

SECTION 1: Identification

1.1. Identification

Product name : OSOM Flu SARS-CoV-2 Combo Test Kit
 Product code : 1080

1.2. Recommended use and restrictions on use

Use of the substance/mixture : For the qualitative and differential detection of SARS-CoV-2, influenza A and influenza B proteins using self-collected anterior nares nasal swab samples. IVD only

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. +1-800-565-0265
 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

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

No labeling applicable

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
Dodecan-1-ol, ethoxylated	(CAS-No.) 9002-92-0	0.1 – 1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 2, H401
Sodium azide	(CAS-No.) 26628-22-8	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

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 after inhalation : Remove person to fresh air and keep comfortable for breathing.
- 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)

No additional information available

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.

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.
- 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 Flu SARS-CoV-2 Combo Test Kit
No additional information available
Sodium azide (26628-22-8)
No additional information available

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USA - ACGIH - Occupational Exposure Limits	
Local name	Sodium azide
ACGIH OEL Ceiling	0.29 mg/m ³ (as Sodium azide) 0.11 ppm (as Hydrazoic acid vapor)
Remark (ACGIH)	TLV® Basis: Card impair; lung dam. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2023
Dodecan-1-ol, ethoxylated (9002-92-0)	
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:

In case of insufficient ventilation, wear suitable respiratory equipment.

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 : No data available
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
Flammability : Not applicable.
Vapor pressure : No data available
Relative vapor density at 20°C : No data available
Relative density : No data available
Solubility : Soluble.

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Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
No data available	: 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

Sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg
LD50 dermal rabbit	20 mg/kg
LC50 Inhalation - Rat	0.054 – 0.52 mg/l air (EPA OPPTS 870.1300)
ATE US (oral)	27 mg/kg body weight
ATE US (dermal)	20 mg/kg body weight

Dodecan-1-ol, ethoxylated (9002-92-0)	
LD50 oral rat	8600 mg/kg
LD50 dermal rat	> 2000 mg/kg body weight OECD 402
ATE US (oral)	500 mg/kg body weight

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
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

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Dodecan-1-ol, ethoxylated (9002-92-0)	
LOAEL (dermal,rat/rabbit,90 days)	5000 mg/kg body weight
NOAEL (oral,rat,90 days)	500 mg/kg body weight OECD 40 (90-d)

Aspiration hazard : Not classified
Viscosity, kinematic : No data available

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.

Sodium azide (26628-22-8)	
LC50 - Fish [1]	2.75 mg/l Oncorhynchus mykiss (Rainbow trout)
EC50 - Crustacea [1]	< 1 mg/l
EC50 - Other aquatic organisms [1]	5 mg/l (Gammarus fasciatus)

Dodecan-1-ol, ethoxylated (9002-92-0)	
LC50 - Fish [1]	5.849 mg/l Carassius auratus
EC50 - Crustacea [1]	9.1313 mg/l Daphnia magna
NOEC (chronic)	0.144 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	0.139 mg/l Test organisms (species): other: Duration: '28 d'

12.2. Persistence and degradability

Dodecan-1-ol, ethoxylated (9002-92-0)	
Persistence and degradability	Readily biodegradable.

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

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SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

Sodium azide	CAS-No. 26628-22-8	< 0.1%
Dodecan-1-ol, ethoxylated	CAS-No. 9002-92-0	0.1 – 1%

Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.

Sodium azide	CAS-No. 26628-22-8	< 0.1%
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Sodium azide (26628-22-8)

CERCLA RQ	1000 lb
RQ (Reportable quantity, section 304 of EPA's List of Lists)	1000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb

Dodecan-1-ol, ethoxylated (9002-92-0)

EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
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15.2. International regulations

CANADA

Sodium azide (26628-22-8)

Listed on the Canadian DSL (Domestic Substances List)

Dodecan-1-ol, ethoxylated (9002-92-0)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

National regulations

Sodium azide (26628-22-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Dodecan-1-ol, ethoxylated (9002-92-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Listed on INSQ (Mexican National Inventory of Chemical Substances)

Component	State or local regulations
Sodium azide(26628-22-8)	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 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

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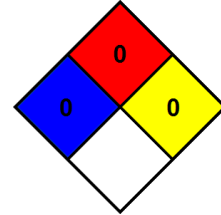
Full text of hazard classes and H-statements:

H300	Fatal if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
H315	Causes skin irritation
H318	Causes serious eye damage
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

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 : 0 Minimal Hazard - No significant risk to health

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:

according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS).

Section	Changed item	Change	Comments
16	Indication of changes	Added	

SDS US (GHS HazCom 2012)

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