Section 1 – Product and Company Identification

1.1 Manufacturer Information

Quidel Corporation
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Athens, OH 45701
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1.2 Product Information

Product Name: Solana GAS Assay (Catalog #: M301)

Intended Use: A *in vitro* diagnostic test for the qualitative detection of Group A β-hemolytic Streptococcus (*Streptococcus pyogenes*) nucleic acids isolated from throat swab specimens obtained from patients with signs and symptoms of pharyngitis, such as sore throat.

Components: Dilution Buffer (0.5 mL/tube), Lysis Buffer (0.5 ml/tube), and Reaction Tubes

Section 2 – Hazards Identification

2.1 Classification of the Substance of Mixture Not a hazardous substance or mixture.

2.2 GHS Label Elements, including Precautionary Statements Not a hazardous substance or mixture.

2.3 Hazards Not Otherwise Classified (HNOC) or not covered by GHS

- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides.
- Follow Universal Precautions when working with the components of this kit.
- Wash skin thoroughly after handling.
- Avoid disposal of this material down sanitary or industrial plumbing systems. Avoid release to the environment.

Section 3 – Composition / Information on Ingredients

3.1 Mixtures

Dilution Buffer: No ingredients are hazardous according to OSHA criteria
Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

Lysis Buffer: No ingredients are hazardous according to OSHA criteria
Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

Reaction Tubes: No ingredients are hazardous according to OSHA criteria
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.

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. Seek medical advice if irritation develops.

Section 4 – First Aid Measures (cont'd)

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.

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

5.4 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 components contained within this kit is unlikely.

6.1	**Personal Precautions**	Avoid breathing vapors, mist or gas.
6.2	**Environmental Precautions**	Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.
6.3	**Methods and Materials for Clean-Up**	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.
6.4	**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.

Section 7 – Handling and Storage

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

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. Keep out of reach of the general public.

7.3 Conditions for Safe Storage (including any incompatibilities)
To maintain efficacy, store according to the package insert instructions.

7.4 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	Dilution Buffer	Lysis Buffer	Reaction Tubes
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H_20 = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	7.0-7.6	7.0-7.6	No data available
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Clear liquid, mild odor	White pellet, odorless

Section 10 – Stability and Reactivity

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

Section 11 – Toxicological Information

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

Single Exposure: No data available Repeated Exposure: No data available

Aspiration Hazard: No data available

Potential Health Effects

Inhalation: May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin: May cause skin irritation upon contact.

Eyes: 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 Liver – Irregularities – Based on human evidence (sodium azide)

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:

Sodium Azide CAS #: 26628-22-8 Revision Date: 2007-07-01

SARA 313 The following chemicals are subject to reporting levels established by SARA Title III, Section 313:

Sodium Azide CAS #: 26628-22-8 Revision Date: 2007-07-01

SARA311/312 Hazards Sodium Azide CAS #: 26628-22-8 Acute Health Hazard, 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
Sodium Azide	26628-22-8	Yes	Yes	Yes	Yes	Yes	Yes

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 – WHMIS Ingredient Disclosure List

Chemical Name	CAS #	Minimum Concentration
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15.4 Additional Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Mixture No data available

Chemical Safety Assessment Not completed for the 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 this kit.*

Section 16 – Other Information

Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

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SUPERSEDES: April 16, 2015

REVISIONS: Change to format of SDS.

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