

**Works:**

Plot Nos. 88/89, Phase II C, Verna Industrial Estate,  
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Tel.: (0832) 6624501-02, 6682000, Fax: (0832) 2783139.  
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Date of issue : 6/12/23

**Material Safety Data Sheet****SECTION 1: Information of the substance/mixture and of the company**

**1.1 Product Name:** Qualisa HBsAg ULTRA - Enzyme Linked Immunosorbent Assay (ELISA) for the detection of Hepatitis B surface antigen (HBsAg) in Human serum and plasma.

**1.2 Product Code:** 404130096  
404130192  
404130480

**1.3 Intended Use:** Qualisa HBsAg ULTRA is intended to be used for the detection of hepatitis B surface antigen (HBsAg) in human serum or plasma.

**1.4 Manufacturer/Supplier:**

Qualpro Diagnostics  
A Division of Tulip Diagnostics (P) Ltd.  
Plot No.88/89,Phase II C,  
Verna Industrial Estate,  
Verna, Goa 403 722  
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E-mail:qualpro@tulipgroup.com

**SECTION 2: HAZARD IDENTIFICATION**

The test kit should be handled only by qualified personnel duly trained in laboratory procedures. Specific harmings and detailed precautions are given in the pack insert. However, the absence of a specific precautions/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.



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**Material Safety Data Sheet****2.1 EMERGENCY OVERVIEW**

**Reagents:** The kit reagents are not considered to be hazardous as they contains less than 1% hazardous chemicals and less than 0.1% carcinogenic chemicals

**Health Hazards:** Possible skin and eye irritant can possibly cause mid 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 the proper personal protective equipment. Appropriate fire-suppression equipment and response training suitable for the situation is also recommended.

**SECTION 3: COMPOSITION CONCENTRATION INFORMATION ON INGREDIENTS****3.1 SUBSTANCE Qualisa HBsAg ULTRA comprises of the following components**

**This substance is a mixture**

**3.2 MIXTURE**

Component	Content
<b>Coated microwells</b>	Microwells are coated with Agglutinating sera for HBsAg EC: Not listed, *Kathon CG - Potential residue of Kathon CG used as production preservative minimized by aspiration prior to drying of strips. Hazard classification: Not Classified, Hazard Phrases: None
<b>Positive Control</b>	HBsAg positive and HIV/HCV non-reactive serum diluted in stabilizer solution with preservatives. Na Chloride EC No.: 231-598-3, BSA EC No.: 232-936-2 *Kathon CG Hazard classification: Not classified, Hazard Phrases: None
<b>Negative Control</b>	Inactivated and stabilized human serum non reactive for HIV- 1 and HIV-2, HBsAg and HCV. Casein (EC No.: 232-555-1), BSA (EC No.: 232-936-2)*Kathon CG Hazard classification: Not classified, Hazard Phrases: None



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Component	Content
<b>Conjugate</b>	Agglutinating sera for HBsAg-HRPO conjugate & preservatives. EC: Not listed, Hazard classification: Not Classified, Hazard Phrases: None
<b>Substrate</b>	Solution containing Tetramethyl benzidine (TMB) and hydrogen peroxide TMB (EC no.:259-364-6) Mixture containing components at a non hazardous concentration. Hazard Phrases:None
<b>Wash buffer</b>	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
<b>Stop Solution</b>	Diluted Sulphuric acid Sulphuric Acid (EC No.:Not listed) Hazard Classification: Highly corrosive, Hazard Phrases:H314 Precaution Phrases:P280-P305,P351,P338

**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. Hence, as long as the pellets remain in a sealed dessiccant pouch in a normal condition it is unlikely to generate significant amount of dust and is therefore not typically considered a health hazard.

**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.

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**Material Safety Data Sheet****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 easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or 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 components in this kit may irritate the skin.

Contact with eyes may cause irritation or redness. This product is to be used 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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## Material Safety Data Sheet

### SECTION 4: FIRST AID MEASURES

First aid personnel should ensure self protection

#### 4.1: DISCRIPTION OF FIRST - AID MEASURES

Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescues should be taken for medical attention, if necessary.

**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 exposure area to fresh air. If breathing becomes laborious, use artificial respiration to support vital functions & seek immediately medical attention.

**Skin Contact:** Flush contact area in excess cold water and wash contacted area with soap and water. Remove exposed or 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 amount of clean water for minimum 15 minutes. Ensure adequate flushing by gently parting the eyelids immediately. Remove contact lenses, if worn. Seek medical attention if irritation persists.

**Ingestion:** If chemical is swallowed, call physician or poison control center for intervention. 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 supporting to eliminate overexposure

### SECTION 5 FIRE-FIGHTING MEASURES

#### 5.1 FIRE EXTINGUISHING MEDIA

Use extinguishing 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 wear 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 this can be done without risk; otherwise, cool with carefully applied water spray. If possible, 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, mucous membranes. Use appropriate laboratory 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-incidental releases.

#### 6.2 ENVIRONMENTAL PRECAUTION

Avoid release to the environment. Prevent possibly hazardous materials from entering sewage, storm drains, waterways, waterbodies or other environmentally sensitive areas.

Ensure that undiluted hazardous products or 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 an appropriate container 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 generations of aerosols. Discard hazardous waste in adequately 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. Protect from physical damage. Keep containers closed when not in use.

### SECTION 8: EXPOSURE CONTROLS - PERSONAL PROTECTION

**VENTILATION AND ENGINEERING CONTROLS:** Use with adequate ventilation to ensure 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 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 solid microtiter plate all others are aqueous liquids some of which may be coloured.

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

**pH:** Most of the liquid components have pH between 5-9. The only exceptions include stop solution.

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

**Evaporation, viscosity:** Not established

**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

**Vapour pressure:** NA

**Vapour density:** NA

**Relative density:** NA

**Solubility:** All liquid components are water soluble

**Autoigniting:** The components do not self - ignite

**Viscosity:** Not Determined

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

**9.2:** 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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**Material Safety Data Sheet****SECTION 11: TOXICOLOGICAL INFORMATION**

**Acute Toxicity:** There is no available information that the product may cause acute toxicity. However, mild irritation of skin & eyes on contact may occur, in case of which immediate rinsing with excess cold clean water.

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

**Skin Corrosivity:** Mild skin damage or burns may occur following direct contact with stop solution or TMB.

**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 very small 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, tetraogenic or germ cell toxicity in humans.

**SECTION 12 ECOLOGICAL INFORMATION**

The product is not known to cause any known significant ecological damage on disposal. A component of the product concentrated sulfuric acid CAS# 7664-93-9 has Fish LC50 - 42 mg/l-96 h

Environmental Fate: No data available

Environmental Toxicity: No data available

Persistence and degradability: No information found

Bioaccumulation potential: No information found

Mobility in soil: No information found

PBT assessment: No information found

Other Adverse Effects: The acidic component stop solution can be hazardous to potable water and aquatic organisms if disposed undiluted or without neutralization of pH. Therefore, an environmental hazard can occur only in the case of unprofessional disposal.

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**Material Safety Data Sheet****SECTION 13: DISPOSAL CONSIDERATIONS**

Disposal of chemical, hazardous or laboratory wastes / waste product and / or 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

All Acidic wastes should be diluted & neutralized before safe sewer disposal. Undiluted material should not be allowed to reach ground waterways.

Uncleaned packaging should be disposed in accordance with applical regulations. Water if necessary together with appropriate cleansing agents may be used for decontamination before disposal.

**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 local/ regional/ national regulations within product transport requirements as specified in the package.

**DOT Classification** Non-regulated material

**DOT Labeling Requirements** None

**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, Information and belief at the date of its publication. The information given is Designed only as guidance for safe handling, use, processing, storage, Transportation, disposal and release and is not be considered as a warranty or Quality specification.

**Department issuing SDS:** Quality Control



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**Qualpro Diagnostics**  
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