

## Section 1 – Product and Company Identification

### Manufacturer Information

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### Product Information

Product Name: MicroVue C1-Inhibitor Plus EIA kit (Catalog #: A037)

Intended Use: The MicroVue C1-Inhibitor Plus Enzyme Immunoassay (EIA) measures the amount of functional C1-Inhibitor protein in human plasma or serum. This kit is for *In Vitro* Diagnostic use.



Components: C1-INH Standards A → E, C1-INH Abnormal Control (Human), C1-INH Normal Control (Human), Microassay Plate, Stop Solution, 20X Wash Solution Concentrate, 5x Specimen Diluent Concentrate, TMB Substrate, C1-Inhibitor Reactant, C1-Inhibitor Conjugate and Hydrating Reagent.

## Section 2 – Hazards Identification



### Classification of Substance or Mixture

Kit Component	OSHA Hazards	Target Organs	GHS Classification
<b>Stop Solution</b> (4% Hydrochloric Acid)	Irritant	Eyes and Skin	Skin Irritation (Category 2) Eye Irritation (Category 2)
<b>20X Wash Solution, 5x Specimen Diluent, Hydrating Reagent</b> (0.035% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
<b>TMB Substrate</b> (Proprietary Mixture)	Irritant	Eyes, Reproductive	Eye Irritation (Category 2A) Reproductive Toxicity (Category 1B) STOT SE (Category 3)

### GHS Label Elements, Including Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
<b>Stop Solution</b> (4% Hydrochloric 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.
<b>20X Wash Solution, 5X Specimen Diluent, Hydrating Reagent</b> (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.

## Section 2 – Hazards Identification (cont'd)

Component	Pictogram	Hazard Statements	Precautionary Statements
<b>TMB Substrate</b> (Proprietary Mixture)	  Danger	H319 Causes serious eye irritation. H336 May cause dizziness or drowsiness. H360 May damage fertility or the unborn child.	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.
<b>Supplemental Hazard Statements</b>		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 is used as a preservative (<0.1%) in the C1-Inhibitor Conjugate (A9525). 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
Stop Solution (A9947)	Hydrochloric Acid	7647-01-0	231-595-7	<4	12 mL
TMB Substrate (5059)	Hydrogen Peroxide 1-Ethyl-2-Pyrrolidone (NEP) Acetone	7722-84-1 2687-91-4 67-64-1	231-765-0 220-250-6 200-662-2	<0.1 1 - 5 1 - 10	12 mL
1. 20X Wash Solution (A9957) 2. 5X Specimen Diluent (A9519) 3. Hydrating Reagent (A3675)	<b>Mixture for Proclin 300:</b> 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	No data available	1. 0.035 2. 0.035 3. 0.035	1. 2 x 50 mL 2. 25 mL 3. 25 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.

### 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 (A9947)	20X Wash Solution (A9957)	5X Specimen Diluent (A9519)	TMB Substrate (5059)	Hydrating Reagent (A3675)
Boiling Point (°C)	No data available	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	No data available
Specific Gravity (H <sub>2</sub> O = 1)	No data available	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	No data available
Vapor Density (Air = 1)	No data available	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	No data available
pH	<1	6.1 to 6.6	Neutral	Neutral	Neutral
Solubility in Water	Soluble	Soluble	Soluble	Soluble	Soluble
Appearance and Odor	Clear liquid, mild odor	Clear liquid, odorless	Slightly brown liquid, odorless	Clear liquid, mild odor	Clear liquid, odorless

## Section 10 – Stability and Reactivity

Characteristic	Stop Solution (A9947)	20X Wash Solution (A9957)	5X Specimen Diluent (A9519)	TMB Substrate (5059)	Hydrating Reagent (A3675)
Component Stability	Stable	Stable	Stable	Stable	Stable
Hazard Reaction Potential	No data available	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	No data available
Materials to Avoid	No data available	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	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		
Hydrochloric Acid	7647-01-0	MW4025000	Oral LD <sub>50</sub>	Rabbit	900 mg/kg
			Inhalation LC <sub>50</sub>	Mouse	1108 PPM/1H
			Dermal LD <sub>50</sub>	No data available	
<b>Mixture for Proclin 300:</b> 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 <sub>50</sub>	Rat	53 mg/kg
			Inhalation LC <sub>50</sub>	No data available	
			Dermal LD <sub>50</sub>	No data available	
TMB Substrate (Proprietary Mixture)	--	Not available	Oral LD <sub>50</sub>	No data available	
			Inhalation LC <sub>50</sub>	No data available	
			Dermal LD <sub>50</sub>	No data available	

#### Potential Health Effects:

Stop Solution (A9947) and TMB Substrate (5059) - Irritant

20X Wash Solution (A9957), 5X Specimen Diluent (A9519), and Hydrating Reagent (A3675) – Sensitizer

<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 the ACGIH, NTP or OSHA.

IARC: 3 – Group 3: Not classifiable as to its carcinogenicity to humans (Hydrochloric acid)

**Reproductive Toxicity**      TMB Substrate (5059):      Damage to fetus possible.

**Teratogenicity**      No data available

#### Specified Target Organ General Toxicity (GHS)

*Single Exposure (GHS):*      TMB Substrate (5059): Inhalation – May cause respiratory irritation.

*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.

TMB Substrate:      Stomach – Irregularities – Based on human evidence (Hydrogen Peroxide)

## Section 12 – Ecological Information

<b>Ecotoxicity</b>	No data available	<b>Mobility in Soil</b>	No data available
<b>Persistence / Degradability</b>	No data available	<b>PBT and vPvB Assessment</b>	No data available
<b>Bioaccumulation</b>	No data available		
<b>Other Adverse Effects</b>	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

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

## Section 15 – Regulatory Information

### Regulatory Information

#### U.S. Federal Regulations

<b>OSHA Hazards</b>	Stop Solution (A9947), 20X Wash Solution (A9957), Complement Sample Diluent (A3670), and Hydrating Reagent (A3675): Irritant TMB Substrate (5059): Irritant, damage to fetus possible.		
<b>SARA 302</b>	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.		
<b>SARA 313</b>	The following chemicals are subject to reporting levels established by SARA Title III, Section 313:		
	Hydrochloric Acid	CAS#: 7647-01-0	Revision Date: 1993-04-24
<b>SARA 311/312</b>	Hydrochloric Acid	CAS#: 7647-01-0	Acute Health Hazard
	Proclin 300	CAS#: 55965-84-9	Acute Health Hazard
	TMB Substrate (Proprietary Mixture)	CAS#: Not available	Acute Health Hazard, Chronic 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
Hydrochloric Acid	7647-01-0	Yes	Yes	Yes	Yes	Yes	Yes
<b>Mixture for Proclin 300:</b> 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
TMB Substrate (Proprietary Mixture)	--	No data available					

**California Prop 65:** TMB Substrate (5059) – **WARNING** – This component contains a chemical known to the State of California to cause birth defects or other reproductive harm.

**Canadian – WHMIS Classification (Raw Material)**

Chemical Name	CAS #	Classification
Hydrochloric Acid	1310-73-2	E Corrosive - Corrosive to metal and skin.
<b>Mixture for Proclin 300:</b> 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
TMB Substrate (Proprietary Mixture)	--	D2B Toxic material causing other toxic effects - Severe eye irritant

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

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

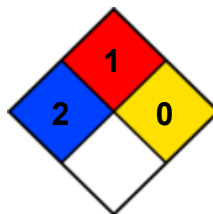
**Chemical Safety Assessment:**

Not completed for the components contained within this kit.

TMB Substrate (5059): 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): 1  
 Reactivity Hazard (yellow): 0  
 Special Hazard (white): None



**Section 16 – Other Information**

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**SUPERCEDES:** May 23, 2017

**REVISIONS:** **Section 4**, added Stop Solution; **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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