

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: Solana C. difficile Assay (Catalog #: M307)

Intended Use: An assay that combines simple sample processing and Helicase-Dependent Amplification (HAD) performed in Solana for the detection of toxigenic *Clostridium difficile* directly from CDAD-suspected diarrheal specimens. Intended for use only with the Solana instrument. **For investigational use only.**


Components: Lysis Buffer (1.0 mL), Dilution Buffer (1.8 mL), Reaction Tubes (25 µL), and Neonatal Flocked Swabs.

Section 2 – Hazards Identification

Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Lysis Buffer (<10% 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 (<10% 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.
Supplemental Hazard Statements	1. Follow Universal Precautions when working with this kit. 2. Sodium Azide is used as a preservative (<0.1%) in the Lysis and Dilution Buffers. Avoid disposal of this material down sanitary or industrial plumbing systems.		

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Lysis Buffer	Triton X-100	9002-93-1	618-344-0	<10	1.0 mL
Dilution Buffer	Glycerol	56-81-5	200-289-5	<7	1.8 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.

- 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.
- Note to Physicians:* 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.

- Extinguishing Media:* For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire.
- Hazardous Combustion Products:* No data available
- Fire Fighting Equipment:* 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.

- 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.
- 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.
- Recovery and Neutralization:* Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
- Environmental Precautions:* 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 *investigational* use only. Not for use by the general public.

Precautions for Safe Handling

As with all chemical and biological substances, avoid getting the solutions 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 ₂ 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

N/A = Do data available

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 ₅₀ Rat 1800 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available

Potential Health Effects: Lysis Buffer (irritant)

Skin Corrosion/Irritation: No data available

Inhalation: May cause respiratory tract irritation.

Serious Eye Damage / Irritation: No data available

Skin: May cause skin irritation upon contact.

Respiratory or Skin Sensitization: No data available

Eyes: May cause serious eye irritation.

Generative Cell Mutagenicity: No data available

Ingestion: 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)

Synergistic Effects No data available

Single Exposure (GHS): No data available

Repeated Exposure (GHS): 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

Ecotoxicity	No data available
Persistence / Degradability	No data available
Bioaccumulation	No data available
Mobility in Soil	No data available
PBT and vPvB Assessment	Assessment not available as chemical safety assessment not required or not conducted for this kit.
Other Adverse Effects	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

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

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards	Lysis Buffer: Irritant			
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: These solutions do not contain any chemical components that exceed threshold (De Minimis) reporting levels established by SARA Title III, Section 313			
SARA 311/312	<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 Classification (Raw Material)

Chemical Name	CAS #	Classification
Triton X-100	9002-93-1	D2B Toxic materials causing other toxic effects (moderate skin irritant, severe eye irritant)

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

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SUPERCEDES: --

REVISIONS: New

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.