

1. Identification

Product identifier	OSOM® BVBLUE® Negative Control
Other means of identification	
Kit number	184
Synonyms	Negative Control
Recommended use	Component of OSOM® BVBLUE® Control Kit (catalog # 184 & 184E). For external quality control testing. For In Vitro Diagnostic use only.
Recommended restrictions	Use in accordance with supplier's recommendations.
Manufacturer/Importer/Supplier/Distributor 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. Hazard(s) identification

Physical hazards	Not classified.	
Health Hazards	Sensitization, respiratory	Category 1
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Precautionary statement		
Prevention	Avoid breathing mist or vapor. In case of inadequate ventilation wear respiratory protection.	
Response	If inhaled: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.	
Storage	None.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
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.
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4. First-aid measures

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.
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Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
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.
Ingestion	If material is ingested, immediately contact a poison control center.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Extinguish with foam, carbon dioxide or dry powder.
Unsuitable extinguishing media	Do not use water jet.
Specific hazards arising from the chemical	None known.
Special 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.
General fire hazards	The product is not flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and cleaning up	Scoop up released material. Decontaminate the spill site following standard procedures for biohazardous, chemical spills.
Environmental precautions	Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe 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.
Conditions for safe storage, including any incompatibilities	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).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Appropriate engineering controls	Use local exhaust ventilation. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear approved safety glasses or goggles.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Wear NIOSH approved respirator appropriate for airborne exposure at the point of use.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and 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
Melting point/freezing point	Not applicable.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under normal storage and handling conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
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.

11. Toxicological information

Information on likely routes of exposure

Inhalation	In high concentrations, vapors may be irritating to the respiratory system.
Skin contact	May cause skin irritation.
Eye contact	May cause eye irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Contact may cause irritation and redness.

Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	May cause redness and pain.
Respiratory or skin sensitization	
Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization	Not a skin sensitizer.
Germ cell mutagenicity	No data available.
Carcinogenicity	Not classified.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	Not available.
Aspiration hazard	Not available.
Chronic effects	Inhalation may result in respiratory sensitization.
Further information	No other specific acute or chronic health impact noted.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Mobility in general	The product is soluble in water.
Other adverse 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.

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.
Hazardous waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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 dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US 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. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65**US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance**

Not listed.

International Inventories

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).

16. Other information, including date of preparation or last revision

Issue date 13-October-2014

Revision date -

Version # 01

NFPA ratings



List of abbreviations LD50: Lethal Dose, 50%.

References ACGIH

HSDB® - Hazardous Substances Data Bank

IARC Monographs. Overall Evaluation of Carcinogenicity

Disclaimer

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1. Identification

Product identifier	OSOM® BVBLUE® Positive Control
Other means of identification	
Kit number	184
Synonyms	Positive Control
Recommended use	Component of OSOM® BVBLUE® Control Kit (catalog # 184 & 184E). For external quality control testing. For In Vitro Diagnostic use only.
Recommended restrictions	Use in accordance with supplier's recommendations.
Manufacturer/Importer/Supplier/Distributor 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. Hazard(s) identification

Physical hazards	Not classified.	
Health Hazards	Sensitization, respiratory	Category 1
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
Precautionary statement		
Prevention	Avoid breathing mist or vapor. In case of inadequate ventilation wear respiratory protection.	
Response	If inhaled: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.	
Storage	None.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
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.
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4. First-aid measures

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.
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Skin contact	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
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.
Ingestion	If material is ingested, immediately contact a poison control center.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Extinguish with foam, carbon dioxide or dry powder.
Unsuitable extinguishing media	Do not use water jet.
Specific hazards arising from the chemical	None known.
Special 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.
General fire hazards	The product is not flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and cleaning up	Scoop up released material. Decontaminate the spill site following standard procedures for biohazardous, chemical spills.
Environmental precautions	Do not allow to enter drains, sewers or watercourses.

7. Handling and storage

Precautions for safe 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.
Conditions for safe storage, including any incompatibilities	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).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	Follow standard monitoring procedures.
Appropriate engineering controls	Use local exhaust ventilation. Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear approved safety glasses or goggles.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Respiratory protection	Wear NIOSH approved respirator appropriate for airborne exposure at the point of use.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and 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
Melting point/freezing point	Not applicable.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under normal storage and handling conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
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.

11. Toxicological information

Information on likely routes of exposure

Inhalation	In high concentrations, vapors may be irritating to the respiratory system.
Skin contact	May cause skin irritation.
Eye contact	May cause eye irritation.
Ingestion	May cause discomfort if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Contact may cause irritation and redness.

Information on toxicological effects

Acute toxicity	May cause discomfort if swallowed.
Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	May cause redness and pain.
Respiratory or skin sensitization	
Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization	Not a skin sensitizer.
Germ cell mutagenicity	No data available.
Carcinogenicity	Not classified.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	Not available.
Aspiration hazard	Not available.
Chronic effects	Inhalation may result in respiratory sensitization.
Further information	No other specific acute or chronic health impact noted.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Mobility in general	The product is soluble in water.
Other adverse 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.

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.
Hazardous waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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 dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US 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. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65**US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance**

Not listed.

International Inventories

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).

16. Other information, including date of preparation or last revision

Issue date 13-October-2014

Revision date -

Version # 01

NFPA ratings



List of abbreviations LD50: Lethal Dose, 50%.

References ACGIH
HSDB® - Hazardous Substances Data Bank
IARC Monographs. Overall Evaluation of Carcinogenicity

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