

SECTION 1: Identification

1.1. Identification

Product form	: Mixture
Product name	: OSOM® BVBLUE® Developer Solution
Product code	: 183; 183-5
Synonyms	: Developer Solution; 1M Sodium hydroxide solution

1.2. Recommended use and restrictions on use

Use of the substance/mixture	: 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 in vitro diagnostics
Restrictions on use	: Restricted to professional users

1.3. Supplier

Sekisui Diagnostics, LLC
6659 Top Gun Street, San Diego, CA 92121, USA
Tel. +1-858-777-2600
Sekisui Diagnostics P.E.I. Inc.
70 Watts Avenue, Charlottetown Prince Edward Island, C1E 2B9 Canada
Tel. 800-565-0265
Sekisui Diagnostics (UK) Limited
Liphook Way, Allington, Maidstone, Kent ME16 0LQ
Tel. +44 (0) 1622 607800
www.sekisuidiagnostics.com
Contact person: info@sekisuidiagnostics.com

1.4. Emergency telephone number

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

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin corrosion/irritation Category 1B	H314 Causes severe skin burns and eye damage
Serious eye damage/eye irritation Category 1	H318 Causes serious eye damage
Full text of H statements	: see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US)



Signal word (GHS US)

: Danger

Hazard statements (GHS US)

: H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage

Precautionary statements (GHS US)

: P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

OSOM® BVBLUE® Developer Solution

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a poison center or doctor.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P363 - Wash contaminated clothing before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
sodium hydroxide, caustic soda	(CAS No) 1310-73-2	2 - 5	Skin Corr. 1A, H314

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures general : Call a physician immediately.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. Call a physician immediately.
First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.
First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Call a physician immediately.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after skin contact : Burns.
Symptoms/effects after eye contact : Serious damage to eyes.
Symptoms/effects after ingestion : Burns.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Exercise caution. Spill area may be slippery. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapors/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

OSOM® BVBLUE® Developer Solution

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapors/spray. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store locked up. Store in a well-ventilated place. Keep cool.
Storage temperature : 2 – 8 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OSOM® BVBLUE® Developer Solution	
No additional information available	
sodium hydroxide, caustic soda (1310-73-2)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Sodium hydroxide
ACGIH Ceiling (mg/m ³)	2 mg/m ³
Remark (ACGIH)	TLV® Basis: URT, eye, & skin irr
Regulatory reference	ACGIH 2020
USA - OSHA - Occupational Exposure Limits	
Local name	Sodium hydroxide
OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Type	Material	Permeation	Thickness (mm)	Penetration
Disposable gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0.11	

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment.

Personal protective equipment symbol(s):

OSOM® BVBLUE® Developer Solution

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless.
Odor	: Odorless
Odor threshold	: No data available
pH	: 13 – 14
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: ≈ 101 °C
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: 1.02 – 1.04
Solubility	: Soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: Product is not explosive.
Oxidizing properties	: Not oxidising.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified

OSOM® BVBLUE® Developer Solution

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Causes severe skin burns. pH: 13 – 14
Serious eye damage/irritation	: Causes serious eye damage. pH: 13 – 14
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects after skin contact	: Burns.
Symptoms/effects after eye contact	: Serious damage to eyes.
Symptoms/effects after ingestion	: Burns.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Before neutralisation, the product may represent a danger to aquatic organisms.

sodium hydroxide, caustic soda (1310-73-2)	
EC50 Daphnia 1	40.4 mg/l Ceriodaphnia sp.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Transport document description	: UN1824 Sodium hydroxide solution, 8, II
UN-No.(DOT)	: UN1824
Proper Shipping Name (DOT)	: Sodium hydroxide solution
Class (DOT)	: 8 - Class 8 - Corrosive material 49 CFR 173.136
Packing group (DOT)	: II - Medium Danger

OSOM® BVBLUE® Developer Solution

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Hazard labels (DOT) : 8 - Corrosive



Other information : No supplementary information available.

Transportation of Dangerous Goods

Transport document description : UN1824 SODIUM HYDROXIDE SOLUTION, 8, II
UN-No. (TDG) : UN1824
Proper Shipping Name (Transportation of Dangerous Goods) : SODIUM HYDROXIDE SOLUTION
TDG Primary Hazard Classes : 8 - Class 8 - Corrosives
Packing group : II - Medium Danger
Passenger Carrying Road Vehicle or Passenger Carrying Railway Vehicle Index : 1 L

Transport by sea

Transport document description (IMDG) : UN 1824 SODIUM HYDROXIDE SOLUTION, 8, II
UN-No. (IMDG) : 1824
Proper Shipping Name (IMDG) : SODIUM HYDROXIDE SOLUTION
Class (IMDG) : 8 - Corrosive substances
Packing group (IMDG) : II - substances presenting medium danger

Air transport

Transport document description (IATA) : UN 1824 Sodium hydroxide solution, 8, II
UN-No. (IATA) : 1824
Proper Shipping Name (IATA) : Sodium hydroxide solution
Class (IATA) : 8 - Corrosives
Packing group (IATA) : II - Medium Danger

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

sodium hydroxide, caustic soda (1310-73-2)

CERCLA RQ	1000 lb
-----------	---------

15.2. International regulations

CANADA

sodium hydroxide, caustic soda (1310-73-2)

Listed on the Canadian DSL (Domestic Substances List) inventory.

EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

Reference code	Applicable	Entry title or description
3(b)	OSOM® BVBLUE® Developer Solution	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

OSOM® BVBLUE® Developer Solution

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance(s) subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

National regulations

No additional information available

15.3. US State regulations

Component	State or local regulations
sodium hydroxide, caustic soda(1310-73-2)	U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities; U.S. - New York City - Right to Know Hazardous Substances List

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date : 10/23/2020

Full text of H-phrases:

H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

NFPA health hazard

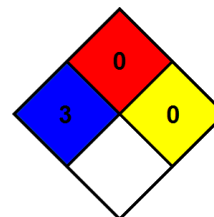
: 3 - Materials that, under emergency conditions, can cause serious or permanent injury.

NFPA fire hazard

: 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity

: 0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating

Health : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given

Flammability : 0 Minimal Hazard - Materials that will not burn

Physical : 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

Personal protection

: B
B - Safety glasses, Gloves

Indication of changes:

Section	Changed item	Change	Comments
2.1	GHS-US classification	Modified	

SDS US (GHS HazCom 2012)

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.