



SAFETY DATA SHEET

OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit

GENERAL USE: The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick, whole blood, venipuncture whole blood and plasma specimens. The kit is intended for use as a point of care test to aid in the diagnosis of infection with HIV-1 and HIV-2. The test is suitable for use in multi-test algorithms designed for statistical validation of rapid HIV test results. When multiple rapid HIV tests are available: this test should be used in appropriate multi-test algorithms. The OraQuick ADVANCE® rapid test is comprised of a single-use test tube containing a pre-measured amount of buffer developer solution and a test device containing a collection pad and assay strip in a plastic housing. Each component is sealed in separate compartments of a single pouch.

ORASURE PRODUCT NUMBERS: 1001-0078, 1001-0079, 1001-0284, 1001-0285, 1001-0352, 1001-0353, 1001-0368, 1001-0369, 3001-1197, 3001-1347, 3001-2584, 3001-1884, 3001-2637.

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

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



ROUTES OF ENTRY: Inhalation, ingestion and absorption.


3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Contents
Test Device	Plastic housing containing several layers of chemically treated assay strips reactive to HIV-1 & HIV-2 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: Sodium phosphate dibasic, Sodium phosphate monobasic, ProClin 950, Polyvinylpyrrolidone, Triton X-100, Sodium Chloride & Sodium Hydroxide.

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 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 HIV-1 or HIV-2.

Chemical Ingredient	Chemical Information
Blocker Pad:	Contains: Avidin (1405-69-2), Polyvinyl Alcohol (9002-89-5), Tween 20 (9005-64-5), Trizma Base (77-86-1), EDTA Salt (6381-92-6), Polyvinylpyrrolidone (9003-39-8) and Hydrochloric Acid (7647-01-0). 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. The material and its container should 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 mixture provided on this strip. Utilize Good Laboratory Practices.

Conjugate Pad:	<p>Contains: Sodium Phosphate Dibasic (7558-79-4), Sodium Phosphate Monobasic (7558-80-7), ProClin 5000/ 300 (2628-20-4/ 55965-84-9), Bovine Serum Albumin (9048-46-8), Recombinant Protein A (N/A), Hydrogen Tetrachloroaurate (16961-25-4), Sodium Citrate Dihydrate (6132-04-3), Sodium Dodecyl Sulfate (151-21-3), Tween 20 (9005-64-5) and Polyethylene Glycol (25322-68-3).</p> <p>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. The material and its container should 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 mixture provided on this strip. Utilize Good Laboratory Practices.</p>		
Nitrocellulose Pad:	<p>Contains: HIV 1 & 2 Peptides/Panel Members (Defibrinated), GP-36 Peptide [Biotinylated](N/A), GP-41 Peptide [Biotinylated](N/A), Modified Avidin (1405-69-02) and F(Ab)² Goat Anti-Human IgG (H+L) (N/A).</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. The material and its container should 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 mixture provided on this strip. Utilize Good Laboratory Practices. NOTE: Pad only contains HIV 1 & 2 peptides, there is no active/live virus contained within the product as offered to the public.</p>		
Sodium Phosphate Dibasic	<p>CAS# 7558-79-4 (Anhydrous); 7782-85-6 (Heptahydrate) (100%) pH: 9.5</p>	<p>Chemical Formula: Na₂HPO₄ 7H₂O Melting Point: 48.1°C (118°F)</p>	<p>Caution, may cause skin, eye and respiratory irritation. May be harmful if swallowed or inhaled. 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.</p>
Sodium Phosphate Monobasic	<p>CAS# 7558-80-7 (Anhydrous); 10049-21-5 (monohydrate) (100%) pH: 9.5</p>	<p>Chemical Formula: NaH₂PO₄ H₂O Melting Point: 100°C (212°F)</p>	<p>Caution, may cause skin, eye and respiratory irritation. May be harmful if swallowed or inhaled. 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.</p>
ProClin 950	<p>CAS#: 2682-20-4 (100%) LD50 (oral-rat): 148 mg/kg (100%) Boiling Point: 188°C Specific Gravity: 1.16 Store Below 120°F (60°C) RCRA Code: P105 (undiluted, 100%) OSHA Hazard: At 100%, corrosive, skin sensitizer, toxic by inhalation. 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>ProClin 950 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.</p>		<p>Flash Point: 214°F Vapor Density (Air=1): 2.62</p> <div data-bbox="1179 991 1523 1113" style="border: 1px solid black; padding: 5px;">  </div>
ProClin 5000	<p>CAS#: N/A LD50 (oral-rat): 148 mg/kg (100%) Boiling Point: 188°C Specific Gravity: 1.16 Store Below 120°F (60°C) RCRA Code: P105 (undiluted, 100%) OSHA Hazard: At 100%, corrosive, skin sensitizer, toxic by inhalation. Hazard Classification: At 100%, corrosive, skin sensitizer, toxic by inhalation. H302, 314, 317, 331, 335 & 400; P261, 273, 280, 305, 351 & 338. ProClin 5000 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.</p>		<p>Flash Point: 214°F Vapor Density (Air=1): 2.62</p> <div data-bbox="1179 1524 1523 1646" style="border: 1px solid black; padding: 5px;">  </div>

Polyvinylpyrrolidone	CAS# 9003-39-8 (100%) Specific Gravity: 1.1-1.3 Caution, may be harmful if swallowed or inhaled. May cause irritation to skin, eyes and respiratory tract. 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.	pH: 3-7 OSHA PEL: 15 mg/m ³ total dust/ 5 mg/m ³ respirable for nuisance dusts.	Melting Point: 100°C (212°F)
Triton X-100	CAS# 9002-93-1 (100%) IATA/DOT/IMDG ID: UN3082 OSHA Hazards: Harmful by ingestion; irritant. GHS Signal Word: DANGER Hazard Statements: H302 Harmful if swallowed; H316 Causes mild skin irritation; H318 Causes serious eye damage; H401 Toxic to aquatic life. 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. 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.	D50 (Oral): 500 mg/kg (rat/male) HMIS codes: H=2, F=1, R=0	LC50 (Dermal): 8000 mg/kg (rabbit) 
Sodium Chloride	CAS# 7647-14-5 (100%) D50 (Inhalation): >42 g/m ³ – 1h RTECS Number: VZ4725000 Synonyms: Salt, saline. 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. 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.	Specific Gravity: 2.165 LD50 (Skin): >10 g/kg (rabbit)	LD50 (Oral): 3 g/kg (rat) Melting Point: 801°C
Sodium Hydroxide (Sodium Hydroxide/ Bal Water)	CAS# 1310-73-2 (0.1-1%)/7732-18-5 (97-99%) GHS Signal Word: DANGER Synonyms: Soda Lye, Caustic Soda. Sodium Hydroxide causes respiratory tract, skin and eye irritation. May be harmful if swallowed; may irritate upon contact with mucous membranes. Avoid contact. Do not ingest. Avoid breathing vapor or mist; keep container closed. Use only with adequate ventilation. The material and its container should 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. Utilize Good Laboratory Practices.	NFPA: Health=1, Flammability=0, Reactivity=0	

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 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.

STORAGE: Store according to product and label instructions. All reagents should be stored refrigerated (2-8°C) when not in use.

NOTE: Handling and storing 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 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, 29CFR1910.134. 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.

INCOMPATIBLE MATERIALS: N/A

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 below Ecological information will be provided based on the individual chemicals contained in the product.

Component	Ecological Information
Triton X-100	LC50 – Pimephales promelas (Fathead minnow) – 8.9 mg/l – 96h EC50 – Daphnia – 26 mg/l – 48h
ProClin 950	Very toxic to aquatic life
ProClin 5000	No data found
Tween 20	LC50 – Other fish – 350 mg/l – 24h

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. As offered for shipping (based on single kit only).

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
Sodium Phosphate Monobasic (100%)	International Inventory List (part 1): US (TSCA), Australia; Japan; EC. International Inventory List (part 2): Korea; Philippines & Canada DSL. SARA 311/312: Acute Health Hazard.
Sodium Phosphate Dibasic (100%)	International Inventory List (part 1): US (TSCA), Australia; Japan; EC. International Inventory List (part 2): Korea; Philippines & Canada DSL. SARA 311/312: Acute Health Hazard.
ProClin 950 (100%)	SARA 311/312: Acute Health Hazard. Canadian DSL: Listed. Pennsylvania & New Jersey Right To Know Components
ProClin 5000 (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.
Triton X-100 (100%)	OSHA: Harmful by ingestion; Irritant. Canadian DSL: Listed. SAR 311/312: Acute Health Hazard. Pennsylvania & New Jersey Right To Know Components, Listed on California Prop 65
Polyvinylpyrrolidone (100%)	International Inventory List (part 1): US (TSCA), Australia; Japan. International Inventory List (part 2): Korea; Philippines & Canada DSL.
Sodium Hydroxide (100%)	SARA 302/304/311/312: Listed. Clean Water Act: 311 WHMIS Listed: Class D1B & E CEPA DSL: Listed. International Inventory List: Australia (NICNAS); Japan (METI); Korea (TCCL) & Philippines (RA6969). Massachusetts, Pennsylvania & New Jersey Right To Know Components
Sodium Chloride (100%)	DSCL (EEC): Irritant (Xn) R36/37/38 Irritating to eyes, respiratory system & skin, S36/37/38 Wear suitable protective clothing, gloves and eye/face protection.

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:

4/12/2011; Information update and reformatted to comply with the Globally Harmonized System.

5/04/2012: OTC product number added (1001-0340).

07/31/2012: Section 10. – Remove sentence after INCOMPATIBLE MATERIALS and add N/A.

08/07/2012: Removed obsolete Item Numbers (1001-0124, 1001-0126, 1001-0140, 1001-0156, 1001-0157, 1001-0158, 1001-0159, 1001-0160, 1001-0161, 1001-0162, 1001-0163, 1001-0164, 1001-0165, 1001-0215, 1001-0217, 1001-0218, 1001-0219, 1001-0237, 1001-0238, 1001-0243, 1001-0244, 1001-0281, 1001-0286, 1001-0287, 1001-0290, 1001-0291).

08/07/2012: Added Item Numbers (3001-1347, 3001-2584).

08/07/2012: Added OraQuick® In-Home HIV Test name to product name and document title.

08/07/2012: Added Proclin 5000 to Composition / Information of Ingredients.

08/07/2012: Added Proclin 5000 to Regulatory Information.

11-29-2012: Added Item Number 1001-0374

TBD: Removed OQ In-Home HIV Test from title and items 1001-0340/1001-0374/3001-1775 as the In-Home test will have a separate SDS item 19409. Added Korean items 1001-0368 and 1001-0369. Added pouched device item numbers 3001-1884 (Brazil), 3001-2637 (Korea). Updated General use section to include the assay strip.