MATERIAL SAFETY DATA SHEET

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	Inhalation. Ingestion. Skin contact. Eye contact.
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

Components	CAS #	Percent
Sodium hydroxide	1310-73-2	3 - 5

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

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	PEL	2 mg/m3

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

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

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

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

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

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

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

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

Mexico. Occupational Exposure Limit Values

Components	Type	Value
Sodium hydroxide (CAS 1310-73-2)	Ceiling	2 mg/m3

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

Appearance Clear, colorless liquid.

Physical state Liquid.

Form Liquid.

Color Clear, colorless.

Odor Odorless.

Odor threshold Not available.

pH 13 - 14

Vapor pressure Not available.

Vapor density Not available.

Boiling point 213.8 °F (101 °C) Approx.

Melting point/Freezing point Not applicable

Solubility (water) Miscible in water

Specific gravity 1.02 - 1.05

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		Species	Test Results
Sodium hydroxide (CAS 1310-73-2)			
Aquatic			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	34.59 - 47.13 mg/l, 48 hours
Fish	LC50	Western mosquitofish (Gambusia affinis)	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	
Marine pollutant	No
Additional information:	
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	
Marine pollutant	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) 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 Controlled

WHMIS classification E - Corrosive

WHMIS labeling

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 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

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Sekisui Diagnostics be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Sekisui Diagnostics has been advised of the possibility of such damages.