

# Safety Data Sheet

Doc. #: SDS-017

Rev #: A.0

Date Effective: 20-Feb-2015

## 1. IDENTIFICATION

### 1.1. Product Identifiers:

Trade Name / Product name: Alere OraTECT<sup>®</sup> Oral Fluid Drug  
Part / Cat. No: AOT-06

### 1.2. Recommended uses of substance and restrictions on use

2. Product Use: *In vitro* diagnostic use. For professional point-of-care use only.  
Chemical Family: Lateral Flow Immunoassay Assay

### 2.1. Details of supplier:

Company: Alere Toxicology Services - Products Division  
Portsmouth, VA 23704

Telephone: Weekdays 7am - 6pm EST  
1-800-340-4029 (Phone)  
1-888-340-4029 (Fax)

### 2.2. Emergency telephone:

Emergency Telephone Number: +1 800-876-4766 (Phone)

## 3. HAZARDS IDENTIFICATION

### 3.1. Classification of the substance:

Not a hazardous substance or mixture as defined in 29 CFR 1910.1200.

### 3.2. Signal word, hazard statement(s), symbols, and precautionary statement(s):

None

## 4. COMPOSITION/INFORMATION ON INGREDIENTS

Component Description	CAS	Concentration
<b><i>in vitro</i> Diagnostic Reagent Test Device.</b> Laminated test strip consisting of Solid Support materials impregnated with dried chemical/biochemical reagents	N/A	N/A
<b>Composition of Oral Fluid Collection Pad</b> Sodium Phosphate, Dibasic (GRAS listed compound)	7558-79-4	N/A

## 5. FIRST AID MEASURES

### 5.1. Description of first aid measures:

#### Routes of Exposure:

Ingestion, inhalation, skin or eye contact.

#### Ingestion:

Wash out mouth with water and seek immediate medical attention if there has been ingestion of this product.

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**Skin contact:**

Wash thoroughly with soap and water.

**Eye contact:**

Flush cautiously with copious amount of water and contact a physician.

**Inhalation:**

If breathing becomes difficult, remove victim to fresh air.

Seek medical assistance immediately.

**5.2. Most important symptoms/effects, acute and delayed:**

No data available.

**6. FIRE FIGHTING MEASURES**

**6.1. Suitable extinguishing media:**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**6.2. Special hazards arising from substance:**

No data available.

**6.3. Advice for firefighters:**

Wear self contained breathing apparatus for firefighting if necessary.

**7. ACCIDENTAL RELEASE MEASURES**

**7.1. Personal precautions protective equipment and emergency procedures:**

Refer to Section 8 for protective measures when handling the spillage.

**7.2. Environmental precautions:**

No data available.

**7.3. Methods for cleaning up:**

Collect material and dispose of waste according to Section 13.

**8. HANDLING AND STORAGE**

**8.1. Precautions for safe handling:**

Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54EC or US regulation 29 CFR 1910.1030 for information on handling biohazardous materials.

**8.2. Conditions for safe storage:**

Store in original container at 15-30°C.

**8.3. Incompatible products:**

No data available.

**9. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**9.1. Control Parameters:**

No control parameters for listed ingredients.

**9.2. Appropriate engineering controls:**

Not relevant for this material.

### 9.3. Personal Protective Equipment:

**Eye protection:**

Safety glasses recommended.

**Skin and body protection:**

Laboratory coat and disposable glove required.

**Respiratory protection:**

Not required under normal use for this product.



## 10. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Plastic device with immobilized drug detection chemistry.
Odor:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point/range:	No data available
Boiling point/range:	No data available
Flash point:	No data available
Color:	Variable depending on product
Evaporation rate:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Solubility:	Insoluble
Partition coefficient (n-octanol/water):	No data available
Auto ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available

## 11. STABILITY AND REACTIVITY

### 11.1. Reactivity

No data available.

**11.2. Stability:**

Stable under recommended storage conditions.

**11.3. Possibility of hazardous reactions:**

No data available.

**11.4. Hazardous decomposition products:**

Produces normal combustion by-products when exposed to fire.

**11.5. Incompatible materials**

Strong acids, strong bases, strong oxidizing agents.

**12. TOXICOLOGY INFORMATION**

**12.1. Likely routes of exposure:**

Ingestion, skin or eye contact.

**12.2. Symptoms related to exposure:**

No data available.

**12.3. Delayed and immediate effects:**

No data available.

**12.4. Numerical measures of toxicity:**

No data available.

**12.5. Carcinogenic effects:**

No data available.

**12.6. Mutagenic effects:**

No data available.

**12.7. Reproductive effects:**

No data available.

**13. ECOLOGICAL INFORMATION**

Not provided.

## 14. DISPOSAL CONSIDERATIONS - Waste treatment methods

**14.1. Product:** Used devices and other contaminated materials should be disposed of as potentially biohazardous waste. Disposal should be in accordance with local, state or national legislation. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

**14.2. Packaging:** Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.

## 15. TRANSPORTATION INFORMATION

Not provided.

## 16. REGULATORY INFORMATION

This product does not present a physical hazard or health hazard under reasonably anticipated circumstances of use or under emergency situations involving a release of only this product. There is no evidence that the ingredient(s) which comprise less than 1% (0.1% carcinogen) could be released from the mixture in concentrations which would exceed an OSHA PEL or ACGIH TLV, or could present a health risk. Therefore, this material is not defined as a "Hazardous Chemical" by the OSHA Hazard Communication Standard (29 CFR 1910.1200) or equivalent standards generated by State agencies.

## 17. OTHER INFORMATION

The information contained herein has been compiled from data presented in various technical sources believed to be accurate. Branam Medical Corporation makes no warranties and assumes no liability in connection with the use of this information. It is the user's responsibility to determine the suitability of this information and to assure the adoption of necessary safety precautions.

End of Safety Data Sheet