

Section 1 – Product and Company Identification

Manufacturer Information

 Quidel Corporation
 10165 McKellar Court
 San Diego, CA 92121

 Phone: 1.800.874.1517
 Fax: 1.858.453.4338
 Emergency #: 1.866.519.4752

 Web: quidel.com
 E-mail: gehs@quidel.com

Product Information

Product Name: MicroVue Pan-Specific C3 Reagent Kit (Catalog #: 20261)

Intended Use: A reagent set used to detect the depletion of Complement protein C3 in various animal species.

Components: C3 Complement Matrix (lyophilized), Specimen Diluent, C3 Converter Reagent (suspension), Stop Solution and Positive Control (lyophilized).


Section 2 – Hazards Identification

Emergency Overview

Significant health effects are not anticipated from routine use of this kit when following the precautions listed within this SDS and the kit specific Package Insert. The **Stop Solution (1254600)**, **Specimen Diluent (1254700)** and the **C3 Converter Reagent (1254500)** contained within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), or the European Union (EU) Directives 1999/45/EC, 67/548/EEC and/or 1272/2008.

Component	OSHA Hazards	Target Organs	GHS Classification
Stop Solution, Specimen Diluent, C3 Converter Reagent (0.5% Proclin 300)	Irritant	Eyes and Skin	Skin Irritation (Category 2) Eye Irritation (Category 2) Skin Sensitizer (Category 1)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
Stop Solution, Specimen Diluent, C3 Converter Reagent (0.5% Proclin 300)	 Warning	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements		1. Follow Universal Precautions when working with this kit. 2. Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Stop Solution (0.5 mL), Specimen Diluent (10 mL) and C3 Converter Reagent (0.5 mL):

Chemical Name	CAS #	Index #	Conc. (%)	Chemical Classification
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	613-167-00-5	0.5	Acute Tox. 3; Skin Corr. 1B; Eye Dam. 1; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 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:* Do NOT induce vomiting. 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:* Wipe up with appropriate absorbent (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.

Section 7 – Handling and Storage

Specific Use: For Research Use Only. Not for use in diagnostic procedures.

Precautions for Safe Handling

Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Wash exposed areas thoroughly after using this kit. Do not eat or drink while using this kit. Universal Precautions should be followed when handling and working with this kit. Keep out of reach of the general public.

Conditions for Safe Storage: To maintain efficacy, store according to the kit specific Package Insert instructions.

Incompatibilities None.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: Contains no components with established occupational exposure limit values.

Exposure Controls:

Engineering Measures Use with adequate ventilation to maintain worker exposure below limits listed above.

Personal Protective Equipment

Respiratory Protection: None needed under normal conditions of use.

Hand Protection: Handle with appropriately rated chemical resistant gloves (nitrile or equivalent). 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: Handle in accordance with good industrial hygiene and safety practice. 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	Stop Solution (1254600)	Specimen Diluent (1254700)	C3 Converter Reagent (1254500)
Boiling Point (°C)	N/A	N/A	N/A
Melting Point (°C)	N/A	N/A	N/A
Specific Gravity (H ₂ O = 1)	N/A	N/A	N/A
Vapor Pressure (mm Hg)	N/A	N/A	N/A
Vapor Density (Air = 1)	N/A	N/A	N/A
Evaporation Rate (Ether = 1)	N/A	N/A	N/A
pH	7.85	7.30	4.5
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Clear liquid, odorless	Clear, odorless	Cloudy white, odorless

Section 10 – Stability and Reactivity

Characteristic	Stop Solution (1254600)	Specimen Diluent (1254700)	C3 Converter Reagent (1254500)
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	Will not occur	Will not occur	Will not occur
Conditions to Avoid	None	None	None
Materials to Avoid	Strong oxidizing agents, reducing agents	Strong oxidizing agents, reducing agents, amines	Strong oxidizing agents, reducing agents, amines
Hazardous Decomposition Products	No data available	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		
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 data available	Oral LD ₅₀	Rat	53 mg/kg
			Inhalation LC ₅₀	No data available	
			Dermal LD ₅₀	No data available	

Potential Health Effects: Stop Solution (12546000), Specimen Diluent (1254700), C3 Converter Reagent (1254500)

<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 component of this kit present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by 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.

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 the components contained within this kit.

Synergistic Effects No data available.

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.

Proclin 300 is very toxic to aquatic life with long lasting effects.

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 (e.g., Canada, EU, Japan, etc.), federal, state and local regulations. If unsure of the applicable regulatory requirements, contact the authorities for information.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)

This kit is not regulated as a hazardous material.

International Air Transportation (IATA)

This kit is not regulated as a dangerous good.

International Maritime Dangerous Goods (IMDG)

This kit is not regulated as a dangerous good.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards Stop Solution (1254600), Specimen Diluent (1254700), C3 Converter reagent (1254500): Irritant

SARA 302 The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
No chemicals in this material 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:
The components of this kit do not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 *Proclin 300*: CAS#: 55965-84-9 Acute Health Hazard
5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one;
2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)

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 product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

Section 15 – Regulatory Information (cont'd)

Canadian - WHMIS IDL No data available.

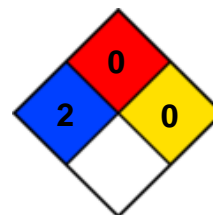
Additional Regulatory Information

Safety, Health and Environmental regulations/legislation specific for the mixture: No data available.

Chemical Safety Assessment: No data available.

HMIS Kit Classification:

NFPA Kit Classification:



Section 16 – Other Information

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

H301+H311+H331	Toxic if swallowed, in contact with skin or inhaled.	Eye Irrit.	Eye irritation
H302	Harmful if swallowed.	Eye Dam.	Eye Damage
H314	Causes severe skin burns and eye damage.	Skin Irrit.	Skin irritation
H317	May cause an allergic skin reaction.	Skin Corr.	Skin Corrosion
H318	Causes serious eye damage.	Resp. Sens.	Respiratory Sensitizer
H332	Harmful if inhaled.	Aquatic Acute	Acute aquatic toxicity
H400	Very toxic to aquatic life.	Aquatic Chronic	Chronic aquatic toxicity
H410	Very toxic to aquatic life with long lasting effects.		

PREPARED BY: Quidel Corporation
10165 McKellar Court, San Diego, CA 92121

SUPERCEDES: New

REVISIONS: GHS compliant format and new brand format

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.

0200RA0314D (03/14)