



**Works:**

Plot Nos. 88/89, Phase II C, Verna Industrial Estate,  
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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 HCV - Enzyme Linked Immunosorbent Assay (ELISA)  
for detection of antibodies to HCV in human serum or plasma

**1.2 Product Code:** 404040096  
404040192  
404040480

**1.3 Intended Use:** Qualisa HCV is a 3<sup>rd</sup> Generation EIA & is intended to be used for  
the detection of antibodies to Hepatitis C Virus 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  
INDIA

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### 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 products.



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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 HCV comprises of the following components**

This substance is a mixture

**3.2 MIXTURE**

<b>Component</b>	<b>Content</b>
<b>Coated microwells</b>	are coated with recombinant antigens representing HCV derived from multiple genotypes of HCV. 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>	Inactivated and stabilized human serum reactive for HCV and non-reactive for HIV & HBsAg 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 & 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>	Goat anti-human IgG - HRPO conjugate EC: Not listed, Hazard classification: Not Classified, Hazard Phrases: None
<b>Conjugate diluent</b>	Buffered solution containing stabilizing proteins and preservatives Tris, Triton X100, Tween 20: EC not listed, Tartrazine (EC: 27-699-5), Cinnamaldehyde (EC: 203-213-9), Glycerol (EC: 200-289-5) Hazard classification: Irritant, Harmful Hazard Phrases: H318, H302
<b>Sample diluent</b>	Buffered solution containing stabilizing proteins and preservatives.
<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: Buffer contains surfactants (20X)</b>	Buffer contains 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



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### 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 desiccant 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.

### 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



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### 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

### SECTION 4: FIRST AID MEASURES

First aid personnel should ensure self protection

#### 4.1: DESCRIPTION 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 person from exposure area to fresh air. If breathing becomes labored 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. If the person is conscious, do not induce vomiting. Rinse mouth thoroughly with water or give diluents (milk or water) to someone who is unconscious, have convulsions, or who cannot swallow. Victims of chemical exposure must be taken for medical attention.

#### 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.



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### 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.

### 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 if it is safe to do so, and immediately move to a safe area, free from contaminants. 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. Avoid contact of the chemical components with clothing by using appropriate laboratory clothing such as labcoat, gloves, face mask and eye protection. Personnel should be trained for spill response operations.

Trained personnel following pre-planned procedures should handle non-incident 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 ground water or ground water course.

### 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 misty, vapours or spray.

**EYE PROTECTION:** 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.

**B. P. & M.P.:** Undetermined

**Flash point:** NA

**Evaporation:** Not established





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**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:** Not established

**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 no 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 & 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. Through 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, tetragenetic 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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### 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. 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 inthe 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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