

OraQuick® HIV Developer Solution (component of the OraQuick® HIV Self-Test)

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Revision Date: 13/03/19 Date of Issue: 13/03/19 Item 19713-EU-ENG

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Form : Mixture
 Product Name : OraQuick® HIV Developer Solution
 Product Code : 3001-3038
 Associated product numbers : 5X4-1000, 5X4-1001, and 5X4-2001

This product is provided as part of a kit. 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.

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® HIV Developer Solution (3001-3038) is a component of the OraQuick® HIV Self-Test (5X4-1000, 5X4-1001, 5X4-2001). The OraQuick® HIV Self-Test is an *in-vitro* diagnostic medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals.

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 According to Regulation (EC) No. 1272/2008 [CLP]

Skin Sens. 1 H317

OraQuick® HIV Developer Solution is provided along with a test device as part of a kit. The test device is not classified according to regulation (EC) No. 1272/2008.

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling According to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



Signal word (CLP) : Warning

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) : 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.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards not contributing to the classification : 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	%	Classification According to Regulation (EC) No. 1272/2008 [CLP]
Sodium chloride	(CAS-No.) 7647-14-5 (EC-No.) 231-598-3	1,8	Not classified
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-substance listed as REACH Candidate (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]) substance listed in REACH Annex XIV (4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues))	(CAS-No.) 9002-93-1 (EC-No.) 618-344-0	<= 0,2	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 2, H411
3(2H)-Isothiazolone, 2-methyl-	(CAS-No.) 2682-20-4 (EC-No.) 220-239-6	<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. 1A, 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.

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

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).
First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

- First-aid measures after 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.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects : Skin sensitisation.
- Symptoms/effects after inhalation : Prolonged exposure may cause irritation.
- Symptoms/effects after skin contact : May cause an allergic skin reaction.
- Symptoms/effects after eye contact : May cause slight irritation to eyes.
- Symptoms/effects after 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: Firefighting 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.
- Hazardous decomposition products in case of fire : Sodium oxides. Hydrogen chloride.

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.

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 responders

- 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 material 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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : 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 (36 - 80 °F)

7.3. Specific end use(s) : The OraQuick® HIV Self-Test is an *in-vitro* diagnostic medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

3(2H)-Isothiazolone, 2-methyl- (2682-20-4)		
Austria	MAK (mg/m³)	0,05 mg/m³
Austria	OEL chemical category (AT)	Skin notation, Skin sensitizer
Switzerland	KZGW (mg/m³)	0,4 mg/m³ (inhalable dust)
Switzerland	MAK (mg/m³)	0,2 mg/m³ (inhalable dust)
Switzerland	OEL chemical category (CH)	Sensitizer
Sodium chloride (7647-14-5)		
Latvia	OEL TWA (mg/m³)	5 mg/m³
Lithuania	IPRV (mg/m³)	5 mg/m³

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.

Personal protective equipment : Gloves. Protective clothing. Protective goggles.



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
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: 7,38 - 7,52
Evaporation rate	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available

Relative density	: No data available
Solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information 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

Acute toxicity : Not classified

3(2H)-Isothiazolone, 2-methyl- (2682-20-4)	
LD50 oral rat	120 mg/kg
LD50 dermal rabbit	200 mg/kg
LC50 inhalation rat (mg/l)	0,11 mg/l/4h
Sodium chloride (7647-14-5)	
LD50 oral rat	3550 mg/kg (Species: Wistar)
LD50 dermal rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 inhalation rat (mg/l)	> 42 g/m ³ (Exposure time: 1 h)
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- (9002-93-1)	
LD50 oral rat	1800 mg/kg

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7,38 - 7,52
Serious eye damage/irritation	: Not classified pH: 7,38 - 7,52
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

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.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Not classified.

Sodium chloride (7647-14-5)	
LC50 fish 1	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340,7 (340,7 - 469,2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC chronic fish	252 mg/l (Species: Pimephales promelas)
Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- (9002-93-1)	
LC50 fish 1	3 mg/l

12.2. Persistence and degradability

OraQuick® HIV Developer Solution	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

OraQuick® HIV Developer Solution	
Bioaccumulative potential	Not established.

Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Poly(oxy-1,2-ethanediyl), .alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy- (9002-93-1)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging 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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

ADR	IMDG	IATA	ADN	RID
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No

14.6. Special precautions for user

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (EC 618-344-0, CAS 9002-93-1)

Contains REACH Annex XIV substances:

Substance name	Authorisation number	Sunset date	REACH authorisation exemptions
4-(1,1,3,3 – Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues) (EC 618-344-0, CAS 9002-93-1)	Not applicable	04/01/2021	Not applicable

3(2H)-Isothiazolone, 2-methyl- (2682-20-4)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

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

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 : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Full Text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), 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
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H301	Toxic if swallowed.
H302	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.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations and Acronyms

ACGIH – American Conference of Governmental Industrial Hygienists
ADN – European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR - European Agreement Concerning the International Carriage of Dangerous Goods by Road
ATE - Acute Toxicity Estimate
BCF - Bioconcentration Factor
BEI - Biological Exposure Indices (BEI)
BOD – Biochemical Oxygen Demand
CAS No. - Chemical Abstracts Service Number
CLP – Classification, Labeling and Packaging Regulation (EC) No 1272/2008
COD – Chemical Oxygen Demand
EC – European Community
EC50 - Median Effective Concentration
EEC – European Economic Community
EINECS – European Inventory of Existing Commercial Chemical Substances
EmS-No. (Fire) - IMDG Emergency Schedule Fire
EmS-No. (Spillage) - IMDG Emergency Schedule Spillage
EU – European Union
ErC50 - EC50 in Terms of Reduction Growth Rate
GHS – Globally Harmonized System of Classification and Labeling of Chemicals
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
IBC Code - International Bulk Chemical Code
IMDG - International Maritime Dangerous Goods
IPRV - Ilgalaikio Poveikio Ribinis Dydis
IOELV – Indicative Occupational Exposure Limit Value
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
MAK – Maximum Workplace Concentration/Maximum Permissible Concentration

EU GHS SDS

MARPOL - International Convention for the Prevention of Pollution
NDS - Najwyższe Dopuszczalne Stezenie
NDSch - Najwyższe Dopuszczalne Stezenie Chwilowe
NDSP - Najwyższe Dopuszczalne Stezenie Pulapowe
NOAEL - No-Observed Adverse Effect Level
NOEC - No-Observed Effect Concentration
NRD - Nevirsytinas Ribinis Dydis
NTP – National Toxicology Program
OEL - Occupational Exposure Limits
PBT - Persistent, Bioaccumulative and Toxic
PEL - Permissible Exposure Limit
pH – Potential Hydrogen
REACH – Registration, Evaluation, Authorisation, and Restriction of Chemicals
RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail
SADT - Self Accelerating Decomposition Temperature
SDS - Safety Data Sheet
STEL - Short Term Exposure Limit
TA-Luft - Technische Anleitung zur Reinhaltung der Luft
TEL TRK – Technical Guidance Concentrations
ThOD – Theoretical Oxygen Demand
TLM - Median Tolerance Limit
TLV - Threshold Limit Value
TPRD - Trumpalaikio Poveikio Ribinis Dydis
TRGS 510 - Technische Regel für Gefahrstoffe 510 - Lagerung von Gefahrstoffen in ortsbeweglichen Behältern
TRGS 552 – Technische Regeln für Gefahrstoffe - N-Nitrosamine
TRGS 900 - Technische Regel für Gefahrstoffe 900 – Arbeitsplatzgrenzwerte
TRGS 903 - Technische Regel für Gefahrstoffe 903 - Biologische Grenzwerte
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
VOC – Volatile Organic Compounds
VLA-EC - Valor Límite Ambiental Exposición de Corta Duración
VLA-ED - Valor Límite Ambiental Exposición Diaria
VLE – Valeur Limite D'exposition
VME – Valeur Limite De Moyenne Exposition
vPvB - Very Persistent and Very Bioaccumulative
WEL – Workplace Exposure Limit
WGK - Wassergefährdungsklasse

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.

SUMMARY OF CHANGES: New Document