

## Section 1 – Product and Company Identification

### Manufacturer Information

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### Product Information

Product Name: Solana Strep Complete Assay (Catalog #: M305)

Intended Use: An *in vitro* diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and identification of *Streptococcus pyogenes* (Group A  $\beta$ -hemolytic Streptococcus) and *Streptococcus dysgalactiae* (pyogenic Group C and G  $\beta$ -hemolytic Streptococcus) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as a sore throat. Intended for use only with the Solana® instrument.


Components: Lysis Buffer (0.5 mL), Dilution Buffer (0.5 mL), GAS Reaction Tubes (25  $\mu$ L), C/G Reaction Tubes (25  $\mu$ L)

## Section 2 – Hazards Identification

### Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Lysis Buffer (1.0% Triton X-100)	Irritant	Eye	Skin Irritation (Category 2A) Chronic Aquatic Toxicity (Category 3)

### GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
Lysis Buffer (1.0% Triton X-100)	 Warning	H319 Causes serious eye irritation.  H412 Harmful to aquatic life with long lasting effects.	P264 Wash hands thoroughly after handling. P273 Avoid release to the environment. P280 Wear eye protection / face protection. P305+P351+P338: IF 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.
<b>Supplemental Hazard Statements</b>		1. Follow Universal Precautions when working with this kit. 2. Maybe harmful if swallowed.	

## Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
Lysis Buffer	Triton X-100	9002-93-1	618-344-0	1.0	0.5 mL	Acute Tox. 4; Eye Irrit. 2A; Aquatic Acute 2; Aquatic Chronic 2; H302,H319, H411
Dilution Buffer	Glycerol	56-81-5	200-289-5	<5.5	0.5 mL	--

## Section 4 – First Aid Measures

### General Advice

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance, as necessary.

<i>If inhaled:</i>	Move the person to fresh air and support breathing as required.
<i>In case of skin contact:</i>	Wash affected area with soap and water. Seek medical advice if irritation develops.
<i>In case of eye contact:</i>	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists get medical attention.
<i>If swallowed:</i>	Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.
<i>Note to Physicians:</i>	Treat symptomatically.

## Section 5 – Fire Fighting Measures

### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

<i>Extinguishing Media:</i>	For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
<i>General Fire Hazards:</i>	The components within this kit will not significantly contribute to the intensity of a fire.
<i>Hazardous Combustion Products:</i>	No data available
<i>Fire Fighting Equipment:</i>	Firefighters should wear full protective gear when responding to fires.

## Section 6 – Accidental Release Measures

### General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. Large spills of the solutions, controls, buffers or reagents contained within this kit are unlikely.

<i>Personal Precautions:</i>	Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the solutions, controls or reagents within this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
<i>Materials and Methods for Clean-Up:</i>	Soak up with inert absorbent material (e.g., paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

## Section 7 – Handling and Storage

**Specific Use:** For *in vitro* diagnostic use only. Not for use by the general public.

### Precautions for Safe Handling

As with all chemical and biological substances, avoid getting this solution ON YOU or IN YOU. Wash exposed areas thoroughly after using this solution. Do not eat or drink while using this solution. This solution should be handled only by qualified clinical or laboratory employees trained on the use of this solution and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with this solution. Keep out of reach of the general public.

**Conditions for Safe Storage:** To maintain efficacy, store according to the kit specific Technical Data Sheet.

**Incompatibilities** To maintain efficacy, store according to the kit specific Technical Data Sheet.

## Section 8 – Exposure Controls and Personal Protection

**Exposure Limits:** No data available for the components in this kit.

### Exposure Controls:

**Engineering Measures** Use with adequate ventilation.

#### Personal Protective Equipment

*Respiratory Protection:* None needed under normal conditions of use.

*Hand Protection:* Handle with appropriately rated chemical resistant gloves. Gloves should be inspected prior to use. Use proper glove technique to remove gloves to avoid contact with skin. Wash hands after handling the components within this kit.

*Eye Protection:* Wear safety glasses with side shields or goggles to prevent eye contact.

*Skin and Body Protection:* Use body protection appropriate for the task. A laboratory coat is recommended.

*Hygiene Measures:* Wash hands before and after use and at the end of the workday.

#### Environmental Exposure Controls

No special environmental controls are required.

## Section 9 – Physical and Chemical Properties

Characteristic	Lysis Buffer	Dilution Buffer
Boiling Point (°C)	No data available	No data available
Melting Point (°C)	No data available	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available
pH	Neutral	Neutral
Solubility in Water	Soluble	Soluble
Appearance and Odor	Clear, Odorless	Clear, Odorless

### Section 10 – Stability and Reactivity

Characteristic	Lysis Buffer	Dilution Buffer
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	No data available	No data available
Materials to Avoid	No data available	No data available
Hazardous Decomposition Products	No data available	No data available

### Section 11 – Toxicological Information

#### Acute Toxicity

**Component Analysis – LD50 / LC50 / Irritation** (No data available for specific kit components)

Chemical Name	CAS #	RTECS #	Information
Triton X-100	9002-93-1	MD0907700	Oral LD <sub>50</sub> Rat 1800 mg/kg Inhalation LC <sub>50</sub> No data available Dermal LD <sub>50</sub> No data available

**Potential Health Effects: Specimen-Stabilizing Solution (A9576)**

<i>Skin Corrosion/ Irritation:</i>	No data available	<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Eyes:</i>	May cause serious eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May be harmful if swallowed.

#### Carcinogenicity

No components within this solution present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the IARC, ACGIH, NTP or OSHA.

**Reproductive Toxicity** No data available

**Teratogenicity** No data available

**Specified Target Organ General Toxicity (GHS)**

*Single Exposure (GHS):* No data available

*Repeated Exposure (GHS):* No data available

**Synergistic Effects** No data available

#### Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

#### Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for this solution.

**Additional Information** None

## Section 12 – Ecological Information

<b>Ecotoxicity</b>	No data available
<b>Persistence / Degradability</b>	No data available
<b>Bioaccumulation</b>	No data available
<b>Mobility in Soil</b>	No data available
<b>PBT and vPvB Assessment</b>	Assessment not available as chemical safety assessment not required or not conducted.
<b>Other Adverse Effects</b>	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment.

## Section 13 – Disposal Considerations

### Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge any of the solutions, reagents or controls into drains, water courses or onto the ground.

### Disposal of Product and Contaminated Packaging

Dispose of waste materials, unused components and contaminated packaging in compliance with country, federal, state and local regulations. If unsure of the applicable regulatory requirements, contact a licensed professional waste disposal service to dispose of this material.

## Section 14 – Transportation Information

<b>U.S. Department of Transportation (DOT)</b>	This kit is not regulated for transport.
<b>International Air Transportation (IATA)</b>	This kit is not regulated for transport.
<b>International Maritime Dangerous Goods (IMDG)</b>	This kit is not regulated for transport.

## Section 15 – Regulatory Information

### Regulatory Information

#### U.S. Federal Regulations

<b>OSHA Hazards</b>	Lysis Buffer: Irritant			
<b>SARA 302</b>	The following chemicals are subject to reporting levels established by SARA Title III, Section 302: No chemicals in this solution are subject to the reporting requirements of SARA Title III, Section 302.			
<b>SARA 313</b>	The following chemicals are subject to reporting levels established by SARA Title III, Section 313: This solution does not contain any chemical components that exceed threshold (De Minimis) reporting levels established by SARA Title III, Section 313			
<b>SARA 311/312</b>	<table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Triton X-100</td> <td style="width: 33%;">CAS#: 9002-93-1</td> <td style="width: 33%;">Acute Health Hazard</td> </tr> </table>	Triton X-100	CAS#: 9002-93-1	Acute Health Hazard
Triton X-100	CAS#: 9002-93-1	Acute Health Hazard		

## Section 15 – Regulatory Information (cont'd)

**State Regulations**

The following chemical(s) appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Triton X-100	9002-93-1	No	No	No	Yes	Yes	No

**California Prop 65:** This solution does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**Canadian – WHMIS IDL**

Chemical Name	CAS #	Minimum Concentration
Triton X-100	9002-93-1	1%

**Additional Regulatory Information**
**Safety, Health and Environmental regulations/legislation specific for the mixture:**

No data available

**Chemical Safety Assessment:**

Not completed for this components contained within this kit.

**HMIS Kit Classification:**

Health Hazard: 1  
 Chronic Health Hazard: \*  
 Flammability: 0  
 Physical Hazard: 0

**NFPA Kit Classification:**

Health Hazard (blue): 1  
 Fire Hazard (red): 0  
 Reactivity (yellow): 0  
 Special Hazards (white): None

*\*Use additional care when handling the components within this kit.*

## Section 16 – Other Information

**Text of H-code(s) mentioned in Section 3:**

Acute Tox.	Acute Toxicity	H302	Harmful if swallowed.
Aquatic Acute	Acute Aquatic Toxicity	H319	Causes serious eye irritation.
Aquatic Chronic	Chronic Aquatic Toxicity	H402	Harmful to aquatic life.
Eye Irrit.	Eye Irritation	H411	Toxic to aquatic life with long lasting effects.
		H412	Harmful to aquatic life with long lasting effects.

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**SUPERCEDES:** --

**REVISIONS:** New

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