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### MATERIAL SAFETY DATA SHEETS

Catalog Number:	Kit Name:
<b>183, 183E</b>	<b>OSOM<sup>®</sup> BVBLUE<sup>®</sup> Test</b>

Item Number:	Component Name:
<b>1086</b>	<b>OSOM<sup>®</sup> BVBLUE<sup>®</sup> Developer Solution</b>
<b>675</b>	<b>OSOM<sup>®</sup> BVBLUE<sup>®</sup> Testing Vessel</b>

Note: The page numbers on the 2 individual MSDSs for this kit are specific to each document. There are a total of 16 pages including this cover sheet.



# MATERIAL SAFETY DATA SHEET

## OSOM® BVBLUE® Developer Solution

### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** OSOM® BVBLUE® Developer Solution

**Synonym(s):** Developer Solution; 1M Sodium hydroxide solution

**Product Use:** For In Vitro Diagnostic Use Only. Component of OSOM® BVBLUE® Test kit (catalog # 183 & 183E). For use in the detection of sialidase enzyme activity in vaginal fluid specimens, to aid in the diagnosis of Bacterial Vaginosis infection.

**Description:** Alkaline solution.

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**Emergency Telephone Numbers**

**Genzyme (U.S.):** 617-562-4555  
**CHEMTREC (U.S.):** 800-424-9300  
**CHEMTREC (Outside U.S.):** 703-527-3887

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### 2. HAZARDS IDENTIFICATION

**Precautionary Statements:**

WARNING! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Corrosive to the eyes, skin, and mucous membranes. Irritating to respiratory system. Avoid contact with eyes and skin. Do not ingest. Avoid aerosol or vapor inhalation. Based upon the small volume and packaging design, this preparation is considered unlikely to produce toxicity through the normal routes of occupational exposure. Preparation appearance: clear, colorless liquid.

**Routes of Exposure:**

Occupational exposure routes may include inhalation, eye and skin contact.

**Potential Health Effects:**

<b>Inhalation</b>	Corrosive! Inhalation of mist can cause irritation, coughing, shortness of breath and wheezing. Substantial inhalation can cause build-up of fluid in the lungs (pulmonary edema), a medical emergency, with severe shortness of breath.
<b>Eye</b>	Corrosive! Contact may cause irritation, severe burns, photophobia (light sensitivity), and permanent eye damage.
<b>Skin</b>	Corrosive! Skin contact causes redness, pain, burns, and ulceration. Symptoms may be delayed. Skin contact may not necessarily be followed by an immediate sensation of irritation or pain. Skin burns from dilute solution may develop slowly from prolonged contact.
<b>Ingestion</b>	Corrosive! Ingestion can cause difficulty swallowing, spontaneous vomiting, and pain and burns in the mouth, throat, and gastrointestinal tract. Symptoms may be delayed.
<b>Chronic Effects</b>	Prolonged or repeated exposure through inhalation may damage the respiratory system.
<b>Target Organs</b>	Eyes, respiratory system and skin.



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Developer Solution

**Regulatory Status:**

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

**Potential Environmental Effects:**

See Section 12.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	96
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Sodium hydroxide	1310-73-2	215-185-5	4
<b>EC R-Phrases:</b> R35	<b>EC Hazard Class:</b> C		

### 4. FIRST AID MEASURES

**Inhalation:**

If inhaled, immediately move from exposure area to fresh air. Seek immediate medical attention if breathing becomes difficult or if cough or other symptoms develop.

**Eye Contact:**

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain immediate medical attention.

**Skin Contact:**

In case of contact, immediately flush skin with copious amounts of cool water and remove contaminated clothing. Avoid spreading material on unaffected skin. Watch for delayed symptoms. Seek medical attention for skin exposures that result in pain, burns, or noticeable redness or irritation.

**Ingestion:**

In case of ingestion, contact a poison control center and seek immediate medical attention. Do not induce vomiting.

### 5. FIRE FIGHTING MEASURES

**Flammable Properties:**

Dilute aqueous solution not considered a fire hazard.

**Suitable Extinguishing Media:**

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

**Unsuitable Extinguishing Media:**

Unknown.

**Specific Hazards Arising from the Chemical:**

None known.

**Standard Protective Equipment and Precautions for Firefighters:**

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Developer Solution

#### 6. ACCIDENTAL RELEASE MEASURES

##### Personal Precautions:

Avoid physical contact with material and avoid aerosol inhalation. Wear Personal Protective Equipment (PPE) as indicated in Section 8. Ensure adequate ventilation. Wash hands thoroughly after handling. Change into clean clothes promptly if clothing has been contaminated.

##### Environmental Precautions:

Follow federal, state, local and provincial environmental regulations.

##### Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent or appropriate neutralizing agent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

#### 7. HANDLING AND STORAGE

##### Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

##### Storage:

Store at 2 - 8°C (36 - 46°F). Keep containers tightly closed in a dry, cool and well-ventilated place. Do not store with incompatible substances; see Section 10.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

##### Exposure Guidelines:

###### ACGIH - Threshold Limits Values - Ceilings (TLV-C)

Sodium hydroxide 1310-73-2 2 mg/m3 Ceiling

###### Canada - Quebec - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m3 Ceiling

###### Israel - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m3 Ceiling

###### Japan - Recommended Exposure Limits - Ceiling Limits

Sodium hydroxide 1310-73-2 2 mg/m3 Ceiling

###### Korea - Occupational Exposure Limits - Ceilings

Sodium hydroxide 1310-73-2 2 mg/m3 Ceiling

###### U.S. - OSHA - Final PELs - Time Weighted Averages (TWAs)

Sodium hydroxide 1310-73-2 2 mg/m3 TWA

##### Engineering Controls:

Minimize potential for aerosolization. Handle within a containment system, with local exhaust ventilation, or with dilution ventilation at a minimum. Facilities storing or using this preparation should be equipped with an eyewash fountain.

##### Personal Protective Equipment (PPE):

###### Respiratory

A respirator is not required under normal conditions of use. A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, European Standard CR 529, or other applicable regulatory standards should be followed whenever exposure limits may be exceeded (if applicable) and engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant the use of respiratory protection.

###### Eye/Face

Wear appropriate protective chemical safety goggles. If splashes are likely to occur, wear a face shield as well.



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Developer Solution

#### Personal Protective Equipment (PPE):

<b>Skin</b>	Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over clothing to minimize contact and contamination of clothing. Select additional impervious protective clothing based on volume of material used and activity. Change into clean clothes promptly if clothing becomes contaminated.
<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colorless liquid	<b>pH:</b>	13 - 14
<b>Odor:</b>	Odorless	<b>Solubility:</b>	Miscible in water
<b>Specific Gravity:</b>	1.02 - 1.05	<b>Vapor Pressure:</b>	Not available
<b>Boiling Point:</b>	101 °C (213.8 °F) (approx.)	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Vapor Density:</b>	Not available
<b>Freezing Point:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not applicable		
<b>Flash Point:</b>	Not available		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

Stable under ordinary conditions of use and storage; (see handling and storage information in Section 7).

#### Conditions to Avoid:

Unknown.

#### Incompatible Materials:

##### Physical Properties - Chemical Incompatibilities

Sodium hydroxide	1310-73-2	Water, acids, flammable liquids, organic halogens, metals: aluminum, tin, zinc; nitromethane and nitro compounds
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#### Hazardous Decomposition Products:

None expected under normal conditions of use.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Developer Solution

#### Acute Effects:

The following irritation data is for sodium hydroxide:

Based on human data, concentrations of 0.5-4.0% were irritating to the skin. Eye irritation data are available for animals. The non-irritant level was 0.2-1.0%, while the corrosive concentration was 1.2% or higher.

#### Eye Irritation/Corrosion:

Rabbit, EPA Criteria, 0.1 mL dose, 0.004-0.2%: Not Irritating; 0.4%: Mildly Irritating; 1.2%: Corrosive.

Rabbit, Modified Draize Test, 0.1 and 0.3%: No conjunctivitis nor iritis; 1.0 and 3%: Conjunctivitis and iritis

Rabbit, OECD Guideline 405, 1%: Not Irritating; 2%: Irritating

#### Skin Irritation/Corrosion:

Human, Patch Test, 0.2 mL dose, 0.5%: Irritating for 55% of volunteers

Human, Patch Test, 0.2 mL, 0.5%: Irritating for 61% of volunteers

Human, Different Protocols, 1.0%: Irritating for ~50% of volunteers

Human, Filter Paper Discs, 0.5 and 1.0%: Irritating

#### Toxicology Data - Selected LD50s and LC50s

Sodium hydroxide 1310-73-2 Dermal LD50 Rabbit: 1350 mg/kg

#### Chronic Effects:

Prolonged or repeated exposure through inhalation may damage the respiratory system.

#### Carcinogenicity:

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

#### Mutagenicity:

No evidence for mutagenic activity. (Sodium hydroxide)

#### Teratogenicity:

No risk for developmental toxicity. (Sodium hydroxide)

#### Reproductive Effects:

No risk for toxicity to reproduction. (Sodium hydroxide)

#### Sensitization:

Data indicates that sodium hydroxide is not a skin sensitizer.

## 12. ECOLOGICAL INFORMATION

#### Ecotoxicity:

##### Ecotoxicity - Freshwater Fish Species Data

Sodium hydroxide 1310-73-2 96 Hr LC50 Oncorhynchus mykiss: 45.4 mg/L [static]

#### Persistence and Degradability:

No data available.

#### Bioaccumulative Potential:

No data available.

#### Mobility in Environmental Media:

No data available.

**MATERIAL SAFETY DATA SHEET**  
**OSOM® BVBLUE® Developer Solution**

**13. DISPOSAL CONSIDERATIONS**

**Methods of Disposal:**

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

**Waste Classification:**

**U.S. - California - 22 CCR - Presumed Hazardous Wastes**

Sodium hydroxide 1310-73-2 Toxic; Corrosive

**14. TRANSPORT INFORMATION**

**DOT**

**Proper Shipping Name** Sodium hydroxide solution

**Hazard Class** 8

**UN Number** UN1824

**Packaging Group** III



**Basic Shipping Description:**

International Air Transport Association (IATA) Dangerous Goods Classification

UN Number: UN 3316

Proper Shipping Name: Chemical Kit

Hazard Class: 9

Hazard Label: Miscellaneous

**15. REGULATORY INFORMATION**

**US Federal Regulations:**

This preparation is a component of an FDA-regulated in vitro diagnostic device.

**Inventory - United States - Section 8(b) Inventory (TSCA)**

Sodium hydroxide 1310-73-2 Present

**U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

Sodium hydroxide 1310-73-2 1000 lb final RQ; 454 kg final RQ

**US State Regulations:**

**U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances**

Sodium hydroxide 1310-73-2 Present

# MATERIAL SAFETY DATA SHEET

## OSOM® BVBLUE® Developer Solution

**International Regulations:**

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

**Canada - WHMIS - Classifications of Substances**

Sodium hydroxide	1310-73-2	E (including 0.08%, 2%, 2.5%, 5%, 0.01 N, 0.04 N, 0.1 N, 10%, 16%, 1 N, 20%, 40%, 50%, 8.7N)
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**Canada - WHMIS - Ingredient Disclosure List**

Sodium hydroxide	1310-73-2	1 %
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**EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification**

Sodium hydroxide	1310-73-2	C;R35
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**EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Concentration Limits**

Sodium hydroxide	1310-73-2	5%≤C: C; R35□2%≤C<5%: C; R34□0.5%≤C<2%: Xi; R36/38
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**EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases**

Sodium hydroxide	1310-73-2	S:1/2-26-37/39-45
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**Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Sodium hydroxide	1310-73-2	ID Number 142, hazard class 1 - low hazard to waters (footnote 8)
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**Inventory - Australia - Inventory of Chemical Substances (AICS)**

Sodium hydroxide	1310-73-2	Present
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**Inventory - Canada - Domestic Substances List (DSL)**

Sodium hydroxide	1310-73-2	Present
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**Inventory - China**

Sodium hydroxide	1310-73-2	Present
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**Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)**

Sodium hydroxide	1310-73-2	215-185-5
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**Inventory - Japan Existing and New Chemical Substances (ENCS)**

Sodium hydroxide	1310-73-2	1-410; 2-1972
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**Inventory - Korea - Existing and Evaluated Chemical Substances**

Sodium hydroxide	1310-73-2	KE-31487
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**Canadian Hazardous Products:**

**WHMIS Status**                      Controlled

**Classification**

E - Corrosive



**European Communities Dangerous Substances/Preparations:**

**EC Hazard Class**                      C - Corrosive

**Symbols**



**Risk Phrases**

R34                                      Causes burns.

**Safety Phrases**

S26                                      In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37/39                                  Wear suitable gloves and eye/face protection.

S45                                      In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**16. OTHER INFORMATION**





## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Developer Solution

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**Further Information:**

BVBLUE® is a registered trademark of Gryphus Diagnostics, LLC.

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals.

**MSDS Origination Date:** June 03, 2004

**Version #:** 4

**Revision Date:** August 06, 2008

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**MATERIAL SAFETY DATA SHEET**  
**OSOM® BVBLUE® Testing Vessel**

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** OSOM® BVBLUE® Testing Vessel

**Synonym(s):** Testing Vessel

**Product Use:** For In Vitro Diagnostic Use Only. Component of OSOM® BVBLUE® Test kit (catalog # 183 & 183E). For use in the detection of sialidase enzyme activity in vaginal fluid specimens, to aid in the diagnosis of Bacterial Vaginosis infection.

**Description:** Aqueous salt solution containing a chromogenic substrate of the sialidase enzyme.

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**Emergency Telephone Numbers**

**Genzyme (U.S.):** 617-562-4555

**CHEMTREC (U.S.):** 800-424-9300

**CHEMTREC (Outside U.S.):** 703-527-3887

**2. HAZARDS IDENTIFICATION**

**Precautionary Statements:**

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May be irritating to eyes and skin. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear liquid.

**Routes of Exposure:**

Occupational exposure routes may include eye and skin contact.

**Potential Health Effects:**

<b>Inhalation</b>	No data available.
<b>Eye</b>	No data available.
<b>Skin</b>	No data available.
<b>Ingestion</b>	Ingestion of potassium acetate produces a diuretic effect (increased urination).
<b>Chronic Effects</b>	No data available.
<b>Target Organs</b>	Unknown.

**Regulatory Status:**

This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Testing Vessel

**Potential Environmental Effects:**

Unknown.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	95
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Potassium acetate	127-08-2	204-822-2	4.9
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
IBX-4041 (chromogenic substrate compound)	Not Assigned	Not Assigned	0.05
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		

### 4. FIRST AID MEASURES

**Inhalation:**

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

**Eye Contact:**

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

**Skin Contact:**

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

**Ingestion:**

In case of ingestion, contact a poison control center or physician for instructions.

### 5. FIRE FIGHTING MEASURES

**Flammable Properties:**

Dilute aqueous solution not considered a fire hazard.

**Suitable Extinguishing Media:**

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

**Unsuitable Extinguishing Media:**

Unknown.

**Specific Hazards Arising from the Chemical:**

None expected.

**Standard Protective Equipment and Precautions for Firefighters:**

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Testing Vessel

#### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:**

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material and avoid aerosol inhalation. Wash hands thoroughly after handling.

**Environmental Precautions:**

No information available.

**Methods and Materials for Containment and Clean-Up:**

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

#### 7. HANDLING AND STORAGE

**Handling:**

Follow good laboratory hygiene practices. Minimize contact and contamination of personal clothing and skin. See Section 8, Engineering Controls. Wash hands thoroughly after handling.

**Storage:**

Store at 2 - 8°C (36 - 46°F). Do not store with incompatible substances; see Section 10.

#### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Guidelines:**

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

**Engineering Controls:**

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

**Personal Protective Equipment (PPE):**

<b>Respiratory</b>	A respirator is not required under normal conditions of use.
<b>Eye/Face</b>	Wear appropriate protective chemical safety glasses.
<b>Skin</b>	Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over clothing to minimize contact and contamination of clothing. Change into clean clothes promptly if clothing becomes contaminated.
<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear liquid	<b>pH:</b>	5.5 - 6.0
<b>Odor:</b>	Not available	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Vapor Pressure:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Freezing Point:</b>	No available	<b>Vapor Density:</b>	Not available



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Testing Vessel

**Flammability/Explosivity Limits in Air, Lower:** Not available  
**Flammability/Explosivity Limits in Air, Upper:** Not available  
**Auto-Ignition Temperature:** Not applicable  
**Flash Point:** Not available

## 10. STABILITY AND REACTIVITY

### Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

### Conditions to Avoid:

Unknown.

### Incompatible Materials:

Unknown.

### Hazardous Decomposition Products:

None expected under normal conditions of use.

### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

## 11. TOXICOLOGICAL INFORMATION

### Acute Effects:

#### Toxicology Data - Selected LD50s and LC50s

Potassium acetate 127-08-2 Oral LD50 Rat: 3250 mg/kg

### Local Effects:

No data available.

### Chronic Effects:

No data available.

### Carcinogenicity:

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

### Mutagenicity:

No data available.

### Teratogenicity:

No data available.

### Reproductive Effects:

No data available.

### Sensitization:

No data available.

## 12. ECOLOGICAL INFORMATION



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Testing Vessel

#### Ecotoxicity:

##### Ecotoxicity - Freshwater Fish Species Data

Potassium acetate 127-08-2 96 Hr LC50 Oncorhynchus mykiss: 6800 mg/L [semi-static]

##### Ecotoxicity - Water Flea Data

Potassium acetate 127-08-2 24 Hr EC50 Daphnia magna: 7170 mg/L

#### Persistence and Degradability:

No data available.

#### Bioaccumulative Potential:

No data available.

#### Mobility in Environmental Media:

No data available.

### 13. DISPOSAL CONSIDERATIONS

#### Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

### 14. TRANSPORT INFORMATION

#### Basic Shipping Description:

International Air Transport Association (IATA) Dangerous Goods Classification

UN Number: UN 3316

Proper Shipping Name: Chemical Kit

Hazard Class: 9

Hazard Label: Miscellaneous

### 15. REGULATORY INFORMATION

#### US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

#### Inventory - United States - Section 8(b) Inventory (TSCA)

Potassium acetate 127-08-2 Present



# MATERIAL SAFETY DATA SHEET

## OSOM® BVBLUE® Testing Vessel

### International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

#### **Canada - WHMIS - Classifications of Substances**

Potassium acetate	127-08-2	Uncontrolled product according to WHMIS classification criteria
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#### **Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes**

Potassium acetate	127-08-2	ID Number 757, hazard class 1 - low hazard to waters
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#### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

Potassium acetate	127-08-2	Present
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#### **Inventory - Canada - Domestic Substances List (DSL)**

Potassium acetate	127-08-2	Present
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#### **Inventory - China**

Potassium acetate	127-08-2	Present
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#### **Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)**

Potassium acetate	127-08-2	204-822-2
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#### **Inventory - Japan Existing and New Chemical Substances (ENCS)**

Potassium acetate	127-08-2	2-692
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#### **Inventory - Korea - Existing and Evaluated Chemical Substances**

Potassium acetate	127-08-2	KE-29069
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#### **Canadian Hazardous Products:**

<b>WHMIS Status</b>	Non-controlled
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#### **European Communities Dangerous Substances/Preparations:**

**EC Hazard Class** None

**Risk Phrases** None

**Safety Phrases** None

## 16. OTHER INFORMATION

#### **Further Information:**

BVBLUE® is a registered trademark of Gryphus Diagnostics, LLC.

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals.

**MSDS Origination Date:** June 03, 2004

**Version #:** 4

**Revision Date:** August 06, 2008



## MATERIAL SAFETY DATA SHEET

### OSOM® BVBLUE® Testing Vessel

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