Federal, state, and local procedures (see section 13, Disposal Considerations.)

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SECTION 7: HANDLING AND STORAGE

7.1 WORK PRACTICES AND HYGIENE PRACTICES: The test kit should be handled only by qualified personnel familiar with the potential hazards. Follow proper good laboratories practices and safety guidelines while handling hazardous material. Keep container tightly closed to avoid splashing, spills and generation of aerosols. Discard hazardous waste in appropriately marked containers. As with all chemicals, avoid direct contact with component chemicals. Wash thoroughly after handling this product. Do not eat, drink, smoke or apply cosmetics while handling this product. Use in a well-ventilated location. Remove contaminated clothing immediately.

7.2 STORAGE AND HANDLING PRACTICES: Store product in properly labeled, closed containers at temperatures between 2-8°C. Keep containers closed when not in use and protect from physical damage.

SECTION 8: EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure that exposure levels are maintained below the established limits.

RESPIRATORY PROTECTION: Do not breathe in mist, vapours or spray.

EYE PROTECTION: Use of splash goggles or safety glasses with side shields is recommended. Avoid using contact lenses when handling hazardous chemicals.

HAND PROTECTION: Compatible protective gloves recommended when handling kit reagents or patient samples. Single use/disposable gloves should be changed often and never be reused. Wash hands thoroughly after removing gloves.

BODY PROTECTION: Use body protection appropriate for task such as lab coat, apron, etc. Disposable clothing is recommended when handling hazardous materials.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Appearance: With the exception of the microtiter plate all others components are liquids. Some liquid components may be coloured.

Odour: Some of the reagents may have a mild pleasant odour on account of the constituent chemicals used.

pH: All the liquid components have pH between 5-9.

B. P., M.P., Flash point: Undetermined

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Evaporation, viscosity: Not established

Vapour pressure, vapour density, relative density: NA

Solubility: All liquid components are water soluble

Fire Hazard: The kit components being aqueous are not expected to be fire hazards. However, some of the packing materials may burn under fire condition

Autoignition: The components do not self-ignite

Danger of explosion: The product is not known to be an explosion hazard

9.3: OTHER INFORMATION: There is not other information established as to the identification or hazard posed by this product.

10 STABILITY AND CHEMICAL REACTIVITY

All components are stable and show no significant inherent reactivity under specified conditions of storage and usage.

10.1 CONDITIONS TO AVOID: Conditions such as temperature, pressure, light, etc. are not known to cause a dangerous reaction when the product is used and stored as intended.

10.2 MATERIALS TO AVOID The product is not known to cause a hazardous reaction in combination with other chemicals.

10.3 HAZARDOUS DECOMPOSITION PRODUCTS: When stored as labeled, no known hazardous decomposition products are formed during the shelf life of this product.

10.4 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: No information available

10.5 HAZARDOUS POLYMERIZATION: Will not occur

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SECTION 11: TOXICOLOGICAL INFORMATION

Acute Toxicity: There is no available information that the product may cause acute toxicity. However, mild irritation of skin and eyes may occur on contact.

Primary Irritancy: Irritation of the skin & eyes may occur with acute exposure over long periods. However, immediate rinsing of the contact area with copious cold clean water will help ameliorate the irritation.

Skin Corrosivity: Mild skin damage or burns may occur following acute exposure.

Eye Damage/Irritation: If in direct contact with the eyes some of the chemical components of the product may cause irritation, rash or temporary impairment of vision.

Aspiration Hazard: Chemical components of the product may cause irritation and corrosion of the buccal cavity or the mucous membranes if ingested or inhaled.

Respiratory or Skin sensitization: Contains Kathon CG and cinnamaldehyde, potentially skin-contact sensitizing preservatives in minimal quantities and very dilute formulations. Though the sensitization potential of these components is greatly reduced by dilution, the occurrence of an allergic reactions in some sensitive individuals cannot be completely ruled out as the sensitization threshold is unknown.

Carcinogenicity: Silica quartz (Cas# 14808-60-7, ACGIH class 2 and IARC Group 1 carcinogen) is known to be carcinogenic in dust form. To mitigate this effect silica has been pelletized and sealed in a dessicant pouch before use. The same poses no carcinogenicity threat as long as it is maintained sealed within the pouch.

Germ cell Mutagenicity: This product of components thereof are not reported to produce any embryotoxic, teratogenic or germ cell toxicity in humans.

SECTION 12 ECOLOGICAL INFORMATION

The product is not known to cause any known significant ecological damage on disposal.

Environmental Fate and Toxicity, Persistence and degradability, bioaccumulation potential, mobility in soil, PBT assessment and other adverse effects : No information found

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal of chemical, hazardous or laboratory wastes and packaging must be carried out in accordance with all applical local/regional official regulations. All material of human origin or other potentially infectious material must be decontaminated and disposed of as infectious material. Acidic wastes should be diluted and neutralized before safe sewer disposal. Undiluted material should not be allowed to reach ground waterways. Unclean packaging should be disposed in accordance with applical regulations.





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SECTION 14: TRANSPORTATION INFORMATION

14.1 UN number: N/A

14.2 Transport hazard class: Non-hazardous for transport. The product should be shipped in accordance with applicable regulations within product transport requirements as specified in the package.

DOT Classification Non-regulated material

DOT Labeling Requirements, IATA Labeling Requirements 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: NA

SECTION 16: OTHER INFORMATION

The information provided on this SDS is correct to the best of our knowledge and belief at the time of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and may not be considered as a warranty or quality specification.

Department issuing SDS: Quality Control

