

Safety Data Sheet

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

Issue date: 11/17/2021 Version: 1.0

#### **SECTION 1: Identification**

1.1. Identification

Product form : Mixture

Product name : Solana SARS-CoV-2 Assay Lyophilized

Product code : M312

1.2. Recommended use and restrictions on use

Recommended use : For medical diagnostic use.

Restrictions on use : Professional Use of Medical Devices

#### 1.3. Supplier

#### Manufacturer

**Quidel Corporation** 

2005 East State Street, Suite 100

Athens, 45701 - USA

T 1.800.874.1517 - F 1.740.592.9820 <u>qehs@quidel.com</u> - <u>quidel.com</u>

#### 1.4. Emergency telephone number

Emergency number : 1.866.519.4752

### 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

## **SECTION 3: Composition/Information on ingredients**

Name	Chemical name	CAS#	%	GHS US classification
Solana SARS-CoV-2 Process Buffer	glycerol	56-81-5	5 – 10	Acute Tox. 4 (Inhalation:dust,mist), H332

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/doctor/physician if you feel unwell.

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

Immediate medical attention and special treatment, : Treat symptomatically.

if necessary

## **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

No additional information available

#### 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.

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#### **SECTION 6: Accidental release measures**

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

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

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.

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

glycerol (56-81-5)				
OSHA	OSHA PEL TWA [1]	15 mg/m³ (Total dust) 5 mg/m³ (Respirable fraction)		
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1		

## 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

## Materials for protective clothing:

Lab coat

**Hand Protection:** 

Protective gloves

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):









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#### Other information:

Do not eat, drink or smoke when using this product.

## **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid

Color : No data available
Odor : No data available
Odor threshold : No data available

pH : All buffers in this kit are neutral

Melting point : Not applicable Freezing point No data available No data available **Boiling point** Flash point No data available Relative evaporation rate (butyl acetate=1) : No data available Flammability (solid, gas) : Not applicable. Vapor pressure No data available : No data available Relative vapor density at 20 °C Relative density No data available Solubility : No data available Partition coefficient n-octanol/water (Log Pow) No data available : No data available Auto-ignition temperature Decomposition temperature : No data available No data available Viscosity, kinematic : No data available Viscosity, dynamic No data available : No data available **Explosion limits Explosive properties** : No data available Oxidizing properties : No data available

## 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**

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

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glycerol (56-81-5)		
LD50 oral rat	27200 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value)	
LC50 Inhalation - Rat	> 2.75 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male, Converted value)	
ATE US (oral)	27200 mg/kg body weight	
ATE US (dust, mist)	1.5 mg/l/4h	
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	
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.

glycerol (56-81-5)	
LC50 - Fish [1]	54000 mg/l (96 h, Salmo gairdneri, Static system, Fresh water, Experimental value)
EC50 - Crustacea [1]	> 10000 mg/l (24 h, Daphnia magna, Static system, Fresh water, Experimental value)

#### 12.2. Persistence and degradability

glycerol (56-81-5)		
Persistence and degradability	Readily biodegradable in water.	
Biochemical oxygen demand (BOD)	0.87 g O₂/g substance	
Chemical oxygen demand (COD)	1.16 g O₂/g substance	
ThOD	1.217 g O₂/g substance	
BOD (% of ThOD)	0.71	

## 12.3. Bioaccumulative potential

glycerol (56-81-5)	
Partition coefficient n-octanol/water (Log Pow)	-1.75 (Experimental value, Equivalent or similar to OECD 107, 25 °C)
Bioaccumulative potential	Not bioaccumulative.

## 12.4. Mobility in soil

glycerol (56-81-5)	
Surface tension	0.0634 N/m (20 °C, 1000 g/l)
Ecology - soil	No (test)data on mobility of the substance available.

#### 12.5. Other adverse effects

No additional information available

## **SECTION 13: Disposal considerations**

## 13.1. Disposal methods

Regional legislation (waste) : Disposal must be done according to official regulations.

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Sewage disposal recommendations : Disposal must be done according to official regulations.

Ecology - waste materials : Avoid release to the environment.

## **SECTION 14: Transport information**

## **Department of Transportation (DOT)**

Not regulated

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#### **International Maritime Dangerous Goods (IMDG)**

Not regulated

International Air Transportation Association (IATA)

Not regulated

### **SECTION 15: Regulatory information**

#### 15.1. US Federal regulations

### Solana SARS-CoV-2 Assay Lyophilized

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

glycerol CAS No 56-81-5 5 – 10%

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372

### 15.2. International regulations

#### **CANADA**

## glycerol (56-81-5)

Listed on the Canadian DSL (Domestic Substances List)

#### **EU-Regulations**

No additional information available

#### **National regulations**

## glycerol (56-81-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active Listed on INSQ (Mexican National Inventory of Chemical Substances)

#### 15.3. US State regulations

California Proposition 65 -

This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

## **SECTION 16: Other information**

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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