

SAFETY DATA SHEET
Q.E.D.® Saliva Alcohol Test Kit

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Q.E.D.® Saliva Alcohol Test Kits (30 count & 100 Count Test Kits)

GENERAL USE: The OraSure Technologies Q.E.D.® Saliva Alcohol Test is intended for the rapid, accurate, quantitative determination of alcohol in saliva for *in vitro* diagnostic use. These products are recommended for professional use in the evaluation of persons suspected of being intoxicated and as an aid in the management of alcoholism.

ORASURE PRODUCT NUMBERS: 31150B, 31150C

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 Q.E.D.® Saliva Alcohol Test Kit should only be used by qualified trained personnel familiar with any 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:
H317 May cause an allergic skin reaction H313 May be harmful in contact with skin	P302 + P350 IF ON SKIN: Gently wash with plenty of soap and water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.





ROUTES OF ENTRY: Ingestion and absorption.


3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Contents
Alcohol Test	Each Test contains alcohol dehydrogenase, diaphorase, NAD, an oxidizing reagent and a tetrazolium salt, all of which are immobilized on a solid substrate.
Specimen Collection Device/ Swab	Cotton ball tipped wand used to collect the oral sample to be tested.

COMMENTS: The following information is furnished for those hazardous constituents that require regulatory control or disclosure at the concentration found in the product. Note that the information here is often based on data for the chemical raw material (LD50, exposure limits, etc.). All known hazardous materials will be listed below.

Chemical Ingredient	Chemical Information
Red Dye	CAS# 25956-17-6 (100%) Chemical Formula: C ₁₈ H ₁₄ N ₂ O 8S ₂ Na Molecular Weight: 496.42 g/mol LD50 (Oral): >10,000 mg/kg (rat) LD50 (Dermal): >10,000 mg/kg (rabbit) Synonyms: Food Red 17, Disodium Salt. May slightly irritating to skin and eyes upon contact. May be irritating if ingested or inhaled.
Sulfuric Acid 1N	CAS# 7664-93-9(<1%)/7732-18-5 (>99%) Chemical Formula: H ₂ O ₄ S Molecular Weight: 98.08 g/mol Melting Point: 10.6°C (51.1°F) Boiling Point: 290°C (554°F) Density: 1.84 g/cm ³ LD50 (Oral): 2140 mg/kg (rat) LD50 (Inhalation): 510 mg/kg (rat) GHS Signal Word: DANGER/POISON At greater concentration than known to be found in product, may be fatal if inhaled, absorbed through skin or if swallowed. Causes severe eye, skin and respiratory tract burns. Do not ingest. Avoid contact with skin and clothing. Avoid breathing vapor or mist; keep container closed. Use only with adequate ventilation. Repeated exposure may cause local skin destruction, dermatitis or lung damage. Repeated exposure or prolong contact with spray or mist may produce chronic eye irritation and severe skin irritation.

Sodium Pyrophosphate	<p> CAS# 13472-36-1 (100%) Chemical Formula: Na₄O₇P₂·10H₂O pH: 9.5 - 10.5 Molecular Weight: 466.06 g/mol Melting Point: 79.5°C (175.1°F) Density: 1.820 g/cm³ OSHA Hazards: Irritant. GHS Signal Word: WARNING. Hazard Statements: H315 Causes skin irritation; H319 Causes serious eye irritation; H335 May cause respiratory irritation. Precautionary Statements: P264 Wash hands thoroughly after handling the chemical components; P280 Wear protective gloves/eye protection/face protection; P302 + P352 IF ON SKIN: Wash with plenty of soap and water; 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 be harmful if inhaled or ingested. Causes respiratory tract irritation. May be harmful if absorbed through skin, Causes skin and eye irritation. </p> 
Surfynol	<p> CAS# 9014-85-1 (100%) LD50 (Ingestion): 6,300 mg/kg (rat) LD50 (Dermal): >2,000 mg/kg (rabbit) Flash Point: >110°C pH: 7 May cause severe eye and mild skin irritation. </p>
Triton X-100	<p> CAS# 9002-93-1 (100%) LD50 (Oral): 500 mg/kg (rat/male) LC50 (Dermal): 8000 mg/kg (rabbit) HMIS codes: H=2, F=1, R=0 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: 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> 
Sodium Hydroxide (1M Solution)	<p> CAS# 1310-73-2 (0.1-1%)/7732-18-5 (97-99%) Chemical Formula: NaOH Molecular Weight: 40.0 g/mol Melting Point: 318°C (604°F) pH: 13.0 - 14 Melting Point: 318°C (604°F) Boiling Point: 1390°C (2534°F) Density: 2.13 g/cm³ GHS Signal Word: WARNING NFPA: Health=1, Flammability=0, Reactivity=0 Synonyms: Soda Lye, Caustic Soda. Causes respiratory tract, skin and eye irritation. May be harmful if swallowed; may irritate upon contact with mucous membranes. Do not ingest. Avoid contact with skin and clothing. Avoid breathing vapor or mist; keep container closed. Use only with adequate ventilation. Repeated exposure can cause local skin destruction, dermatitis or lung damage. Repeated exposure or prolonged contact with spray or mist may produce chronic eye irritation and severe skin irritation </p>
Gelatin	<p> CAS# 9000-70-8 (100%) Density (H₂O=1): 1 May be slightly hazardous in cases of skin or eye contact, ingestion and inhalation (irritant). In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention if necessary </p>
Trizma Base	<p> CAS# 77-86-1 (100%) Chemical Formula: C₄H₁₁NO₃ pH: 10.5 - 12 Molecular Weight: 121.14 g/mol LD50 (Oral): 5,900 mg/kg (rat) Boiling Point: 219-220°C (426-428°F) Melting Point: 171.2-172.3°C (340.2-342.1°F) OSHA Hazards: Irritant. GHS Signal Word: WARNING. Hazard Statements: H315 Causes skin irritation; H319 Causes serious eye irritation; H335 May cause respiratory irritation. Precautionary Statements: P264 Wash hands thoroughly after handling the chemical components; P280 Wear protective gloves/eye protection/face protection; P302 + P352 IF ON SKIN: Wash with plenty of soap and water; 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 be harmful if inhaled or ingested; causes respiratory tract irritation. May be harmful if absorbed through skin; causes skin and eye irritation. </p> 
MTT	<p> CAS# 298-93-1 (100%) Chemical Formula: C₁₈H₁₆N₅SBr Molecular Weight: 414.33 g/mol Synonym: Thiazoyl Blue. May be harmful if inhaled, ingested or absorbed through the skin. May cause eye and skin irritation. </p>
Ethanolamine (141-43-5)	<p> CAS# 141-43-5 (100%) Chemical Formula: C₂H₇NO Molecular Weight: 61.08 g/mol Melting Point: 10-11°C (50-52°F) Boiling Point: 170°C (338°F) Density: 1.012 g/cm³ Flash Point: 86°C (187°F) LD50 (Oral): 1,720 mg/kg (rat) LD50 (Dermal): 1,015 mg/kg (rat) GHS Signal Word: DANGER Hazard Statements: H227 Combustible liquid; H302 + H312 Harmful if swallowed or in contact with eyes; H314 Causes severe skin burns and eye damage. Precautionary Statements: 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. At greater concentration than known to be found in product, may be harmful if inhaled, absorbed through skin or swallowed. Causes eye, skin and respiratory tract burns. </p> 

Acetonitrile	CAS# 75-05-8 (100%)	Chemical Formula: C ₂ H ₃ N	Molecular Weight: 41.05 g/mol
	Boiling Point: 81-82°C (178-180°F)	Melting Point: -48°C (-54°F)	Flash Point: 2°C (35.6°F)
	LD50 (Oral): 2460 mg/kg (rat)	LD50 (Dermal): 2000 mg/kg (rabbit)	Density: 0.786 g/cm ³
	LD50 (Inhalation): 7551 ppm (rat) – 8h		
	OSHA Hazards: Flammable liquid, Harmful by ingestion & skin absorption, Irritant. GHS Signal Word: DANGER		
	Hazard Statements: H302 + H312 Harmful if swallowed or in contact with eyes; H316 Causes mild skin irritation; H318 Causes serious eye damage.		
	Precautionary Statements: 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.		
	At greater concentration than known to be found in product, may be harmful if inhaled, absorbed through skin or swallowed. Causes eye and skin irritation.		
			

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: May be fatal if swallowed. Onset of symptoms may be delayed 18-24 hours after exposure. **DO NOT** induce vomiting. **OBTAIN MEDICAL ATTENTION IMMEDIATELY.**

INHALATION: Remove person from exposure area to fresh air. Treat apparent signs and symptoms. If not breathing give artificial respiration; if breathing is difficult give oxygen. **OBTAIN MEDICAL ATTENTION.**

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, mist 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. Test kits should be stored at room temperature: 15-30°C (59 – 86°F).

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, 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: General chemical/industrial hygiene practices are recommended when working with the product. Facilities that are storing, handling or using the product should be equipped with an emergency eyewash/shower or appropriate means for proper flushing of the eyes and/or body.

Chemical Name	ACGIH	NIOSH	OSHA
Sulfuric Acid (100%)	0.2 mg/m ³ , 8 hour(s), TWA	1 mg/m ³ , 10 hour(s), TWA	1 mg/m ³ , 8 hour(s), TWA
Sodium Pyrophosphate (100%)	N/A	N/A	5 mg/m ³ , 8 hour(s), TWA
Sodium Hydroxide (100%)	Ceiling: 2 mg/m ³ , TLV	Ceiling: 2 mg/m ³	Ceiling: 2 mg/m ³ , TWA
Ethanolamine (100%)	3 ppm/ STEL 6 ppm TLV, TWA	N/A	3 ppm (8 mg/m ³)/ STEL 6 ppm (15 mg/m ³), TWA
Acetonitrile (100%)	N/A	20ppm TLV, TWA	40 ppm (70 mg/m ³)/ STEL 60 ppm (105 mg/m ³), TWA

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 recommended storage conditions.

CONDITIONS TO AVOID: Avoid excessive heat; maintain ambient temperatures. Avoid exposure to direct sunlight.

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

Component	Ecological Information
Sulfuric Acid (100%)	LC50 – Crustaceans 70,000-80,000 ug/l – 48 h LC50 – Fish 42,000 ug/l – 96 h
Surfynol (100%)	LC50 – Turbot - 776 mg/l – 96 h LC50 – Acartia tonsa – 353 mg/l – 48 h EC50 – Skeletonema – 253 mg/l – 72 h
Triton X-100 (100%)	LC50 – Pimephales promelas – 8.9 mg/l – 96 h EC50 – Daphnia – 26mg/l – 48 h
Sodium Hydroxide (100%)	LC50 – Gambusia affinis – 125 mg/l – 96 h EC50 – Daphnia – 40.38 mg/l – 48h (Immobilization)
Ethanolamine (100%)	LC50 – Pimephales promelas – 227 mg/l – 96 h EC50 – Daphnia magna – 65mg/l – 48 h EC50 – Desmodemus subspicatus – 15 mg/l – 72 h
Acetonitrile (100%)	LC50 – Pimephales promelas – 1,640 mg/l – 96 h EC50 – Daphnia magna – 3,600mg/l – 48 h

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 product 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 product 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.

Component	Additional Requirements
FD&C Red Dye (100%)	TSCA 8(b) Inventory: Listed.
Sulfuric Acid (100%)	Clean Water Act: Listed. California Prop. 65: Listed. SARA 302/304/311/312 Extremely hazardous substances/Hazardous chemicals: Listed. SARA 302/304 Emergency planning & notification: Listed. Massachusetts, Pennsylvania, New Jersey & New York Right-to Know Components. WHMIS: CEPA DSL/NDSL: Listed. Class C: Oxidizing. Class D-1A: Material causing immediate and serious toxic effects. Class E: Corrosive Material. EU Hazard symbol: Irritant. EU Risk Phrases: R22 – Harmful if swallowed. EU Safety Phrases: S2 Keep out of the reach of children, S46 If swallowed; seek medical advice immediately. Chemical Inventory List: Australia, China, Japan, Korea, New Zealand & Philippines.
Sodium Pyrophosphate (100%)	SARA 311/312: Acute Health Hazard. Massachusetts, Pennsylvania & New Jersey Right-to Know Components.
Surfynol (100%)	SARA 312: Acute Health Hazard. TSCA 8(b) Inventory: Listed. WHMIS: Toxic Material Causing Other Toxic Effects.
Triton X-100 (100%)	SARA 311/312: Acute Health Hazard. Massachusetts, Pennsylvania & New Jersey Right-to Know Components. WHMIS: DSL Listed.
Sodium Hydroxide (100%)	SARA 311/312: Acute Health Hazard. Massachusetts, Pennsylvania & New Jersey Right-to Know Components.
Trizma Base (100%)	SARA 311/312: Acute Health Hazard. Pennsylvania & New Jersey Right-to Know Components. WHMIS: DSL Listed.
MTT (100%)	TSCA 8(b) Inventory: Listed. EU Hazard Designation: Irritant (X ₁). EU Risk Phrases: R36/38 Irritating to eyes and skin.
Ethanolamine (100%)	SARA 311/312: Fire Hazard, Acute Health Hazard, Chronic Health Hazard. Massachusetts, Pennsylvania & New Jersey Right-to Know Components. WHMIS: DSL Listed.
Acetonitrile (100%)	SARA 311/312: Fire Hazard, Acute Health Hazard, Chronic Health Hazard. Massachusetts, Pennsylvania & New Jersey Right-to Know Components. WHMIS: DSL Listed.

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: 8/11/2011; Information update and reformatted to comply with the Globally Harmonized System.

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