

Section 1 – Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name: Solana GBS Assay (Catalog #: M311)

Intended Use: The Solana GBS Assay amplifies and detects Group B *Streptococcus* from broth culture. This assay is for *in vitro* diagnostic use only. Intended for use only with the Solana® instrument.

Components: Process Buffer (1.0 mL), Reaction Tubes (lyophilized cake in 0.2 mL tube)

Section 2 – Hazard Identification

- 2.1 Classification of the Substance or Mixture** Not a hazardous substance or mixture.
- 2.2 GHS Label Elements, including Precautionary Statements**
- | | |
|------|---|
| P264 | Wash hands thoroughly after handling. |
| P273 | Avoid release to the environment. |
| P281 | User personal protective equipment as required. |
- 2.1 Hazards Not Otherwise Classified (HNOC) or not covered by GHS**
- Follow Universal Precautions when working with this kit. Refer to additional Universal Precautions information in Section 7, Handling and Storage.

Section 3 – Composition / Information on Ingredients

3.1 Mixtures

Process Buffer Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200). Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

3.2 No chemicals need to be disclosed according to the applicable regulations for the components in this kit.

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Process Buffer	Glycerol (50%)	56-81-5	200-289-5	<11	1.55 mL

Section 4 – First Aid Measures

4.1 Description of First Aid Measures

If inhaled: Move the person to fresh air and support breathing as required.

In case of skin contact: Wash affected area with soap and water. Seek medical advice if irritation develops.

In case of 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 attention.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops.

4.2 Most Important Symptoms and Effects (both acute and delayed)

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

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific measures identified. Physicians should treat symptomatically.

Section 5 – Fire Fighting Measures

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

5.1 Suitable Extinguishing Media

For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 Special Hazards Arising from the Substance or Mixture

Nature of decomposition products not known.

5.3 Hazardous Combustion Products

No data available

5.4 General Fire Hazards

The components within this kit will not significantly contribute to the intensity of a fire.

5.5 Fire Fighting Equipment

Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of the Process Buffer contained within this kit is unlikely.

6.1 Personal Precautions

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.

6.2 Materials and Methods for Clean-Up

Wipe 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.

6.3 Recovery and Neutralization

Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

6.4 Environmental Precautions

Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

Section 7 – Handling and Storage**7.1 Specific Use**

Refer to product specific package insert.

7.2 Precautions for Safe Handling

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

7.3 Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

7.4 Conditions for Safe Storage (including any incompatibilities)

To maintain efficacy, store according to the package insert instructions.

7.5 Incompatibilities

To maintain efficacy, store according to the package insert instructions.

Section 8 – Exposure Controls and Personal Protection

- 8.1 Exposure Limits** No data available for the components within this kit.
- 8.2 Exposure Controls**
- Engineering Measures Use with adequate ventilation.
 - Personal Protective Equipment
 - Respiratory Protection* None needed under normal conditions of use.
 - Skin 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.
 - Body Protection* Use body protection appropriate for the task. A laboratory coat is recommended.
 - Hygiene Measures* Wash hands before use, after use and at the end of the workday.
- 8.3 Environmental Exposure Controls** No special environmental controls are required.
- 8.4 Special Notes** No data available.

Section 9 – Physical and Chemical Properties

Characteristic	Process Buffer
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H ₂ O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available
pH	Neutral
Solubility in Water	Soluble
Appearance and Odor	Clear liquid, mild odor

Section 10 – Stability and Reactivity

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

Section 11 – Toxicological Properties

11.1 Information on Toxicological Effects

Acute Toxicity	No data available	
Skin Corrosion / Irritation	No data available	
Respiratory or Skin Sensitization	No data available	
Generative Cell Mutagenicity	No data available	
Carcinogenicity	No component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.	
Reproductive Toxicity	No data available	
Teratogenicity	No data available	
Specified Target Organ Toxicity		
<u>Single Exposure:</u>	No data available	
<u>Repeated Exposure:</u>	No data available	
Aspiration Hazard	No data available	
Potential Health Effects		
<i>Inhalation:</i>	May cause respiratory tract irritation.	<i>Skin:</i> May cause skin irritation upon contact.
<i>Ingestion:</i>	May be harmful if swallowed.	<i>Eyes:</i> May cause eye irritation.

11.2 Signs and Symptoms of Exposure

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

11.3 Additional Information

Kidneys – irregularities – Based on Human Evidence (Glycerol)

Section 12 – Ecological Information

12.1 Toxicity	No data available
12.2 Persistence and Degradability	No data available
12.3 Bioaccumulative Potential	No data available
12.4 Mobility in Soil	No data available
12.5 PBT and vPvB Assessment	No data available
12.6 Other Adverse Effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13 – Disposal Considerations

13.1 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.

13.2 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

- 14.1 U.S Department of Transportation (DOT)** This kit is not regulated for transport.
- 14.2 International Air Transportation Association (IATA)** This kit is not regulated for transport.
- 14.3 International Maritime Dangerous Goods (IMDG)** This kit is not regulated for transport.

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards None

SARA 302 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.

SARA 313 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.

SARA311/312 Hazards

Glycerol CAS #: 56-81-5 Chronic Health Hazard

15.2 State Regulations

The following chemicals appear on one or more of the following state hazardous substance lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Glycerol	56-81-5	No	Yes	No	Yes	Yes	No

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

15.3 Canadian Classification (Raw Material)

Chemical Name	CAS #	Classification
Glycerol	56-81-5	Not controlled or classified

15.4 Additional Regulatory Information
Safety, Health and Environmental Regulations/Legislation Specific for the Mixture

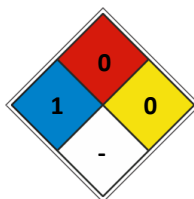
European Union – Regulation (EC) No. 1907/2006

Chemical Safety Assessment

Not completed for the components contained within this kit.

NFPA Kit Classification:

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



Section 16 – Other Information

PREPARED BY: Quidel Corporation
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SUPERSEDES: New

REVISIONS: New SDS

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability, fitness for a particular purpose or of any other type, expressed or implied, with respect to products described or data or information provided, and we assume no liability resulting from the use of such products, data or information. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event, shall Quidel be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages of any kind, howsoever arising, even if Quidel has been advised of the possibility of such damages.

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