
ASSURE-100 COVID-19 Test Device

Safety Data Sheet

This document has been prepared in accordance with 29 CFR 1910.1200.

Date Posted: Feb 17, 2022

SECTION 1: IDENTIFICATION

1.1 Identification

Product Form: Mixture
Product Name: ASSURE-100 Rapid COVID-19 Test Kit

1.2 Recommended use and Restrictions of Use

Use of substance / mixture: For in vitro diagnostic use
Restrictions on use: Restricted to professional users

1.3 Manufacturer Information

Oceanit Foundry, LLC
828 Fort Street Mall, Suite 600
Honolulu, HI 96813
U.S.A
T +1 855 929 6011
Email: info@assure-test.com

SECTION 2: HAZARD(S) IDENTIFICATION

2.1 Classification of the substance or mixture

GHS U.S. Classification: Not classified

2.2 GHS Label Elements, including Precautionary Statements

Signal word: WARNING

Hazard pictograms:



Health hazards: Serious eye damage / eye irritation – Category 2

Environmental hazards: Not hazardous

Hazard statements: H319 – Causes serious eye irritation

Precautionary Statements

Prevention:	P280 - Wear protective gloves/protective clothing/eye protection/face protection P264 - Wash hands thoroughly after handling
Response:	P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice/attention
Storage:	Not applicable
Disposal:	Not applicable
Physical Hazards:	Not Hazardous
HMIS:	Health – 2 Flammability – 0 Reactivity - 0

2.3 Other hazards which do not result in classification

Contains a known or suspected endocrine disruptor.

2.4 Unknown acute toxicity (GHG U.S.)

Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	Concentration	CAS No.
Diluent (Proprietary)	97.5%	N/A
Triton X-100 (Poly(oxy-1,2-ethanediyl).alpha.-[4-(1,1,3,3-tetramethylbutyl)phenyl]-.omega.-hydroxy-)	1%	9002-93-1
EDTA-disodium salt (Edetate disodium dihydrate)	1.5%	6381-92-6

Trade Secret Statement (OSHA §1910.1200(i))

The specific chemical identities and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4: FIRST-AID MEASURES

4.1 Description of first aid measures

General Advice:	If symptoms persist, call a physician.
Inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration.
Skin Contact:	Wash off with soap and plenty of water.
Eye Contact:	Flush eyes with water.
Ingestion:	Rinse mouth with water, call a poison center/doctor/physician if you feel unwell.

4.2 Most important symptoms and effects (acute and delayed)

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or in Section 11.

4.3 Immediate medical attention and special treatment, if necessary

Description of first aid measures:

Skin contact:	Rinse skin with water. Immediate medical attention is not required.
Eye contact:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion:	Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.
Inhalation:	Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.
Notes to Physician:	Treat symptomatically.

Most important symptoms and effects, both acute and delayed

H319 - Causes serious eye irritation

Indication of any immediate medical attention and special treatment needed

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Get medical advice/attention if you feel unwell.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Water spray. Carbon dioxide (CO₂). Dry chemical. Foam.

Unsuitable extinguishing media: No information available.

5.2 Specific hazards arising from the chemical

Not known.

5.3 Special protective equipment and precautions for firefighters

Protection during firefighting: Standard procedure for chemical fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment, and emergency procedures

Avoid breathing vapors, mist, or gas.

For personal protection, see Section 8.

6.2 Environmental Precautions

Avoid release to the environment. Do not let product enter drains. Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.

6.3 Methods and material for containment and cleaning up

Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal, refer to Section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Ensure adequate ventilation. Wear personal protective equipment as required. See Section 8 for more information.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Product must only be kept in original packaging. Avoid freezing or extreme heat.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Chemical Name	OSHA PEL	OSHA PEL (Ceiling)	ACGIH OEL (TWA)	OEL (STEL)
Triton X-100	None	None	None	None

8.2 Appropriate Engineering Controls

Appropriate engineering controls: Ensure good ventilation, especially in confined areas

Environmental exposure controls: Avoid release to the environment. Prevent product from entering drains. Do not allow material to contaminate ground water system

8.3 Individual protection measures/Personal protective equipment

Personal protective equipment:

Hand protection: Wear suitable gloves. Glove material: Compatible chemical-resistant gloves.

Eye protection: Tight sealing safety goggles

Skin and body protection: Wear suitable protective clothing.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice

Respiratory protection: In case of insufficient ventilation wear respirators and components tested and approved under appropriate government standards.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	
Physical State	Liquid
Color	Off-white, opaque liquid
Odor	Not determined
Odor threshold	Not determined
pH	9.5
Melting point/freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash point	Not determined
Evaporation rate	Not determined
Flammability (solid, gas)	Not determined
Explosive properties	Not determined

Lower explosion limit	Not determined
Upper explosion limit	Not determined
Vapor Pressure	Not determined
Vapor Density	Not determined
Density	Not determined
Water Solubility	Not determined
Partition coefficient:	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Viscosity	Not determined
Oxidizing properties	Not determined

9.2 Other information

No additional information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

None under recommended storage and handling conditions (see Section 7).

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO_x)

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO_x), Sodium oxides

Other decomposition products - No data available

In the event of fire: See Section 5

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Triton X-100	= 1800 mg/kg (rat)	No data available	No data available

Principal Routes of Exposure

Acute toxicity:	Data are conclusive but insufficient for classification.
Skin corrosion/irritation:	Data are conclusive but insufficient for classification
Serious eye damage/irritation:	Irritating to eyes
Respiratory or skin sensitization:	Data are conclusive but insufficient for classification
Specific target organ toxicity (STOT) – single exposure:	Data are conclusive but insufficient for classification
Specific target organ toxicity (STOT) – repeated exposure	Data are conclusive but insufficient for classification
Carcinogenicity:	Data are conclusive but insufficient for classification
Germ cell mutagenicity:	Data are conclusive but insufficient for classification
Reproductive toxicity:	Data are conclusive but insufficient for classification
Aspiration hazard:	Data are conclusive but insufficient for classification

SECTION 12: ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Hazardous to the Aquatic Environment.

Chemical Name	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates	Toxicity to Fish	Microtox Data	log Pow
Triton X-100	No data available	No data available	No data available	No data available	No data available

12.2 Persistence and degradability

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

Contains a known or suspected endocrine disruptor.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in accordance to approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations. Do not empty into drains. Do not dispose of waste into sewer.

SECTION 14: TRANSPORT INFORMATION

14.

ATA /ADR / DOT-US / IMDG:	Not regulated in the meaning of transport regulations
UN Number:	Not applicable
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Special precautions for user:	Not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1 US Federal regulations

Component US TSCA		
Triton X-100	9002-93-1 (0.1-2.4)	Listed

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)

This product does not contain HAPs.

15.2 International regulations

Canada regulations - No additional information available

EU regulations-

Chemical Name	CAS. No.	EU CLP (1272/2008)	EU_BA Directive 2000/54/EC	EU REACH: List of Substances of Very High Concern (SVHC)
Triton X-100	9002-93-1	Not Listed	Not Listed	Listed

National regulations – Brazil

Chemical Name	CAS. No.	National Agency for Sanitary Surveillance (ANVISA)	National List of Carcinogen Agents to Humans (LINACH)
Triton X-100	9002-93-1	Not Listed	Not Listed

15.3 US State regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

WHMIS Hazard Class: D2B - Toxic materials

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

Edetate disodium dihydrate CAS-No.-6381-92-6

New Jersey Right To Know Components

Edetate disodium dihydrate CAS-No.-6381-92-6

SECTION 16: OTHER INFORMATION

This document has been prepared in accordance with 29 CFR 1910.1200.

The information in this Safety Data Sheet was compiled through thorough extensive research and the recommendations are based on professional assessment and judgement. Material properties presented here are not guaranteed and the SDS will be updated as more data becomes available. All materials should be handled in accordance with good industrial hygiene and safety practices and treated as potentially hazardous. Oceanit Laboratories Inc. shall not be held liable for the improper handling of the product as described in this document, or incidental breakage or leakage caused during shipment and transportation of the product, which is intended to be used for the purposes of health and environmental safety.

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