

SECTION 1: Identification

1.1. Identification

Product form	: Mixture
Product name	: OSOM® BVBLUE® Positive Control
Product code	: 184
Synonyms	: Positive Control

1.2. Recommended use and restrictions on use

Use of the substance/mixture	: Component of OSOM® BVBLUE® Control Kit (catalog # 184 & 184E) For external quality control testing 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
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SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Respiratory sensitization, Category 1 H334 May cause an allergy or asthma symptoms or breathing difficulties if inhaled
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)	: H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled
Precautionary statements (GHS US)	: P261 - Avoid breathing dust/fume/gas/mist/vapors/spray. P284 - [In case of inadequate ventilation] wear respiratory protection. P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor. 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

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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
Neuraminidase	(CAS No) 9001-67-6	2 – 5	Resp. Sens. 1, H334

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 poison center or a doctor if you feel unwell.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a doctor.
- First-aid measures after skin contact : Wash skin with plenty of water.
- First-aid measures after eye contact : Rinse eyes with water as a precaution.
- First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

- Symptoms/effects after inhalation : May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

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 breathing 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".

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. Wear personal protective equipment. Avoid breathing dust/fume/gas/mist/vapors/spray.

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Hygiene measures : 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 in a well-ventilated place. Keep cool.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OSOM® BVBLUE® Positive Control

No additional information available

Neuraminidase (9001-67-6)

No additional information available

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:

Wear respiratory protection.

Device	Filter type	Condition
Gas filters	Filter A2/B2	vapor protection

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.
Color : Colorless.
Odor : No data available
Odor threshold : No data available
pH : 6.5 – 7.5
Melting point : Not applicable
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available

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Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
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
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified pH: 6.5 – 7.5
Serious eye damage/irritation	: Not classified pH: 6.5 – 7.5
Respiratory or skin sensitization	: May cause an allergy or asthma symptoms or breathing difficulties if inhaled.
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 inhalation	: May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

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

Not applicable

Transportation of Dangerous Goods

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

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

Neuraminidase (9001-67-6)

EPA TSCA Regulatory Flag

XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

15.2. International regulations

CANADA

Neuraminidase (9001-67-6)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

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
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3(b)	OSOM® BVBLUE® Positive Control	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
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Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

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

No additional information available

SECTION 16: Other information

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

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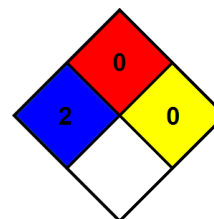
Full text of H-phrases:

H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
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NFPA health hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual 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 : 2 Moderate Hazard - Temporary or minor injury may occur

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 : G

G - Safety glasses, Gloves, Vapor respirator

SDS US (GHS HazCom 2012)

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