

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: Specimen-Stabilizing Solution (Catalog #: A9576)

Intended Use: The Quidel Specimen Stabilizing Solution is intended for use with all assays designed to assess complement activation fragments, specifically the MicroVue™ iC3b, C3a, C4d, Bb Plus and SC5b-9 Plus EIA kits. For Research Use Only. Not for use in diagnostic procedures.


Components: Typically 25 mL vials.

Section 2 – Hazards Identification

Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Specimen-Stabilizing Solution	Irritant	Skin	Skin Sensitizer (Category 1)

GHS Classification and Label Elements

Component	Pictogram	Signal Word	Hazard Statements	Precautionary Statements
Specimen-Stabilizing Solution		Warning	H317 May cause an allergic skin reaction.	P264 Wash hands thoroughly after handling. P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P333+P313: If skin irritation or rash occurs: Get medical attention.
Supplemental Hazard Statements		1. Follow Universal Precautions when working with this kit. 2. Avoid release to the environment.		

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
Specimen-Stabilizing Solution	Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	0.035	25 mL	Acute Tox. 3; Skin Corr. 1B; Eye Dam. 1; Resp. Sens. 1; Acute Aq. 1; Chronic Aq. 1; H301+H311+H331, H314, H334, H410

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 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:* 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.
- 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 Research Use Only. Not for use in Diagnostic Procedures. 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 this solution.

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	Specimen-Stabilizing Solution (A9576)
Boiling Point (°C)	N/A
Melting Point (°C)	N/A
Specific Gravity (H ₂ O = 1)	N/A
Vapor Pressure (mm Hg)	N/A
Vapor Density (Air = 1)	N/A
Evaporation Rate (Ether = 1)	N/A
pH	Neutral
Solubility in Water	Soluble
Appearance and Odor	Clear, colorless with no odor

Section 10 – Stability and Reactivity

Characteristic	Specimen-Stabilizing Solution (A9576)
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 Information

Acute Toxicity

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

Chemical Name	CAS #	RTECS #	Information
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	Not available	Oral LD ₅₀ Rat 53 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ 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 ACGIH, NTP or OSHA.

Reproductive Toxicity No data available

Teratogenicity No data available

Synergistic Effects No data available

Specified Target Organ General Toxicity (GHS)

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 Sensitization: Contains a small volume of a very dilute, sensitizing preservative (Proclin 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

Section 12 – Ecological Information

Ecotoxicity	No data available	Mobility in Soil	No data available
Persistence / Degradability	No data available	PBT and vPvB Assessment	No data available
Bioaccumulation	No data available		
Other Adverse Effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid release to the environment. <i>Proclin 300 is very toxic to aquatic life with long lasting effects.</i>		

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 solution is not regulated for transport.
International Air Transportation (IATA)	This solution is not regulated for transport.
International Maritime Dangerous Goods (IMDG)	This solution is not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards	Specimen-Stabilizing Solution:	Irritant
SARA 302	The following chemicals are subject to reporting levels established by SARA Title III, Section 302: There are no chemicals in this solution that 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	
SARA 311/312	Proclin 300	CAS#: 55965-84-9 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
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	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
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	No data available

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 this kit.*

Section 16 – Other Information

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

H314	Causes severe skin burns and eye damage.	Skin Corr.	Corrosive to skin
H334	Causes severe skin burns and eye damage.	Eye. Dam.	Eye damage
H301+H311+H331	Toxic if swallowed, in contact with skin or inhaled.	Acute Tox.	Acute toxicity
H410	Very toxic to aquatic life with long lasting effects.	Resp. Sens.	Respiratory sensitizer
		Acute Aq.	Acute aquatic
		Chronic Aq.	Chronic aquatic

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REVISIONS: Revised to GHS format, replaced preservative Thimerosal with Proclin 300.

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.