OraSure Technologies, Inc.

Effective Date: 03/11/11
Expiration Date: 2 years from Effective Date

SAFETY DATA SHEET

OraQuick® HCV Kit Controls

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: OraQuick® HCV Kit Controls

GENERAL USE: OraQuick® HCV Kit Controls are quality control reagents for use only with the OraQuick® HCV Rapid Antibody Test. The kit control components are human plasma-based reagents. The kit controls are specifically formulated and manufactured to ensure proper performance of the test. The HCV Positive Control will produce a reactive reddish-purple line at the Test (T) Zone. The HCV Negative Control will generate a non-reactive test result (no reddish-purple line at the Test (T) Zone).

GENERIC NAME: OraQuick® HCV Kit Controls

MANUFACTURER
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015
Phone: 800-869-3538
www.orasure.com

EMERGENCY CONTACT INFORMATION
INFOTRAC US: 1-800-535-5053
INFOTRAC INTERNATIONAL: +1-352-323-3500
CANUTEC: 613-996-6666

COMMENTS: To the best of our knowledge, this Safety Data Sheet conforms to the requirements of the US OSHA 29 CFR 1910.1200, Regulation EC 1907/ 2006 and Canadian Hazardous Products Act.

2. HAZARD IDENTIFICATION

The OraQuick® HCV Kit Controls individual components should be used only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

NOTE: Handling, storing or shipping of the complete packaged kit should pose no threat to the individual. If no leak or excessive damage is noted there is no recommended Personal Protective Equipment (PPE) required. If the products' integrity is in question due to excessive damage or unforeseen circumstances, utilize proper safety procedures and handle using universal precautions including PPE (safety glasses/face protection and gloves) as per 29 CFR 1910.1030.

Components	Contents
1 vial of 0.75ml HCV Positive Control (Purple Cap)	0.2ml of photochemcially inactivated human plasma positive for antibodies to HCV, diluted in a defibrinated pool of normal human plasma. Preservative: 2-methyl-4-isothiazolin-3-one.
1 vial of 0.75ml HCIV Negative Control (White Cap)	0.2ml of defibrinated pool of normal human plasma negative for antibodies to HCV. Preservative: 2-methyl-4-isothiazolin-3-one.

COMMENTS: The Positive Control (purple capped vial) contains 0.2ml of photochemically inactivated human plasma positive for antibodies to HCV, diluted in a defibrinated pool of normal human plasma. The Negative Control (white capped vial) contains 0.2ml of defibrinated pool of normal human plasma. All control vials contain the chemical 2-methyl-4-isothiazolin-3-one as a preservative. All control vials are negative for Hepatitis B surface antigen and HIV-1/2 antibody. The vials contain no known active viruses; the test indication is based on the response to the antibody only.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Contents
Plasma, HCV Positive Photochemically Treated [1 vial (0.75ml) containing 0.2ml of plasma & 2-methyl-4-isothiazolin-3-one]	Although the plasma contained in the kit is in De minimis amounts and is photochemically treated to render non-infectious, while in direct contact with interior components, universal precautions should be followed as per 29 CFR 1910.1030. HCV antibodies are added to the treated plasma to ensure the proper response. The vial contains HCV antibodies only and is not known to carry any active infectious diseases. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ proper decontamination procedures with an appropriate disinfectant (1:10 dilution of household bleach and water, or equivalent). Dispose of this material in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this kit. Utilize Good Laboratory Practices.

Plasma, HCV Negative [1 vial (0.75ml) containing 0.2ml of plasma &2-methyl-4-isothiazolin-3-one]	Although the plasma contained in the kit is in De minimis amounts, while in direct contact with interior components, universal precautions should be followed as per 29 CFR 1910.1030. The vial is not known to carry any active infectious diseases. Do not inhale mists or aerosols; avoid contact with skin, eyes, mucous membranes and clothing. In case of contact with eyes, immediately rinse with copious water and seek medical attention. Employ proper decontamination procedures with an appropriate disinfectant (1:10 dilution of household bleach and water, or equivalent). Dispose of this material in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this kit. Utilize Good Laboratory Practices.
2-methyl-4-isothiazolin-3-one	CAS#: 2682-20-4 Flash Point: 214°F Specific Gravity: 1.16 Do not store above: 120°F (60°C) LD50 (oral-rat): 148 mg/kg (100%) Boiling Point: 188°C Vapor Density (Air=1): 2.62 RCRA Code: P105 (undiluted, 100%) Hazard Classification: At 100%, corrosive, skin sensitizer, toxic by inhalation. H302, 314,317,331,335 & 400; P261, 273, 280, 305, 351 & 338. 2-methyl-4-isothiazolin-3-one is harmful if ingested; it has been evident to burn skin and damage eyes upon contact. Toxic if inhaled (more than contained in kit). May cause eye, skin or respiratory tract irritation. Avoid contact. If swallowed, seek medical advice immediately. Keep away from strong oxidizing agents. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this kit. Utilize Good Laboratory Practices.

COMMENTS: The following information is furnished for those hazardous constituents that require regulatory control or disclosure at the concentration found in the kit. Note that the information here is often based on data for the chemical raw material (LD50, exposure limits, etc.). The kit contains a significantly diluted concentration in an aqueous solution; thus, the assessment below has taken hazard reduction processing into consideration when possible.

4. FIRST AID MEASURES

EYES: Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.

SKIN: Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs, or if more severe symptoms develop, consult a physician.

INGESTION: If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

INHALATION: Remove person from exposure area to fresh air. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations. Treat symptomatically and supportively.

HEALTH EFFECTS: Symptoms of overexposure may include headache, dizziness, congestion and breathing difficulty. Skin contact may result in dermatitis and may cause allergic skin reaction upon repeated exposure.

NOTES TO PHYSICIAN: According to the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030), universal precautions apply.

5. FIRE FIGHTING MEASURE

EXTINGUISHING AGENT: Use extinguishing media appropriate for the surrounding fire.

FIRE FIGHTING PROCEDURES: Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

6. ACCIDENTAL RELEASE MEASURES

SMALL SPILL/ LEAK: Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, acid absorbent pads, etc.) which is secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal. Infectious, chemical and laboratory wastes must be handled and discarded in accordance with all Local, State and Federal regulations. Utilize appropriate Personal Protective Equipment (PPE), including gloves, lab coat or apron and eye/face protection.

GENERAL PROCEDURES: Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab Personal Protective Equipment (PPE) including gloves, lab coat and eye/face protection. In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area, free from potential aerosols, to decontaminate and/or safely remove any contaminated clothing, as necessary. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.

7. HANDLING AND STORAGE

HANDLING: The individual components within the test kit should be handled only by qualified personnel. Utilize Good Laboratory Practices and safety guidelines for handling chemicals and other hazards. Wear appropriate Personal Protective Equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols. Handle all specimens, materials and equipment used to perform the operations as though they were capable of transmitting infectious disease, as per universal precautions.

STORAGE: Store according to product and label instructions, 2-8°C (35-46°F). Open kit vials can be recapped and stored in their original containers at 2-8°C (35-46°F).

NOTE: Handling, storing or shipping of the complete packaged kit should pose no threat to the individual. If no leak or excessive damage is noted there is no recommended Personal Protective Equipment (PPE) required. If the products' integrity is in question due to excessive damage or unforeseen circumstances, utilize proper safety procedures and handle using universal precautions including PPE (safety glasses/face protection and gloves) as per 29 CFR 1910.1030.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

NOTE: The following personal protective equipment (PPE) is recommended to prevent blood or other potentially infectious or hazardous materials from reaching the user's work or street clothes, skin, mouth, mucous membranes and eyes under normal conditions of use and for the time during which the protective equipment is utilized:

VENTILATION: Adequate ventilation is required. It is recommended that users handle potentially infectious human source material/patient samples in a biological safety cabinet (BSC), expressly if aerosols might be generated.

EYE PROTECTION: Wear ANSI approved safety glasses, goggles or face shield with safety glasses or goggles. Contact lenses should not be worn when handling lab hazards.

PROTECTIVE GLOVES: Suitable gloves must be worn at all times when handling kit reagents or patient samples to provide skin protection from splash and intermittent contact. Synthetic gloves, such as nitrile, neoprene and vinyl, are recommended because they are sturdy, effective and contain no natural latex ingredients associated with latex glove allergic reactions. Disposable (single use) gloves should be changed often and never reused. Wash hands thoroughly after removing gloves.

PROTECTIVE CLOTHING: Wear a lab coat, clinic jacket, gown, apron and/or smock. Disposable clothing is strongly recommended when handling biohazardous material. If reusable clothing is used, procedures for handling potentially infectious laundry under the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) are required.

OTHER: All personal protective equipment should be removed before leaving the work area and placed in an appropriately designated area or container for storage, processing, decontamination or disposal. Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent pads used to cover equipment and/or surfaces must be removed and replaced if they become overtly contaminated.

COMMENTS: Exposure limit values and health hazard data were given in Section 3. Environmental controls are included in following sections. The above listed PPE is required during the utilizing of the kit during testing procedures. Handling of the packaged kit should not pose any threat to the shipper. If the product integrity is in question, due to excessive damage utilize proper safety procedures and handle using universal precautions including PPE (safety glasses/face protection and gloves) as per 29 CFR 1910.1030.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: Various
ODOR: Various
COLOR: Mixed
pH: The liquid chemical components are between pH 5 and 9
BOILING POINT: Not estimated
MELTING POINT: Not estimated
SOLUBILITY IN WATER: Liquid chemical components are 100% soluble in water.
COMMENT:

FIRE HAZARD: Components have not been tested for fire and explosion data; being water-based, they are not expected to be fire hazards. Some of the kit packaging materials may burn under normal fire conditions.

10. STABILITY AND REACTIVITY

STABLE: Stable under normal use and storage conditions.
CONDITIONS TO AVOID: None known.
HAZARDOUS DECOMPOSITION PRODUCTS: None known.
INCOMPATIBLE MATERIALS: May react when in contact with strong oxidizers or oxidizing agents.

11. TOXICOLOGICAL INFORMATION

ACUTE:

TOXICITY: Harmful if swallowed.
PRIMARY IRRITANT EFFECT: May irritate eyes or skin, based on amount and contact time.
OTHER ACUTE HEALTH AFFECTS: No other significant health effects known.

BIOHAZARD POTENTIAL: Human blood or serum, though verified to be non-infectious, should be handled with universal precautions, as if capable of transmitting infectious disease. The human serum in the components was tested and found non-reactive for Hepatitis B surface antigen and Hepatitis C antibodies. No known test method can offer complete assurance that HIV, Hepatitis B or C virus or other infectious agents are absent. Moreover, patient blood samples tested with this kit represent an unknown, heightened hazard. Utilize universal precautions; handle these reagents, all human blood and specimens as if capable of transmitting infectious disease as per 29 CFR 1910.1030. Handling, storing or shipping of the complete packaged kit should not pose any threat to the shipper. If the product integrity is in question due to excessive damage, utilize proper safety procedures and handle using universal precautions including PPE (safety glasses/face protection and gloves) as per 29 CFR 1910.1030.

COMMENTS: To the best of our knowledge, the chemical, physical and toxicological properties have NOT been thoroughly investigated for some of the component chemicals and/or mixtures.

12. ECOLOGICAL INFORMATION

NO DATA FOUND

13. DISPOSAL CONSIDERATION

DISPOSAL METHOD: Disposal of hazardous wastes, product or packaging must be conducted in accordance with all applicable Local, State and Federal Regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the kit components may change waste management requirements and options. Contact the authority having jurisdiction for your area for specific disposal requirements. Recommended Product Disposal:

All **human source and other potentially infectious material** must be appropriately decontaminated or disposed of as infectious material; check your Local, State and Federal Regulations accordingly.

14. TRANSPORTATION INFORMATION

Must be shipped in accordance with all applicable Local, State and Federal Regulations. Processing, use or contamination of this kit or its components may change shipping requirements and options.

15. REGULATORY INFORMATION

UNITED STATES:

2-methyl-4-isothiazolin-3-one (100%)



Acute Toxicity: Oral; Cat. 4
Inhalation; Cat. 3
Skin corrosion/sensitization: Cat. 1A/cat 1
Serous eye damage: Cat. 1
Specific target organ toxicity-single: Cat. 3
Acute aquatic toxicity: Cat. 1

CANADA: This MSDS contains the required information in accordance with the WHMIS hazard classification criteria for this product.

EUROPEAN COMMUNITY: This MSDS contains the required information in accordance with the REACH hazard classification criteria for this product.

16. OTHER INFORMATION

SUMMARY OF CHANGES: 3/1/2011; Information update and reformatted to comply with The Globally Harmonized System.