

**Works:**

Plot Nos. 88/89, Phase II C, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
Tel.: (0832) 6624501-02, 6682000, Fax: (0832) 2783139.
E-mail: qualpro@tulipgroup.com

Date of issue: 11/01/23

SAFETY DATA SHEET**1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**

1.1 Product name: **Combiqic HIV & HCV Device** - Rapid immunoconcentration assay for Detection of Antibodies to HIV-1&2 and HCV in human serum/Plasma

1.2 Product Code: 402080010
402080050

1.3 Intended use: **Combiqic HIV & HCV** is rapid, qualitative, immunoconcentration (flow through) assay for the simultaneous and differential detection of antibodies to HIV1&2 and HCV in human serum/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
Telephone : +91-(0832) 6682000,6624501-02
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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.

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.



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SAFETY DATA SHEET**3 COMPONENTS AND HAZARDOUS INGREDIENTS**

Kit Component	HAZARDOUS INGREDIENT	CLASSIFICATION SUBSTANCE	EINECS NR.
Wash buffer	0.1% Sodium azide (NaN ₃)	T+;R28-32 N;R50-53	247-852-1
Test device	material from animal origin		

3.1 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 IARC 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.

3.2 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



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SAFETY DATA SHEET

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

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 person from exposure area to fresh air. If breathing becomes laboreaes 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 minimu 15 mins. 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 concious, do not induce vomiting. Rinse mouth thoroughly with water or give diluents (milk or water) to someone who is unconsconscious, 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



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SAFETY DATA SHEET**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.

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**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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SAFETY DATA SHEET**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 at temperature between 2-8° C. Protect from physical damage.

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.

9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid

Odour: Odourless

pH : Between 7-9

B. P. & M.P.: Undetermined

Flash point: NA

Evaporation: 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: Not established

Solubility: liquid component is 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

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



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SAFETY DATA SHEET**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

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

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 potentially skin-contact sensitizing preservatives in very small quantities and very dilute formulations.

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 desiccant 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, tetragenic or germ cell toxicity in humans.



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SAFETY DATA SHEET**12 ECOLOGICAL INFORMATION**

The product is not known to cause any known significant ecological damage on disposal. A component of the product Sodium azide:

LC50 (96 h): 0.8 mg/l (SALMO GAIARDNERI/ONCORHYNCHUS MYKISS)

LC50 (96 h): 0.7 mg/l (LEPOMIS MACROCHIRUS)

LC50 (48 h): 9 mg/l (GAMMARUS SP)

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.

13 DISPOSAL CONSIDERATIONS

Disposal of chemical, hazardous or laboratory wastes / waste product and / or packaging must be carried out in accordance with all applicable 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.

14 TRANSPORT 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





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15 REGULATORY INFORMATION

15.1 Classification: according to directives 67/548/EEC, 1995/45/EC.

Contains sodium azide

Xn



Harmful

R22: Harmful if swallowed

S23: Do not breathe vapour

S46: If swallowed, seek medical advice immediately and show this container or label

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

R&R

