



SAFETY DATA SHEET

OraQuick® HCV Rapid Antibody Test

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: OraQuick® HCV Rapid Antibody Test

GENERAL USE: The OraQuick® HCV Rapid Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Hepatitis C Virus (anti-HCV) in fingerstick, whole blood, venipuncture whole blood and plasma specimens. The OraQuick® HCV Rapid Antibody Test results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HCV (state of infection or associated disease not determined) in persons with signs or symptoms of Hepatitis and in persons at risk for Hepatitis C infection.

ORASURE PRODUCT NUMBERS: 1001-0180, 1001-0181, 1001-0270, 1001-0274, 1001-0350, 1001-0337, 1001-0338, 1001-0370, 1001-0371, 1001-0403.

MANUFACTURER

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EMERGENCY CONTACT INFORMATION

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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

This test kit 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.

GHS LABEL:

Hazard Statements:	Precautionary Statements:
H303 May be harmful if swallowed H315 May cause skin irritation H333 May be harmful if inhaled	P626 Do not get in eyes, on skin, or on clothing. P332 + P313 If skin irritation occurs: Get medical advice/attention P273 Avoid release to the environment

ROUTES OF ENTRY: Absorption and ingestion.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Contents
Test Device	Plastic housing containing several layers of chemically treated assay strips reactive to HCV antibodies. The test device consists of a multi-layered chemically treated pad that, when combined and applied to a sample, renders an appropriate response.
Developer Solution	1 ml of a buffered solution containing polymers and antimicrobial agent. The solution contains the following chemicals: Tris Spectrum, Sodium Chloride, Hydrochloric Acid, ProClin 950 & Triton X-100.

COMMENTS: The following information is furnished for those hazardous constituents that may 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 device contains a significantly diluted dried concentration of an aqueous solution that has been applied to an assay strip; thus, unless otherwise noted the assessment below has NOT taken hazard reduction processing into consideration. This kit **DOES NOT** contain any live or active levels of the Hepatitis C Virus.

Chemical Ingredient	Chemical Information
Blocker Pad	Contains: Water/Tris Spectrum (77-86-1)/ EDTA (6381-92-6)/ Hydrochloride Acid (7647-01-0) Solution, Tween 20 (9005-64-5), ProClin (2682-20-4) and various buffer solutions. Blocker Pad Concentration: Contains 0.01-0.1% concentration or less of the chemicals listed above. The mixture (in the concentration provided) is not known to be an OSHA hazardous chemical or other regulatory listed material. The mixture may cause skin and eye irritation upon contact in highly sensitive individuals.
Conjugate Pad	Contains: ProClin (2682-20-4), Bovine Serum Albumin (9048-46-8), Polyethylene Glycol (25322-68-3), Dextran (9004-54-0), Sodium Tetraborate (1303-96-4), Tween 20 (9005-64-5), Sucrose (57-50-1), Protein A Gold Concentration, Sodium Hydroxide Solution and a phosphate buffer solution. Conjugate Pad Concentration: Contains 0.01-0.1% concentration or less of the chemicals listed above. The mixture (in the concentration provided) is not known to be an OSHA hazardous chemical or other regulatory listed material. The mixture may cause skin and eye irritation upon contact in highly sensitive individuals

Nitrocellulose Pad	<p>Contains: Multiple HCV antigens (N/A), EDTA Solution (6381-92-6), Sodium Dodecylbenzenesulfonate (25155-30-0), Potassium Chloride (7447-40-7), Potassium Phosphate Monobasic (7778-77-0), Sodium Chloride (7647-14-5), Sodium Phosphate Dibasic Solution (7558-79-4) and F(Ab)₂ Goat Anti-Human IgG (H+L) (N/A) and the addition of a premade HCV Combi Conjugate Solution.</p> <p>Nitrocellulose Pad Concentration: Contains 0.01-0.1% concentration or less of the chemicals listed above. The mixture (in the concentration provided) is not known to be an OSHA hazardous chemical or other regulatory listed material. The mixture may cause skin and eye irritation upon contact in highly sensitive individuals.</p>		
Hydrochloric Acid	<p>CAS# 7647-01-0 Melting/Freezing Point: -74°C (-101°F) Vapor Density: >1 (Air = 1)</p> <p>Molecular Weight: 36.46 g/mol Specific Gravity: 1.2 (Water = 1)</p> <p>LD50 (Oral): 900 mg/kg (rabbit) LD50 (Inhalation): 1108 ppm (mouse) 1h</p> <p>Boiling Point: 110°C (230°F) Odor: Pungent</p> <p>Vapor Pressure: 21.3 kPa (160 mmHg)(@20°C)</p> <p>Synonyms: Muriatic acid RTECS Number: MW4025000</p> <p>GHS Signal Word: DANGER/POISON/CORROSIVE</p> <p>OSHA Hazards: Harmful if ingested; Corrosive.</p> <p>Hazard Statements: H303 May be harmful if swallowed; H314 Causes severe skin burns and eye damage; H331 Toxic if inhaled; H335 May cause respiratory irritation.</p> <p>Precautionary Statements: P261 Avoid breathing dust/fumes/gas/mist/vapors/spray; 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 so. Continue rinsing; P310 Immediately call a POISON CENTER or doctor/ physician.</p> <p>Hydrochloric Acid may be fatal if inhaled or swallowed; causes severe eye and skin burns. Causes severe respiratory tract irritation. Causes damage to the following organs: lungs, respiratory tract, skin, eye (lens or cornea).</p>		
ProClin 950	<p>CAS#: 2682-20-4 LD50 (Oral-rat): 2834 mg/kg Melt/Freeze Point: -20 - 15°C (-4 - 59°F)</p> <p>Boiling Point: 100°C (212°F) LD50 (Dermal-rat): >5000 mg/kg Vapor Pressure: 22.66</p> <p>Density: 1.02 g/cm³ pH: 5 - 8</p> <p>OSHA Hazard: Corrosive, Skin Sensitizer, Toxic by Inhalation.</p> <p>GHS Signal Word: Danger</p> <p>Hazard Statements: H302 Harmful if swallowed; H314 Causes severe skin burns and eye damage; H317 May cause an allergic skin reaction; H331 Toxic if inhaled; H335 May cause respiratory irritation & H400 Very toxic to aquatic life.</p> <p>Precautionary Statement: P261 Avoid breathing dust/fumes/gas/mist/vapors/spray; 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 so. Continue rinsing; P310 Immediately call a POISON CENTER or doctor/ physician.</p> <p>May be harmful if ingested; it has been evident to burn skin and damage eyes upon contact. Toxic if inhaled (more than contained in product). May cause eye, skin or respiratory tract irritation. Avoid contact. If swallowed, seek medical advice immediately. Keep away from strong oxidizing agents</p>		
Sodium Chloride	<p>CAS# 7647-14-5 Specific Gravity: 2.165 LD50 (Oral): 3 mg/kg (rat)</p> <p>LD50 (Inhalation): >42 mg/m³ - 1h LD50 (Skin): >10 mg/kg (rabbit) Melting Point: 801°C (1474°F)</p> <p>RTECS Number: VZ4725000</p> <p>Synonyms: Salt, saline.</p> <p>Sodium Chloride may cause skin, eye and respiratory irritation. In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention.</p>		
Tris Spectrum	<p>CAS# 77-88-1 Chemical Formula: C₄H₁₁NO₃ LD50 (Oral): 5900 mg/kg (rat)</p> <p>Boiling Point: 219.5°C (427.1°F) Melting Point: 171°C (339.8°F) RTECS Number: TY2900000</p> <p>Molecular Weight: 121.14 g/mol</p> <p>Synonyms: Spectris, Tris buffer, Tris (hydroxymethyl) aminomethane sodium.</p> <p>May be slightly hazardous in cases of contact with the skin or eyes. May cause irritation to the respiratory tract. May also cause irritation if ingested.</p>		
Triton X-100	<p>CAS# 9002-93-1 D50 (Oral): 500 mg/kg (rat/male) LC50 (Dermal): 8000 mg/kg (rabbit)</p> <p>ATA/DOT/MDG ID: UN3082 HMIS codes: H=2, F=1, R=0</p> <p>OSHA Hazards: Harmful by ingestion; irritant.</p> <p>GHS Signal Word: DANGER</p> <p>Hazard Statements: H302 Harmful if swallowed; H316 Causes mild skin irritation; H318 Causes serious eye damage; H401 Toxic to aquatic life.</p> <p>Precautionary Statements: P280 Wear protective gloves and eye/face protection; P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. May cause eye, skin or tissue irritation. Avoid contact. If swallowed, seek medical advice immediately</p>		

NOTE: Pertaining to each chemical evaluated above: the material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Unless otherwise stated no known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.

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. Check for and if possible remove contact lenses. OBTAIN MEDICAL ATTENTION.

SKIN: Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. Obtain medical attention if symptoms occur.

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. If breathing is difficult give oxygen. If not breathing provide artificial respiration.

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.

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 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 creating dust or 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. 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 product 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.

STORAGE: Store according to product and label instructions. All reagents should be stored refrigerated 2-30°C (36-86°F) when not in use.

NOTE: Handling and storing of the product 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 appropriate PPE.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

VENTILATION: Adequate ventilation is required. Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29 CFR 1910.134. Always use a NIOSH approved respirator when necessary.

EYE PROTECTION: Wear appropriate eye protection to prevent eye contact conforming to ANSI Z87.1-2003 (US) or EN 166 (EU) Standards.

PROTECTIVE GLOVES: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

SKIN AND BODY: Wear appropriate body protection to the amount and concentration of the chemical present at the location to prevent contact.

COMMENTS: Exposure limit values and health hazard data were given in Section 3 for the individual chemicals. General chemical/ industrial hygiene practices are recommended when working with the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

AVAILABLE PHYSICAL/CHEMICAL PROPERTIES AND CHARACTERISTICS ARE LISTED IN SECTION 3.

10. STABILITY AND REACTIVITY

STABLE: The product is known to be stable under normal use and storage conditions.

CONDITIONS TO AVOID: Avoid excessive heat; maintain ambient temperatures. Avoid strong acids, bases, oxidizers and organic compounds.

HAZARDOUS DECOMPOSITION PRODUCTS: May emit toxic fumes under normal fire conditions.

11. TOXICOLOGICAL INFORMATION

ACUTE: The product is not known to have any specific health or toxicological effects if used as offered for its intended purpose.

CHRONIC TOXICITY: None known if used as offered for its intended purpose.

COMMENTS: Individual chemical toxicological information has been made available in section 3.

12. ECOLOGICAL INFORMATION

NOTE: As offered, the product is not known to have a negative effect on the environment. The Ecological information will be provided based on the individual chemicals contained in the product.

Component	Ecological Information
Hydrochloric Acid	LC50 – Gambusia affinis (Mosquito fish) – 282 mg/l – 96h
ProClin 950	Very toxic to aquatic life
Tween 20	LC50 – Other fish – 350 mg/l – 24h
Triton X-100	LC50 – Pimephales promelas (Fathead minnow) – 8.9 mg/l – 96h EC50 – Daphnia – 26 mg/l – 48h

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.



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.

DOT: Not a dangerous good. **IMDG:** Not a dangerous good. **IATA:** Not a dangerous good.

15. REGULATORY INFORMATION

NOTE: The information here is often based on data for the chemical raw material. The kit contains a significantly diluted concentration in an aqueous solution; thus, unless otherwise noted the assessment below has NOT taken hazard reduction processing into consideration when possible.

Component	Additional Requirements
Hydrochloric Acid	TSCA Inventory: Listed 8(b) Clean Water/Air Act: 311/ 112 SARA 302/304/311/312/313: Extremely hazardous substance/chemical, emergency action plan, notification & form R Reporting. EU Risk Phrases: R23 Toxic by inhalation; R35 Causes severe burns. EU Safety Phrases: S1/2 Keep locked up and out of the reach of children; S9 Keep container in well ventilated place; S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advise; S36/37/39 Wear suitable protective clothing, gloves and eye/face protection; S45 In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).   WHMIS: D1A Material causing immediate and serious toxic affects/ CLASS E: Corrosive liquid. DSL/NDSL: Listed International Inventory List: Australia (AICS); China (IECSC); Japan (ENCS); Korea (KECI); Philippines (PICCS) & New Zealand (NZIoC). Massachusetts, Pennsylvania, New York & New Jersey Right To Know Components
ProClin 950	SARA 311/312: Acute Health Hazard. WHMIS: DSL: Listed Pennsylvania & New Jersey Right To Know Components
Sodium Chloride	SARA 311/312: Acute Health Hazard. Chemical Inventory List (Part 1): EC, Japan, TSCA & Australia. Chemical Inventory List (Part 2): Korea, DSL & Philippines.
Sodium Hydroxide	SARA 302/304/311/312: Listed. Clean Water Act: 311 WHMIS Listed: ClassD1B & E CEPA DSL: Listed International Inventory List: Australia (NICNAS); Japan (METI); Korea (TCCL) & Philippines (RA6969). Massachusetts, Pennsylvania & New Jersey Right To Know Components
Triton X-100	SARA 311/312: Acute Health Hazard. WHMIS: DSL: Listed OSHA: Harmful by ingestion; Irritant. Pennsylvania & New Jersey Right To Know Components, Listed on California Prop 65

16. OTHER INFORMATION

The information contained herein is accurate to the best of our knowledge. OraSure Technologies Inc. makes no warranty of any kind, expressed or implied, concerning the safe use of this material in the process or in combination with other substances.

SUMMARY OF CHANGES: 5/17/2011; Information update and reformatted to comply with the Globally Harmonized System.

12/6/2011; Title change and add part number.

2/17/2012: OraSure part number 1001-0343 removed; Additional OraSure part numbers added (1001-0350, 1001-0337, 1001-0338); minor formatting changes and updates.

1-14-2013: Added Item Numbers 1001-0370, 1001-0371.

SUMMARY OF CHANGES: 01/31/14, Removing the Expiration Date.

SUMMARY OF CHANGES: 04/29/14, Added new item number 1001-0403.