1. Product and Company Identification

Material name: OSOM® BVBLUE® Developer Solution

Version #: 01
Issue date: 05-24-2013
Revision date: -
Supersedes date: -
CAS #: Mixture
Kit number: 183; 183-5
Product use: 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.

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

Manufacturer information
Corporate Headquarters: Sekisui Diagnostics, LLC
4 Hartwell Place, Lexington, MA 02421, USA
www.sekisuidiagnostics.com
Phone: 800-332-1042

Emergency Telephone Numbers
Americas 1-760-476-3962
Europe, Middle East & Africa +1-760-476-3961
Asia Pacific +1-760-476-3960
Access code 333512

2. Hazards Identification

Physical state: Liquid.
Appearance: Clear, colorless liquid.
Emergency overview: DANGER

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized.
Causes skin and eye burns. Prolonged exposure may cause chronic effects.

OSHA regulatory status: This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).

Potential health effects
Routes of exposure
Eyes: This product causes eye burns.
Skin: Causes skin burns.
Inhalation: In high concentrations, mists/vapors may irritate throat and respiratory system and cause coughing.

Ingestion: Can burn mouth, throat, and stomach.

Target organs: Eyes. Respiratory system. Skin. Gastro-intestinal tract
Chronic effects: Prolonged skin contact may defat the skin and produce dermatitis.
Signs and symptoms: May cause burns in mucous membranes, throat, esophagus and stomach.

Potential environmental effects: The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS #</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>3 - 5</td>
</tr>
</tbody>
</table>

Composition comments: All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.
4. First Aid Measures

First aid procedures

Eye contact
Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.

Skin contact
Immediately flush thoroughly with water for at least 15 minutes. Get medical attention if irritation develops and persists.

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Get medical attention immediately.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Notes to physician
Symptoms may be delayed.

General advice
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties
This product is not flammable.

Extinguishing media
Suitable extinguishing media
Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media
None known.

Protection of firefighters
Specific hazards arising from the chemical
None known.

Protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products
Hydrogen chloride gas.

6. Accidental Release Measures

Personal precautions
Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions
Do not allow to enter drains, sewers or watercourses.

Methods for containment
Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up
Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information
Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling
Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

Storage
Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (CAS 1310-73-2)</td>
<td>Ceiling</td>
<td>2 mg/m3</td>
</tr>
</tbody>
</table>
### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (CAS 1310-73-2)</td>
<td>PEL</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

### Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (CAS 1310-73-2)</td>
<td>Ceiling</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

### Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (CAS 1310-73-2)</td>
<td>Ceiling</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

### Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (CAS 1310-73-2)</td>
<td>Ceiling</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

### Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (CAS 1310-73-2)</td>
<td>Ceiling</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

### Mexico. Occupational Exposure Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (CAS 1310-73-2)</td>
<td>Ceiling</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

#### Exposure guidelines
Follow standard monitoring procedures.

#### Engineering controls
Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

#### Personal protective equipment
- **Eye / face protection**: Wear approved safety glasses or goggles.
- **Skin protection**: Wear lab coat or other protective garments. Remove contaminated clothing promptly.
- **Respiratory protection**: Under normal conditions, respirator is not normally required.
- **General hygiene considerations**: Handle in accordance with good industrial hygiene and safety practice.

### 9. Physical & Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Clear, colorless liquid.</td>
</tr>
<tr>
<td><strong>Physical state</strong></td>
<td>Liquid.</td>
</tr>
<tr>
<td><strong>Form</strong></td>
<td>Liquid.</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Clear, colorless.</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless.</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>13 - 14</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Vapor density</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Boiling point</strong></td>
<td>213.8 °F (101 °C) Approx.</td>
</tr>
<tr>
<td><strong>Melting point/Freezing point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Solubility (water)</strong></td>
<td>Miscible in water</td>
</tr>
<tr>
<td><strong>Specific gravity</strong></td>
<td>1.02 - 1.05</td>
</tr>
</tbody>
</table>
Flash point Not available.
Flammability limits in air, upper, % by volume Not available.
Flammability limits in air, lower, % by volume Not available.
Auto-ignition temperature Not applicable

10. Chemical Stability & Reactivity Information
Chemical stability Stable under normal storage and handling conditions.
Conditions to avoid None under normal conditions.
Incompatible materials Strong bases.
Hazardous decomposition products No data available.
Possibility of hazardous reactions Hazardous polymerization does not occur.

11. Toxicological Information
Sensitization Not a skin sensitizer.
Acute effects Hydrochloric acid solutions can readily release high concentrations of hydrogen chloride gas, which is very toxic and corrosive and poses a serious inhalation hazard.
Local effects Irritating to respiratory system.
Chronic effects Prolonged skin contact may defat the skin and produce dermatitis.
Carcinogenicity Not classified.
Epidemiology Not available.
Mutagenicity No data available.
Neurological effects Not available.
Reproductive effects No data available.
Teratogenicity Not available.
Symptoms and target organs May cause burns in mucous membranes, throat, esophagus and stomach.
Further information No other specific acute or chronic health impact noted.

12. Ecological Information
Ecotoxicological data
Components Sodium hydroxide (CAS 1310-73-2)
Species Water flea (Ceriodaphnia dubia), Western mosquitofish (Gambusia affinis)
Test Results 34.59 - 47.13 mg/l, 48 hours, 125 mg/l, 96 hours

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Environmental effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Aquatic toxicity Not classified.
Persistence and degradability No data is available on the degradability of this product.
Bioaccumulation / Accumulation Not available.
Mobility in environmental media This product is miscible in water.

13. Disposal Considerations
Disposal instructions Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency.
Waste from residues / unused products Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport Information

DOT

Basic shipping requirements:
- UN number: UN1824
- Proper shipping name: Sodium hydroxide solution
- Hazard class: 8
- Packing group: II
- Environmental hazards: No

Additional information:
- Marine pollutant: No
- Special provisions: B2, IB2, N34, T7, TP2
- Packaging exceptions: 154
- Packaging non bulk: 202
- Packaging bulk: 242

IATA

UN number: UN1824
- UN proper shipping name: Sodium hydroxide solution
- Transport hazard class(es): 8
- Packing group: II
- Environmental hazards: No

ERG code: 8L

IMDG

UN number: UN1824
- UN proper shipping name: SODIUM HYDROXIDE SOLUTION
- Transport hazard class(es): 8
- Packing group: II
- Environmental hazards: No

EmS: F-A, S-B

TDG

UN number: UN1824
- Proper shipping name: SODIUM HYDROXIDE SOLUTION
- Hazard class: 8
- Packing group: II
- Marine pollutant: No

15. Regulatory Information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Sodium hydroxide: 1000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
- Immediate Hazard - Yes
- Delayed Hazard - Yes
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A)

No

SARA 311/312 Hazardous chemical

Yes
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)

Canadian regulations
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status
Controlled

WHMIS classification
E - Corrosive

Inventory status

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

State regulations
This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance
Sodium hydroxide (CAS 1310-73-2) Listed.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance
Not listed.

US - New Jersey RTK - Substances: Listed substance
Sodium hydroxide (CAS 1310-73-2) Listed.

US. Massachusetts RTK - Substance List
Sodium hydroxide (CAS 1310-73-2) Listed.

US. New Jersey Worker and Community Right-to-Know Act
Not regulated.

US. Pennsylvania RTK - Hazardous Substances
Sodium hydroxide (CAS 1310-73-2) Listed.

Mexico regulations
This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions
Use in accordance with supplier's recommendations.

Further information
HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 3*
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 3
Flammability: 0
Instability: 0
Disclaimer

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1. Product and Company Identification

Material name: OSOM® BVBLUE® Testing Vessel
Version #: 01
Issue date: 09-04-2012
Revision date: -
Supersedes date: -
CAS #: Mixture
Kit number: 183; 183-5
Product use: 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. For In Vitro Diagnostic use only.
Synonym(s): Testing Vessel
Manufacturer information
Corporate Headquarters: Sekisui Diagnostics, LLC
31 New York Avenue, Framingham, MA 01701 USA
www.sekisuidiagnostics.com
Phone: 800-332-1042
Emergency Telephone Numbers
Americas 1-760-476-3962
Europe, Middle East & Africa +1-760-476-3961
Asia Pacific +1-760-476-3960
Access code 333512

2. Hazards Identification

Physical state: Liquid.
Appearance: Clear liquid.
Emergency overview: The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized.
OSHA regulatory status: This product is not hazardous according to OSHA 29CFR 1910.1200.
Potential health effects
Routes of exposure: Skin contact. Eye contact.
Eyes: May cause eye irritation.
Skin: May cause skin irritation.
Inhalation: In high concentrations, vapors may be irritating to the respiratory system.
Ingestion: May cause discomfort if swallowed.
Target organs: Eyes.
Chronic effects: No data available.
Signs and symptoms: Direct contact with skin and eyes may cause irritation.
Potential environmental effects: The product components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

4. First Aid Measures

First aid procedures
Eye contact: In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin contact: For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
Inhalation
Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion
If material is ingested, immediately contact a poison control center.

Notes to physician
Provide general supportive measures and treat symptomatically.

General advice
Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures
Flammable properties
This product is not flammable.

Extinguishing media
Suitable extinguishing media
Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media
None known.

Protection of firefighters
Specific hazards arising from the chemical
None known.

Protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Use standard firefighting procedures and consider the hazards of other involved materials.

Hazardous combustion products
None known.

6. Accidental Release Measures
Personal precautions
Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions
Do not allow to enter drains, sewers or watercourses.

Methods for containment
Absorb spillage with non-combustible, absorbent material.

Methods for cleaning up
Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

Other information
Clean up in accordance with all applicable regulations.

7. Handling and Storage
Handling
Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

Storage
Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

8. Exposure Controls / Personal Protection
Occupational exposure limits
No exposure limits noted for ingredient(s).

Exposure guidelines
Follow standard monitoring procedures.

Engineering controls
Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.

Personal protective equipment
Eye / face protection
Wear approved safety glasses or goggles.

Skin protection
Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection
Under normal conditions, respirator is not normally required.

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties
Appearance
Clear liquid.

Physical state
Liquid.

Form
Liquid.

Color
Clear.

Odor
Not available.
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor threshold</td>
<td>Not available.</td>
</tr>
<tr>
<td>pH</td>
<td>5.5 - 6</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Boiling point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting point/Freezing point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility (water)</td>
<td>Soluble</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limits in air, upper, % by volume</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limits in air, lower, % by volume</td>
<td>Not available.</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### 10. Chemical Stability & Reactivity Information

- **Chemical stability**: Material is stable under normal conditions.
- **Conditions to avoid**: Avoid high temperatures.
- **Incompatible materials**: Strong oxidizers, strong acids, and strong bases.
- **Hazardous decomposition products**: None known.
- **Possibility of hazardous reactions**: Hazardous polymerization does not occur.

### 11. Toxicological Information

- **Sensitization**: Not classified.
- **Acute effects**: May cause discomfort if swallowed.
- **Local effects**: Ingestion may cause irritation and malaise.
- **Chronic effects**: No data available.
- **Carcinogenicity**: Not classifiable as to carcinogenicity to humans.
- **Epidemiology**: No epidemiological data is available for this product.
- **Mutagenicity**: Not classified.
- **Reproductive effects**: Not classified.
- **Symptoms and target organs**: Direct contact with skin and eyes may cause irritation.
- **Further information**: No other specific acute or chronic health impact noted.

### 12. Ecological Information

- **Ecotoxicity**: The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
- **Environmental effects**: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
- **Persistence and degradability**: No data is available on the degradability of this product.
- **Bioaccumulation / Accumulation**: Not available.
- **Mobility in environmental media**: The product is completely soluble in water.

### 13. Disposal Considerations

- **Disposal instructions**: Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
- **Waste from residues / unused products**: Dispose in accordance with all applicable regulations.
- **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal.
14. Transport Information

DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

TDG
Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations
This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)
None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th>Immediate Hazard - No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Delayed Hazard - No</td>
</tr>
<tr>
<td></td>
<td>Fire Hazard - No</td>
</tr>
<tr>
<td></td>
<td>Pressure Hazard - No</td>
</tr>
<tr>
<td></td>
<td>Reactivity Hazard - No</td>
</tr>
</tbody>
</table>

Section 302 extremely hazardous substance (40 CFR 355, Appendix A) No

Section 311/312 (40 CFR 370) No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)
Not controlled

Canadian regulations
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status
Non-controlled

Inventory status

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

State regulations
This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.
US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance
Not listed.

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not regulated.

US. Pennsylvania RTK - Hazardous Substances
Not regulated.

Mexico regulations
This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions
Use in accordance with supplier's recommendations.

Further information
HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 0
Flammability: 0
Instability: 0

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