

SECTION 1: Identification
1.1. Identification

Product form : Mixture
 Product name : Solana Strep Complete Assay
 Product code : M305

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
gehs@quidel.com - quidel.com


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

Components	GHS US classification
Solana GAS+ CG Lysis Buffer	Eye Irrit. 2, H319

2.2. GHS Label elements, including precautionary statements
GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Solana GAS+ CG Lysis Buffer		Warning	H319 - Causes serious eye irritation	P264 - Wash hands thoroughly after handling. P280 - Wear eye protection. 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 attention.

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Solana GAS Dilution Buffer	Glycerol	56-81-5	5 – 10	Acute Tox. 4 (Inhalation:dust,mist), H332
Solana GAS+ CG Lysis Buffer	Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether	9002-93-1	1 – 5	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318

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 cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
 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)

Symptoms/effects after eye contact : Eye irritation.
 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

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.

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. Avoid contact with skin and eyes.

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. Avoid contact with skin and eyes. 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) (mg/m ³)	15 mg/m ³ (Total dust) 5 mg/m ³ (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

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):



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
Appearance	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
pH solution	: Buffers are neutral.
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 (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
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	: 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

Glycerol (56-81-5)	
LD50 oral rat	27200 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value)
LC50 inhalation rat (mg/l)	> 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

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
LD50 oral rat	1800 mg/kg (Rat, Literature study)
LD50 dermal rabbit	8000 mg/kg (Rabbit, Literature study)
ATE US (oral)	1800 mg/kg body weight
ATE US (dermal)	8000 mg/kg body weight

Skin corrosion/irritation : Not classified
 Serious eye damage/irritation : Causes serious eye irritation.
 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
 Symptoms/effects after eye contact : Eye irritation.

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 Daphnia 1	> 10000 mg/l (24 h, Daphnia magna, Static system, Fresh water, Experimental value)

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

LC50 fish 1	8.9 mg/l (96 h, Pimephales promelas, Literature study)
EC50 Daphnia 1	26 mg/l (48 h, Daphnia magna, Literature study)

12.2. Persistence and degradability
Glycerol (56-81-5)

Persistence and degradability	Readily biodegradable in water.
Biochemical oxygen demand (BOD)	0.87 g O ₂ /g substance
Chemical oxygen demand (COD)	1.16 g O ₂ /g substance
ThOD	1.217 g O ₂ /g substance
BOD (% of ThOD)	0.71

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

Persistence and degradability	Not readily biodegradable in water.
Chemical oxygen demand (COD)	2.19 mg/g
ThOD	2.16 g O ₂ /g substance

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.

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

Partition coefficient n-octanol/water (Log Pow)	4.86 (Estimated value)
Bioaccumulative potential	Potential for bioaccumulation (4 ≥ Log Kow ≤ 5).

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.

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

Ecology - soil	No (test)data on mobility of the substance available.
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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 applicable

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information**15.1. US Federal regulations****Glycerol (56-81-5)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

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****Glycerol (56-81-5)**

Listed on the Canadian DSL (Domestic Substances List)

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

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

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

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.