

OraQuick ADVANCE® HIV-1/2 Developer Solution(component of the OraQuick ADVANCE® HIV-1/2 Rapid Antibody Test)

Safety Data Sheet

In accordance with The Model Work Health and Safety Regulations, and the Globally Harmonized System of Classification and Labelling of Chemicals 3rd Revised Edition.

Revision Date: 03/13/19

Date of Issue: 03/13/19

Item 19407-AUS-ENG

SECTION 1: PRODUCT IDENTIFIER & IDENTIFIER FOR THE CHEMICAL

1.1 Product Identifier

Product Form : Mixture

Product Name : OraQuick ADVANCE® HIV-1/2 Developer Solution (component of the OraQuick ADVANCE HIV -1/2 Rapid Antibody Test)

Product Code: 3001-1214

Associated product numbers: 1001-0352, 1001-0353, 3001-2584

This product is provided as part of a kit. The kit and its components should be handled 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

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture: The OraQuick ADVANCE® HIV-1/2 Developer Solution is a component of the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test (1001-0352, 1001-0353, 3001-2584). 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 in the diagnosis of infection with HIV-1 and HIV-2. The OraQuick ADVANCE® rapid test is comprised of: 1) a single-use test tube containing a pre-measured amount of buffer developer solution (Developer Solution), and 2) a test device containing a collection pad and assay strip in a plastic housing (Test Device). Each component is sealed in separate compartments of a single pouch.

1.2.2. Uses advised against

Refer to product instructions for limitations/restrictions

1.3. Details of the supplier of the safety data sheet

Company

OraSure Technologies, Inc.

220 East First Street

Bethlehem, PA 18015

Phone: 800-869-3538

www.orasure.com

1.4. Emergency telephone number

Emergency number : INFOTRAC INTERNATIONAL: +1-352-323-3500

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

Classification (GHS-AU)

Skin Sens.1 H317

Oraquick ADVANCE HIV – 1/2 Developer Solution is provided along with a test device as part of a kit. The test device is not classified. Full text of hazard classes and H statements: see section 16

2.2 Label Elements

GHS-AU Labelling

Hazard Pictograms (GHS-AU)

:



GH507 - Exclamation mark

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Signal Word (GHS-AU)	: Warning
Hazard Statements (GHS-AU)	: H317 - May cause an allergic skin reaction.
Precautionary Statements (GHS-AU)	: P261 - Avoid breathing vapors, mist, or spray. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves, protective clothing, and eye protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment (see section 4 on this SDS). P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

Non-GHS Hazards Not available

2.3 Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not Applicable

3.2 Mixture

Name	Product Identifier	%*	GHS-AU Classification
3(2H)-Isothiazolone, 2-methyl-	(CAS-No.) 2682-20-4	<0.01	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation:dust,mist), H331 Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Acute 1, H400

Other ingredients present in this mixture are either non-hazardous and/or are present at amounts under reporting limits.

Test Device

Plastic housing containing several layers of chemically treated assay strips reactive to HIV-1 and 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. Ingredients present in this kit component are either non-hazardous and/or are present at amounts under reporting limits.

This kit DOES NOT contain any live or active levels of HIV-1 or HIV-2.

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%)

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

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Personal Protection in First Aid and Measures: Not available

4.2 Most Important Symptoms and Effects Both Acute and Delayed

General: Skin sensitisation.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2 Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3 Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Sodium oxides. Hydrogen chloride.

HAZCHEM Emergency Action Code (Australia): Not available

5.4 Reference to Other Sections

Refer to Section 9 for Flammability Properties

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing (vapor, mist, spray). Do not get in eyes, on skin, or on clothing.

6.1.1 For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2 Environmental Precautions

Prevent entry to sewers and public waters.

6.3 Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4 Reference to Other Sections

See Heading 8. Exposure controls and personal protection. See Section 13, Disposal Considerations.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Precautions for safe handling: The kit and kit components should be handled only by qualified personnel. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapours, mist, spray. Handling and storing of the kit or its components 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

Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store according to product and label instructions.

Incompatible Materials: Strong oxidizers. Water reactive materials.

Storage Temperature: 2 - 27 °C

7.3 Specific End Use(s)

The OraQuick ADVANCE® HIV-1/2 Developer Solution is a component of the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test. 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 in the diagnosis of infection with HIV-1 and HIV-2. The OraQuick ADVANCE® rapid test is comprised of: 1) a single-use test tube containing a pre-measured amount of buffer developer solution (Developer Solution), and 2) a test device containing a collection pad and assay strip in a plastic housing (Test Device). Each component is sealed in separate compartments of a single pouch

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1 Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), and Australia OELs.

8.2 Exposure Controls

Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

8.2.1. Personal Protective Equipment

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing: Not available

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Not available
Odour	: Not available

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Odour threshold	: Not available
pH	: 7.38 - 7.52
Evaporation Rate	: Not available
Melting Point	: Not available
Freezing Point	: Not available
Boiling Point	: Not available
Flash Point	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Lower Flammable Limit	: Not available
Upper Flammable Limit	: Not available
Vapour pressure	: Not available
Relative vapour density at 20 °C	: Not available
Relative Density	: Not available
Specific Gravity	: Not available
Solubility	: Not available
Partition Coefficient n-Octanol/Water	: Not available
Viscosity	: Not available

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2 Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3 Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4 Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5 Incompatible Materials:** Strong oxidizers. Water reactive materials.
- 10.6 Hazardous Decomposition Products:** Thermal decomposition generates: Sodium oxides. Hydrogen chloride gas.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects - Product

- Acute Toxicity (Oral):** Not classified
- Acute Toxicity (Dermal):** Not classified
- Acute Toxicity (Inhalation):** Not classified
- LD50 and LC50 Data:** Not available
- Skin Corrosion/Irritation:** Not classified
- pH:** 7.38 - 7.52
- Serious Eye Damage/Irritation:** Not classified
- pH:** 7.38 - 7.52
- Respiratory or Skin Sensitization:** May cause an allergic skin reaction.
- Germ Cell Mutagenicity:** Not classified
- Carcinogenicity:** Not classified
- Specific Target Organ Toxicity (Repeated Exposure):** Not classified
- Reproductive Toxicity:** Not classified
- Specific Target Organ Toxicity (Single Exposure):** Not classified
- Aspiration Hazard:** Not classified
- Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.
- Symptoms/Injuries After Skin Contact:** May cause an allergic skin reaction.
- Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.
- Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.
- Chronic Symptoms:** None expected under normal conditions of use.

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Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

3(2H)-Isothiazolone, 2-methyl- (2682-20-4)	
LD50 Oral Rat	120 mg/kg
LD50 Dermal Rabbit	200 mg/kg
LC50 Inhalation Rat	0.11 mg/l/4h

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute Aquatic Toxicity: Not classified

Chronic Aquatic Toxicity: Not classified

Ecology - General: Not classified.

12.2 Persistence and Degradability

OraQuick ADVANCE® HIV-1/2 Developer Solution	
Persistence and Degradability	Not established.

12.3 Bioaccumulative Potential

OraQuick ADVANCE® HIV-1/2 Developer Solution	
Bioaccumulative Potential	Not established.

12.4 Mobility in Soil Not available

12.5 Other Adverse Effects

Other Information: Avoid release to the environment.

Ozone: Not classified

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations, processing, use or contamination of the solution may change waste management requirements and options.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 National Regulations

3(2H)-Isothiazolone, 2-methyl- (2682-20-4)
Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on the Canadian DSL (Domestic Substances List)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Japanese ISHL (Industrial Safety and Health Law)
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Listed on INSQ (Mexican National Inventory of Chemical Substances)
Listed on the TCSI (Taiwan Chemical Substance Inventory)

International Agreements

No additional information available

Australia National Regulations

No additional information available

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Australia Territory Regulations

No additional Information available

SECTION 16: ADDITIONAL INFORMATION

Date of Preparation or Latest Revision : 03/13/19

Revision

Data Sources : Information and data obtained and used in the authoring of this safety data sheet could come from database subscriptions, official government regulatory body websites, product/ingredient manufacturer or supplier specific information, and/or resources that include substance specific data and classifications according to GHS or their subsequent adoption of GHS.

Other Information : In accordance with The Model Work Health and Safety Regulations, and the Globally Harmonized System of Classification and Labelling of Chemicals 3rd Revised Edition.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Acute Tox. 5 (Oral)	Acute toxicity (oral), Category 5
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Acute 2	Hazardous to the aquatic environment — Acute Hazard, Category 2
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
Press. Gas (Comp.)	Gases under pressure : Compressed gas
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H280	Contains gas under pressure; may explode if heated.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H303	May be harmful if swallowed
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H401	Toxic to aquatic life
H411	Toxic to aquatic life with long lasting effects.

Indication of Changes No additional information available

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Abbreviations and Acronyms

ACGIH – American Conference of Governmental Industrial Hygienists

ADG – Australian Dangerous Goods (Code)

AIHA – American Industrial Hygiene Association

ATE - Acute Toxicity Estimate

AU - Australia

BCF - Bioconcentration Factor

BEI - Biological Exposure Indices (BEI)

BOD – Biochemical Oxygen Demand

CAS No. - Chemical Abstracts Service Number

COD – Chemical Oxygen Demand

EC50 - Median Effective Concentration

ErC50 - EC50 in Terms of Reduction Growth Rate

EU - European Union

GHS – Globally Harmonized System of Classification and Labeling of Chemicals

IARC - International Agency for Research on Cancer

LC50 - Median Lethal Concentration

LD50 - Median Lethal Dose

LOAEL - Lowest Observed Adverse Effect Level

LOEC - Lowest-Observed-Effect Concentration

Log Koc - Soil Organic Carbon-water Partitioning Coefficient

Log Kow - Octanol/water Partition Coefficient

Log Pow - Ratio of the equilibrium concentration (C) of a dissolved substance in a two-phase system consisting of two largely immiscible solvents, in this case octanol and water

NOAEL - No-Observed Adverse Effect Level

NOEC - No-Observed Effect Concentration

NTP – National Toxicology Program

OEL - Occupational Exposure Limits

pH – Potential Hydrogen

SADT - Self Accelerating Decomposition Temperature

SDS - Safety Data Sheet

STEL - Short Term Exposure Limit

ThOD – Theoretical Oxygen Demand

TLM - Median Tolerance Limit

TLV - Threshold Limit Value

TPQ - Threshold Planning Quantity

TWA - Time Weighted Average

UN – United Nations

UN RTDG – United Nations Recommendations on the Transport of Dangerous Goods

VOC – Volatile Organic Compounds

WEEL - Workplace Environmental Exposure Levels

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Australia GHS SDS

SUMMARY OF CHANGES: New SDS for AU