

1. Product and Company Identification

Material name	OSOM® BVBLUE® Positive Control
Version #	01
Issue date	05-24-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number	184
Product use	Component of OSOM® BVBLUE® Control Kit (catalog # 184 & 184E). For external quality control testing. For In Vitro Diagnostic use only.
Synonym(s)	Positive Control
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	WARNING The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May cause allergic respiratory reaction.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Inhalation. Eye contact. Skin contact.
Eyes	May cause itching and redness.
Skin	Contact may cause irritation, redness and/or drying.
Inhalation	May cause respiratory tract irritation. May cause allergic respiratory reaction. Although there is no evidence that the enzyme(s) in this preparation induces specific respiratory hypersensitivity, all proteins are potential respiratory allergens and may result in respiratory sensitization in certain individuals after repeated and/or prolonged inhalation exposure, producing mild to severe symptoms similar to pollen allergy or asthma, including mucous membrane or eye irritation, itching of the skin or eyes, sneezing, nasal or sinus congestion, coughing, and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.
Ingestion	May cause discomfort if swallowed.
Target organs	Respiratory system
Chronic effects	Inhalation may result in respiratory sensitization.
Signs and symptoms	Irritation of eyes and mucous membranes.
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

Components	CAS #	Percent
Neuraminidase	9001-67-6	8 - 12

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 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 If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. 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. 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 foam, carbon dioxide or dry powder.

Unsuitable extinguishing media Do not use water jet.

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 Fire will generate toxic and irritating gases.

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. Avoid inhalation of vapors and contact with skin and eyes.

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 Scoop up released material. Decontaminate the spill site following standard procedures for biohazardous, chemical spills.

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 Do not breathe mist or vapor. Avoid contact with skin and eyes. Persons susceptible for allergic reactions should not handle this product. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

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

8. Exposure Controls / Personal Protection

Occupational exposure limits No exposure limits noted for ingredient(s).

Exposure guidelines Follow standard monitoring procedures.

Engineering controls	Use local exhaust ventilation. 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. Wear NIOSH approved respirator appropriate for airborne exposure at the point of use.
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	Not available.
Odor threshold	Not available.
pH	6.5 - 7.5
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not applicable
Solubility (water)	Soluble
Specific gravity	Not available.
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 available.

10. Chemical Stability & Reactivity Information

Chemical stability	Stable under normal storage and handling conditions.
Conditions to avoid	High temperatures.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	By heating and fire, irritating vapors/gases may be formed.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Sensitization	May cause allergic respiratory reaction.
Acute effects	May cause discomfort if swallowed.
Chronic effects	Inhalation may result in respiratory sensitization.
Carcinogenicity	Not classified.
Epidemiology	No epidemiological data is available for this product.
Mutagenicity	No data available.
Reproductive effects	No data available.
Symptoms and target organs	Contact may cause irritation and redness.
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 soluble in water.

13. Disposal Considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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. Contract with a licensed chemical disposal agency.
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 a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. CERCLA/SARA Hazardous Substances - Not applicable. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.
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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 - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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Section 302 extremely hazardous substance (40 CFR 355, Appendix A)	No
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SARA 311/312 Hazardous chemical	Yes
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Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled
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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.
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WHMIS status	Controlled
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WHMIS classification

D2A - Other Toxic Effects-VERY TOXIC

WHMIS labeling



Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
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 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: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings

Health: 2
Flammability: 0
Instability: 0

Disclaimer

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1. Product and Company Identification

Material name	OSOM® BVBLUE® Negative Control
Version #	01
Issue date	05-24-2013
Revision date	-
Supersedes date	-
CAS #	Mixture
Kit number	184
Product use	Component of OSOM® BVBLUE® Control Kit (catalog # 184 & 184E). For external quality control testing. For In Vitro Diagnostic use only.
Synonym(s)	Negative Control
Manufacturer information	
Corporate Headquarters	Sekisui Diagnostics, LLC 4 Hartwell Place, Lexington, MA 02421, USA www.sekisuidiagnostics.com Phone: 800-332-1042 Americas 1-760-476-3962
Emergency Telephone Numbers	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	WARNING The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. May cause allergic respiratory reaction.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Inhalation. Eye contact. Skin contact.
Eyes	May cause itching and redness.
Skin	Contact may cause irritation, redness and/or drying.
Inhalation	May cause respiratory tract irritation. May cause allergic respiratory reaction. Although there is no evidence that the enzyme(s) in this preparation induces specific respiratory hypersensitivity, all proteins are potential respiratory allergens and may result in respiratory sensitization in certain individuals after repeated and/or prolonged inhalation exposure, producing mild to severe symptoms similar to pollen allergy or asthma, including mucous membrane or eye irritation, itching of the skin or eyes, sneezing, nasal or sinus congestion, coughing, and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.
Ingestion	May cause discomfort if swallowed.
Target organs	Respiratory system
Chronic effects	Inhalation may result in respiratory sensitization.
Signs and symptoms	Irritation of eyes and mucous membranes.
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

Components	CAS #	Percent
Neuraminidase	9001-67-6	2 - 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 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 If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. 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. 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 foam, carbon dioxide or dry powder.

Unsuitable extinguishing media Do not use water jet.

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 Fire will generate toxic and irritating gases.

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. Avoid inhalation of vapors and contact with skin and eyes.

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 Scoop up released material. Decontaminate the spill site following standard procedures for biohazardous, chemical spills.

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 Do not breathe mist or vapor. Avoid contact with skin and eyes. Persons susceptible for allergic reactions should not handle this product. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

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

8. Exposure Controls / Personal Protection

Occupational exposure limits No exposure limits noted for ingredient(s).

Exposure guidelines Follow standard monitoring procedures.

Engineering controls	Use local exhaust ventilation. 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. Wear NIOSH approved respirator appropriate for airborne exposure at the point of use.
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	Not available.
Odor threshold	Not available.
pH	6.5 - 7.5
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	Not applicable
Solubility (water)	Soluble
Specific gravity	Not available.
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 available.

10. Chemical Stability & Reactivity Information

Chemical stability	Stable under normal storage and handling conditions.
Conditions to avoid	High temperatures.
Incompatible materials	Strong oxidizers, strong acids, and strong bases.
Hazardous decomposition products	By heating and fire, irritating vapors/gases may be formed.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

11. Toxicological Information

Sensitization	May cause allergic respiratory reaction.
Acute effects	May cause discomfort if swallowed.
Chronic effects	Inhalation may result in respiratory sensitization.
Carcinogenicity	Not classified.
Epidemiology	No epidemiological data is available for this product.
Mutagenicity	No data available.
Reproductive effects	No data available.
Symptoms and target organs	Contact may cause irritation and redness.
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 soluble in water.

13. Disposal Considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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. Contract with a licensed chemical disposal agency.
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 a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. CERCLA/SARA Hazardous Substances - Not applicable. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.
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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 - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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Section 302 extremely hazardous substance (40 CFR 355, Appendix A)	No
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SARA 311/312 Hazardous chemical	Yes
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Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Not controlled
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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.
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WHMIS status	Controlled
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WHMIS classification

D2A - Other Toxic Effects-VERY TOXIC

WHMIS labeling



Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
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 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: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 2
Flammability: 0
Instability: 0

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