

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: MicroVue SC5b-9 Plus EIA kit (Catalog #: A020, A029)

Intended Use: A020 For Research Use Only in the United States. Not for use in diagnostic procedures.

A029 The MicroVue SC5b-9 Plus Enzyme Immunoassay for the quantitation of SC5b-9 in human serum, plasma, or experimental samples. For in vitro diagnostic use only. Not for sale in the United States or Canada.


Components: SC5B-9 Standards A → E, High Control, Low Control, Coated Strips, Stop Solution, 20x Wash Solution Concentrate, Specimen Diluent, TMB Substrate, and SC5b-9 Plus Conjugate.

Section 2 – Hazards Identification




Classification of Substance or Mixture

Component	OSHA Hazards	Target Organs	GHS Classification
Stop Solution (<10% Sulfuric Acid)	Corrosive	Eyes and Skin	Skin Irritation (Category 2) Eye Irritation (Category 2)
20X Wash Solution (0.035% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
Specimen Diluent (0.035% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
TMB Substrate Buffer (Proprietary Mixture)	Irritant	Eyes, Skin and Respiratory System	Skin Irritation (Category 2) Eye Irritation (Category 2A) Reproductive Toxicity (Category 1B) STOT SE (Category 3) Respiratory STOT RE (Category 2)

GHS Label Elements, Including Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
Stop Solution (<10% Sulfuric Acid)	 Warning	H315 Causes skin irritation. 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.

Section 2 – Hazards Identification (cont'd)

Component	Pictogram	Hazard Statements	Precautionary Statements
20X Wash Solution (0.035% Proclin 300) Specimen Diluent (0.035% Proclin 300)	 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.
TMB Substrate (Proprietary Mixture)	  Danger	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H360 May damage fertility or the unborn child. H373 May cause damage to organs through prolonged or repeated exposure.	P264 Wash hands thoroughly after handling. P280 Wear protective gloves and safety glasses. 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. 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. Refer to additional Universal Precaution information in Section 7, Handling and Storage. 2. Prolonged or repeated contact may dry skin and cause irritation (TMB Substrate) 3. Avoid release to the environment.		

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Stop Solution (4978)	Sulfuric Acid	7664-93-9	231-639-5	<10	12 mL
TMB Substrate (A9946)	Proprietary Mixture	--	--	--	12 mL
1. 20X Wash Concentrate (A9957) 2. Specimen Diluent (A3670)	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	0.035	1. 2x50 mL 2. 50 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 (do not swallow). Seek medical advice if irritation develops. **TMB Substrate or Stop Solution:** Do not induce vomiting.
- 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 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: Refer to product specific Package Insert.

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.

Section 7 – Handling and Storage (cont'd)

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 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

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

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

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the specific components within 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	Stop Solution (4978)	TMB Substrate (A9946)	20X Wash Solution Concentrate (A9957)	Specimen Diluent (A3670)
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
pH	<1	5.1	6.1 to 6.6	Neutral
Solubility in Water	Soluble	Soluble	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Clear liquid, odorless	Clear liquid, odorless	Slightly brown liquid, odorless

Section 10 – Stability and Reactivity

Characteristic	Stop Solution (4978)	TMB Substrate (A9946)	20X Wash Solution Concentrate (A9957)	Specimen Diluent (A3670)
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

Acute Toxicity

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

Chemical Name	CAS #	RTECS #	Information
Sulfuric Acid	7664-93-9	WS5600000	Oral LD ₅₀ Rat 2140 mg/kg Inhalation LC ₅₀ Rat (2h) 51 mg/m ³ Dermal LD ₅₀ No data available
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: Stop Solution (4978) – Corrosive
 TMB Substrate (A9946) – Irritant, Reproductive
 20X Wash Solution Concentrate (A9957) and Specimen Diluent (A3670) – Irritant

<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.

TMB Substrate: May cause damage to organs through prolonged or repeated exposure. Prolonged or repeated contact can deft the skin and lead to irritation.

Carcinogenicity

IARC: Group 1 Carcinogen (Sulfuric Acid Mist) OSHA: Select Carcinogen (Sulfuric Acid Mist)

Reproductive Toxicity No data available_

Teratogenicity TMB Substrate (A9946): May damage the unborn child.

Specified Target Organ General Toxicity (GHS)

Single Exposure (GHS): TMB Substrate (A9946): Inhalation – May cause respiratory irritation.

Repeated Exposure (GHS): No data available

Section 11 – Toxicological Information (cont'd)

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

TMB Substrate: Bone marrow – irregularities – Based on Human Evidence (1-Methyl-2-Pyrrolidinone)

Stop Solution: Stomach - Irregularities - Based on Human Evidence (Sulfuric acid)

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.

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, 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	Stop Solution (4978): Corrosive 20X Wash Solution Concentrate (A9957): Irritant Specimen Diluent (A3670): Irritant TMB Substrate (A9946): Irritant, Reproductive
SARA 302	The following chemicals are subject to reporting levels established by SARA Title III, Section 302: Sulfuric Acid CAS #: 7664-93-9 Revision Date: 2007-07-01
SARA 313	The following chemicals are subject to reporting levels established by SARA Title III, Section 313: Sulfuric Acid CAS #: 7664-93-9 Revision Date: 2007-07-01
SARA 311/312	Sulfuric Acid CAS #: 7664-93-9 Acute Health Hazard, Chronic Hazard Proclin 300 CAS #: 55965-84-9 Acute Health Hazard TMB Substrate CAS #: Proprietary Acute Health Hazard, Chronic Hazard, Fire Hazard

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
Sulfuric Acid	7664-93-9	Yes	Yes	Yes	Yes	Yes	Yes
TMB Substrate	Proprietary	No data available					
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: TMB Substrate (A9946) – **WARNING** – This component contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Stop Solution (4978) – **WARNING** – This component contains a chemical know to the State of California to cause cancer.

Sulfuric Acid (Mist) CAS #: 7664-93-9 Revision: 2003-03-14

Canadian – WHMIS Classification (Raw Material)

Chemical Name	CAS #	Classification
Sulfuric Acid	7664-93-9	E Corrosive - Corrosive to skin.
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	D2B Toxic material causing other toxic effects - Skin sensitizer

Section 15 – Regulatory Information (cont'd)

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

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

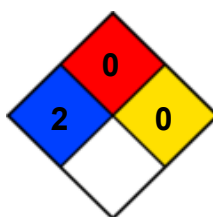
Chemical Safety Assessment:

Not completed for the components contained within this kit.

TMB Substrate (A9946): The employer shall assess the working conditions and if there is any risk to the safety or health and effects on the pregnancy or breastfeeding of workers, take necessary measures to adjust the working conditions.

NFPA Kit Classification:

Health Hazard (blue):	2
Fire Hazard (red):	0
Reactivity Hazard (yellow):	0
Special Hazard (White):	None



Section 16 – Other Information

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SUPERCEDES: May 19, 2017

REVISIONS: **Section 4**, added Stop Solution statement; **Section 7**, updated specific use statement; **Section 15**, added EU regulatory reference and removed HMIS kit classification.

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.

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