MATERIAL SAFETY DATA SHEET



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

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Emergency Telephone

Numbers

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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 overviewThe 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 exposureSkin contact. Eye contact.EyesMay cause eye irritation.SkinMay 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 irritiation.

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.

OSOM® BVBLUE® Testing Vessel CPH MSDS NA

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.

None known.

Protection of firefighters

Specific hazards arising

from the chemical

Protective equipment and

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Use standard firefighting procedures and consider the hazards of other involved materials.

precautions for firefighters Fire fighting

equipment/instructions

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.

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of **Engineering controls**

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.

OSOM® BVBLUE® Testing Vessel 906219 Version #: 01 Revision date: - Issue date: 09-04-2012 Odor threshold Not available.

pH 5.5 - 6

Vapor pressureNot available.Vapor densityNot available.Boiling pointNot available.Melting point/Freezing pointNot applicable

Solubility (water) Soluble

Specific gravityNot available.Flash pointNot available.Flammability limits in air,Not available.

Flammability limits in air upper, % by volume

Flammability limits in air,

Not available.

lower, % by volume
Auto-ignition temperature

Not applicable

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.

CarcinogenicityNot classifiable as to carcinogenicity to humans.EpidemiologyNo epidemiological data is available for this product.

MutagenicityNot classified.Reproductive effectsNot classified.

Symptoms and target organs Direct contact with skin and eyes may cause irritiation.

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 / Not available.

Accumulation

nulation

Mobility in environmental

media

The product is completely soluble in water.

13. Disposal Considerations

Disposal instructionsContaminated 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.

OSOM® BVBLUE® Testing Vessel

3/5

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)

Hazard categories Immediate Hazard - No

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

Section 302 extremely hazardous substance (40

hazardous substance (4 CFR 355, Appendix A)

Section 311/312 (40 CFR No

370)

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

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes
*A "Yes" indicates this product co	amplies with the inventory requirements administered by the governing country(s)	

*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.

OSOM® BVBLUE® Testing Vessel

906219 Version #: 01 Revision date: - Issue date: 09-04-2012

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

Flammability: 0 Physical hazard: 0

NFPA ratings Health: 0

Flammability: 0 Instability: 0

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best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE,

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5/5