

Section 1 – Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name:

MicroVue Complement Multiplex Assay – Standard 8-plex (Catalog #: A900)
MicroVue Complement Multiplex Assay – Custom 3 to 8 plex (Catalog #: A903, A904, A905, A906, A907, A908)
MicroVue Complement Multiplex Calibrators and Controls (Catalog #: A950)

Suggested Use: This kit is for Research Use Only and not for use in diagnostic procedures.


Components: Arrayed Microplate, Multiplexed Calibrators (silver caps), High/Low Controls (red caps), Specimen Diluent (blue cap), Specimen Diluent Competitor (blue cap), Detection Mix (green cap), Detection Competitor (green cap), Wash Buffer Concentrate 20x (clear cap), Streptavidin-HRP (white cap), Substrate A (brown cap), and Substrate B (brown cap).

Section 2 – Hazards Identification

2.1 Classification of Substance or Mixture

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Specimen Diluent (<0.0085% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
Specimen Diluent Competitor (<0.0085% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
Detection Mix (<0.0015% Kathon LX)	Irritant	Skin	Skin Sensitizer (Category 1)
Detection Competitor (<0.0015% Kathon LX)	Irritant	Skin	Skin Sensitizer (Category 1)

2.2 GHS Label Elements, Including Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
Specimen Diluent (<0.0085% Proclin 300) Specimen Diluent Competitor (<0.0085% Proclin 300) Detection Mix (<0.0015% Kathon LX) Detection Competitor (<0.0015% Kathon LX)	 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.

Section 2 – Hazards Identification (cont'd)

Supplemental Hazard Statements

1. Follow Universal Precautions when working with this kit. Refer to additional Universal Precaution information in Section 7, Handling and Storage.
2. Avoid release to the environment.
3. Sodium azide (<0.1%) used as a preservative in the Sample Diluent.
4. Prevent the components listed above from entering drains.

Section 3 – Composition / Information on Ingredients

3.1 Mixtures

Component	Chemical Name	CAS #	EINECS #	Conc. (%)
1. Specimen Diluent 2. Specimen Diluent Competitor	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	<0.0085
1. Detection Mix 2. Detection Competitor	Kathon LX 1.5% Biocide	No data available	No data available	<0.0015

Section 4 – First Aid Measures

4.1 Description of First Aid Measures

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: Drink 1 to 2 glasses of water. Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops.

Note to Physicians: Treat symptomatically.

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 Extinguishing Media

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

5.2 General Fire Hazards

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

5.3 Hazardous Combustion Products

No data available

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. Large spills of the solutions, controls or reagents contained within this kit are 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 Methods and Materials 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 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 into the environment must be avoided.

Section 7 – Handling and Storage

7.1 Specific Use

Refer to product specific Package Insert. 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.

Section 7 – Handling and Storage (cont'd)

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 or other human/animal derived 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

To maintain efficacy, store according to the kit specific Package Insert instructions.

7.5 Incompatibilities

To maintain efficacy, store according to the kit specific Package Insert instructions.

Section 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits

No data available for the specific 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.

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.

8.3 Environmental Exposure Controls

No special environmental controls are required.

Section 9 – Physical and Chemical Properties

Characteristic	Specimen Diluent	Specimen Diluent Competitor	Detection Mix	Detection Mix Competitor
Boiling Point (°C)	No data available	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available	No data available

Section 9 – Physical and Chemical Properties (cont'd)

Characteristic	Specimen Diluent	Specimen Diluent Competitor	Detection Mix	Detection Mix Competitor
pH	7.2 – 7.4	7.2 – 7.4	7.2 – 7.4	7.2 – 7.4
Solubility in Water	Soluble	Soluble	Soluble	Soluble
Appearance and Odor	Light brown liquid, odorless	Light brown liquid, odorless	Clear liquid, odorless	Clear liquid, odorless

Section 10 – Stability and Reactivity

Characteristic	Specimen Diluent	Specimen Diluent Competitor	Detection Mix	Detection Mix Competitor
Component Stability	Stable	Stable	Stable	Stable
Hazard Reaction Potential	No data available	No data available	No data available	No data available
Conditions to Avoid	No data available	No data available	No data available	No data available
Materials to Avoid	No data available	No data available	No data available	No data available
Hazardous Decomposition Products	No data available	No data available	No data available	No data available

Section 11 – Toxicological Information

11.1 Information on Toxicological Effects

Specimen Diluent, Specimen Diluent Competitor, Detection Mix, Detection Mix Competitor – Sensitizer

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
Kathon LX	--	Not available	Oral LD ₅₀ Rat 3,310 mg/kg Inhalation LC ₅₀ Rat (4-hr mist) >5 mg/L (est.) Dermal LD ₅₀ Rabbit >5000 mg/kg

Acute Toxicity No data available

Skin Corrosion/ Irritation No data available

Serious Eye Damage / Irritation: No data available

Section 11 – Toxicological Information (cont'd)

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, NTP or OSHA.
Reproductive Toxicity	No data available
Teratogenicity	No data available
Specified Target Organ Toxicity	
<i>Single Exposure (GHS):</i>	No data available
<i>Repeated Exposure (GHS):</i>	No data available

Potential Health Effects

<i>Inhalation</i>	May cause respiratory tract irritation.
<i>Ingestion</i>	May be harmful if swallowed.
<i>Skin</i>	May cause skin irritation upon contact.
<i>Eyes</i>	May cause serious eye irritation.

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Synergistic Effects

No data available

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 contained within this kit.

11.3 Additional Information

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

Section 12 – Ecological Information

12.1 Ecotoxicity	No data available
12.2 Persistence / Degradability	No data available
12.3 Bioaccumulation	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. Avoid release to the environment and municipal or industrial drains.

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

Kathon LX is very toxic to aquatic life with long lasting effects.

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 (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 Specimen Diluent, Specimen Diluent Competitor, Detection Mix, Detection Mix Competitor: **Sensitizer**

SARA 302 The following chemicals are subject to reporting levels established by SARA Title III, Section 302:
No chemicals in this kit 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:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313.

SARA 311/312	Proclin 300	CAS#: 55965-84-9	Acute Health Hazard
	Kathon LX	CAS#: Not available	Acute Health Hazard

15.2 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
Kathon LX	7647-01-0	Yes	Yes	Yes	Yes	Yes	Yes

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

15.3 Additional Regulatory Information

Safety, Health and Environmental regulations/legislation specific for the mixture:

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

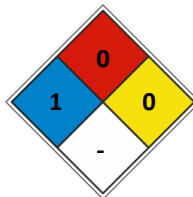
Section 15 – Regulatory Information (cont'd)

Chemical Safety Assessment:

Not completed for the components contained within this kit.

NFPA Kit Classification:

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



Section 16 – Other Information

PREPARED BY: Quidel Corporation
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SUPERCEDES: New SDS

REVISIONS: Section 1.2, added reference to MicroVue Complement Multiplex Calibrators and Controls, Catalog #: A950

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