

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 10/13/2014 Revision date: 10/23/2020 Supersedes: 10/13/2014

SECTION 1: Identification Identification 1.1. Product form : Mixture Product name : OSOM® BVBLUE® Negative Control Product code 184 Synonyms : Negative Control 1.2. Recommended use and restrictions on use : Component of OSOM® BVBLUE® Control Kit (catalog # 184 & 184E) Use of the substance/mixture 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

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

Asia Pacific +1-760-476-3960 Access code 333512

2.2. GHS Label elements, including pro	ecautionary 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	t in classification

No additional information available

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Unknown acute toxicity (GHS US) 2.4. Not applicable SECTION 3: Composition/Information on ingredients **Substances** 3.1. Not applicable **Mixtures** 3.2. Name **Product identifier** % **GHS US classification** (CAS No) 9001-67-6 Neuraminidase 2 - 5Resp. Sens. 1, H334 Full text of hazard classes and H-statements : see section 16 **SECTION 4: First-aid measures Description of first aid measures** 4.1. First-aid measures general : Call a poison center or a doctor if you feel unwell. : Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory First-aid measures after inhalation symptoms: Call a poison center or a doctor. First-aid measures after skin contact : Wash skin with plenty of water. First-aid measures after eve 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. Immediate medical attention and special treatment, if necessary 4.3. Treat symptomatically. SECTION 5: Fire-fighting measures Suitable (and unsuitable) extinguishing media 5.1. Suitable extinguishing media : Water spray, Dry powder, Foam, Carbon dioxide, Specific hazards arising from the chemical 5.2. Hazardous decomposition products in case of : Toxic fumes may be released. fire Special protective equipment and precautions for fire-fighters 5.3. 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 : Do not attempt to take action without suitable protective equipment. For further information Protective equipment refer to section 8: "Exposure controls/personal protection". **Environmental precautions** 6.2. Avoid release to the environment. Methods and material for containment and cleaning up 6.3. 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** Precautions for safe handling 7.1. 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® Negative 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

Туре	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 chemica	al properties
9.1. Information on basic physical and	d 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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SECTIO	N 12: Ecological information	
12.1.	Toxicity	
Ecology - g	general :	The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
12.2. I	Persistence and degradability	
No addition	nal information available	
12.3. I	Bioaccumulative potential	
No addition	nal information available	
12.4.	Mobility in soil	
No addition	nal information available	
12.5.	Other adverse effects	
No addition	nal information available	
SECTIO	N 13: Disposal considerations	

13.1. Dispos	al methods			
Waste treatment	methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.		
SECTION 14:	Transport information			
Department of T	ransportation (DOT)			
In accordance wit	h DOT			
Not applicable				
Transportation o	of Dangerous Goods			
Not applicable				
Transport by sea	a			
Not applicable				
Air transport				
Not applicable				
SECTION 15:	Regulatory information			
15.1. US Federal	regulations			
	of this product are listed, or excluntrol Act (TSCA) inventory	uded from listing	I, on the United States Environmental Protection Agency Toxic	
Neuraminidase	9001-67-6)			
EPA TSCA Reg	ulatory Flag	XU - XU - indi Rule, (40 CFF	icates a substance exempt from reporting under the Chemical Data Reporting R 711).	
15.2. Internation	al regulations			
CANADA				
	(9001-67-6)			
Neuraminidase	(
	e Canadian DSL (Domestic Subst	tances List)/NDS	SL (Non-Domestic Substances List)	
Not listed on the EU-Regulations	Canadian DSL (Domestic Subst			
Not listed on the EU-Regulations	Canadian DSL (Domestic Subst		SL (Non-Domestic Substances List) of the REACH Regulation (EC) No 1907/2006:	

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3(b)	OSOM® BVBLUE®	-	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 REA	CH candidate substan	се	
	CH Annex XIV substa		
Contains no subs import of hazardo		ation (EU) No 649/201	2 of the European Parliament and of the Council of 4 July 2012 concerning the export and
•		gulation (EU) No 2019/	1021 of the European Parliament and of the Council of 20 June 2019 on persistent
organic pollutant		gulation (20) 10 2010,	
National regulat	tions		
No additional info	ormation available		
15.3. US State re	•		
No additional inform	nation available		
SECTION 16	Other information	on	
Ū	al Register / Vol. 77, No. 5	••••••	12 / Rules and Regulations
Revision date		: 10/23/2020	
Full text of H-phr	ases:		
H334		May cause an allergy	y or asthma symptoms or breathing difficulties if inhaled
NFPA health haz	ard		Is that, under emergency conditions, can cause incapacitation or residual injury.
NFPA fire hazaro	i	including in	Is that will not burn under typical fire conditions, trinsically noncombustible materials such as tone, and sand.
NFPA reactivity		: 0 - Materia under fire c	I that in themselves are normally stable, even conditions.
			~
Hazard Rating			
0		: 2 Moderat	e Hazard - Temporary or minor injury may occur
Hazard Rating Health Flammability			te Hazard - Temporary or minor injury may occur Hazard - Materials that will not burn
Health		: 0 Minimal : 0 Minimal	
Health Flammability	on	: 0 Minimal : 0 Minimal	Hazard - Materials that will not burn Hazard - Materials that are normally stable, even under fire conditions, and will NOT

SDS US (GHS HazCom 2012)

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