

Section 1 – Product and Company Identification

Manufacturer Information

Quidel Corporation
2005 East State Street, Suite 100
Athens, OH 45701

Phone: 1.800.874.1517
Fax: 1.740.592.9820
Emergency #: 1.866.519.4752

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

Product Information

Product Name: MicroVue Factor H EIA kit (Catalog #: A040)

Suggested Use: An enzyme immunoassay for the quantitative measurement of complement Factor H in human plasma or serum.



Components: Factor H Standards A → E, Factor H Low Control, Factor H High Control, Microassay Plate, Stop Solution, 20X Wash Solution Concentrate, Complement Specimen Diluent, TMB Substrate, and Factor H Conjugate.

Section 2 – Hazards Identification




Emergency Overview

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Stop Solution (4% Hydrochloric Acid)	Irritant	Eyes and Skin	Skin Irritation (Category 2) Eye Irritation (Category 2)
20X Wash Solution, Complement Specimen Diluent, Factor H Standards and Controls (0.035% Proclin 300)	Irritant	Skin	Skin Sensitizer (Category 1)
TMB Substrate (Proprietary Mixture)	Flammable Liquid Irritant	Eyes, Skin and Respiratory System	Eye Irritation (Category 2A) Skin Irritation (Category 2) Reproductive Toxicity (Category 1B) STOT SE (Category 3)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
Stop Solution (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.
20X Wash Solution, Complement Specimen Diluent, Factor H Standards and Controls (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
TMB Substrate (Proprietary Mixture)	   Danger	H225 Highly flammable liquid and vapor. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H360 May damage fertility or the unborn child.	P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat/sparks/open flames/hot surfaces – no smoking. 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. 2. Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
Stop Solution (A9947)	Hydrochloric Acid	7647-01-0	231-595-7	<4	12 mL	Met. Corr. 1; Skin Corr. 1B; Eye Dam. 1; STOT SE 3; H290, H314, H335
TMB Substrate (5059)	Proprietary Mixture	--	--	<20	12 mL	Flam. Liq. 2; Skin Irrit. 2; Eye Dam. 1; Repr. 1B; STOT SE 3; H225, H315, H318, H335, H360
1. 20X Wash Solution (A9957) 2. Complement Specimen Diluent (A9784) 3. Factor H Standards and Controls	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. 50 mL 2. 50 mL 3. 1 mL/ea	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.

<i>If inhaled:</i>	Move the person to fresh air and support breathing as required.
<i>In case of skin contact:</i>	Wash affected area with soap and water. Seek medical advice if irritation develops.
<i>In case of eye contact:</i>	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.
<i>If swallowed:</i>	Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.
<i>Note to Physicians:</i>	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.

<i>Extinguishing Media:</i>	For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
<i>General Fire Hazards:</i>	The components within this kit will not significantly contribute to the intensity of a fire.
<i>Hazardous Combustion Products:</i>	No data available
<i>Fire Fighting Equipment:</i>	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.

<i>Personal Precautions:</i>	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.
<i>Materials and Methods for Clean-Up:</i>	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.
<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	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 by the general public.

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.

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)	Complement Specimen Diluent (A9784)	TMB Substrate (5059)	Factor H Standards and Controls
Boiling Point (°C)	N/A	N/A	N/A	N/A	N/A
Melting Point (°C)	N/A	N/A	N/A	N/A	N/A
Specific Gravity (H ₂ O = 1)	N/A	N/A	N/A	N/A	N/A
Vapor Pressure (mm Hg)	N/A	N/A	N/A	N/A	N/A
Vapor Density (Air = 1)	N/A	N/A	N/A	N/A	N/A
Evaporation Rate (Ether = 1)	N/A	N/A	N/A	N/A	N/A
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, mild odor

N/A = Do data available

Section 10 – Stability and Reactivity

Characteristic	Stop Solution (A9947)	20X Wash Solution (A9957)	Complement Specimen Diluent (A9784)	TMB Substrate (5059)	Factor H Standards and Controls
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	Heat, flames, sparks	No data available
Materials to Avoid	Bases, amines, alkali metals, metals, fluorine, permanganates	Strong oxidizing agents, reducing agents, amines	Strong oxidizing agents, reducing agents, amines	Bases, strong oxidizing agents, reducing agents, acid chlorides	Strong oxidizing agents
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 ₅₀ Rabbit 900 mg/kg Inhalation LC ₅₀ Mouse 1108 PPM/1H 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
Proprietary Mixture	--	Not available	Oral LD ₅₀ No data available Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available

Potential Health Effects: Stop Solution (A9947), 20X Wash Solution (A9957), Complement Specimen Diluent (A9784), TMB Substrate (5059) and Factor H Standards and Controls

<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

Section 11 – Toxicological Information (cont'd)

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.

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 (e.g., Canada, EU, Japan, etc.), 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 (A9947), 20X Wash Solution (A9957), Complement Sample Diluent (A9784), TMB Substrate (5059) and Factor H Standards and Controls: Irritant									
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: <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Hydrochloric Acid</td> <td style="width: 33%;">CAS#: 7647-01-0</td> <td style="width: 33%;">Revision Date: 1993-04-24</td> </tr> <tr> <td>Proprietary Mixture</td> <td>CAS#: 872-50-4</td> <td>Revision Date: 2007-07-01</td> </tr> </table>	Hydrochloric Acid	CAS#: 7647-01-0	Revision Date: 1993-04-24	Proprietary Mixture	CAS#: 872-50-4	Revision Date: 2007-07-01			
Hydrochloric Acid	CAS#: 7647-01-0	Revision Date: 1993-04-24								
Proprietary Mixture	CAS#: 872-50-4	Revision Date: 2007-07-01								
SARA 311/312	<table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">Hydrochloric Acid</td> <td style="width: 33%;">CAS#: 7647-01-0</td> <td style="width: 33%;">Acute Health Hazard</td> </tr> <tr> <td>Proclin 300</td> <td>CAS#: 55965-84-9</td> <td>Acute Health Hazard</td> </tr> <tr> <td>Proprietary Mixture:</td> <td>CAS#: Not available</td> <td>Fire Hazard, Acute Health Hazard, Chronic Health Hazard</td> </tr> </table>	Hydrochloric Acid	CAS#: 7647-01-0	Acute Health Hazard	Proclin 300	CAS#: 55965-84-9	Acute Health Hazard	Proprietary Mixture:	CAS#: Not available	Fire Hazard, Acute Health Hazard, Chronic Health Hazard
Hydrochloric Acid	CAS#: 7647-01-0	Acute Health Hazard								
Proclin 300	CAS#: 55965-84-9	Acute Health Hazard								
Proprietary Mixture:	CAS#: Not available	Fire Hazard, Acute Health Hazard, Chronic Health 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
Hydrochloric Acid	7647-01-0	Yes	Yes	Yes	Yes	Yes	Yes
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
<i>Proprietary Mixture</i>	--	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. CAS #: 872-50-4 (2009-02-01)

Canadian – WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
Hydrochloric Acid	1310-73-2	1%
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
<i>Proprietary Mixture</i>	--	No data available

Additional Regulatory Information

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

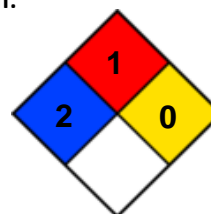
TMB Substrate (5059): The employer shall assess the working conditions and if there is any risk to the safety or health and effects on the pregnancy or breastfeeding of workers, take necessary measures to adjust the working conditions.

Chemical Safety Assessment:

Not completed for this components contained within this kit.

Section 15 – Regulatory Information (cont'd)

HMIS Kit Classification:

NFPA Kit Classification:


Section 16 – Other Information

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

H225	Highly flammable liquid and vapor.	Met. Corr.	Metal corrosion
H290	May be corrosive to metals.	Skin. Corr.	Skin corrosion
H314	Causes severe skin burns and eye damage.	Eye. Dam.	Eye damage
H315	Causes skin irritation.	Flam. Liq.	Flammable liquid
H318	Causes serious eye damage.	Skin Irrit.	Skin irritation
H334	Causes severe skin burns and eye damage.	Resp. Sens.	Respiratory sensitizer
H335	May cause respiratory irritation.	Repr.	Reproductive toxicity
H360	May damage fertility or the unborn child.	Acute Tox.	Acute toxicity
H301+H311+H331	Toxic if swallowed, in contact with skin or inhaled.	Acute Aq.	Acute aquatic
H410	Very toxic to aquatic life with long lasting effects.	Chronic Aq.	Chronic aquatic

PREPARED BY: Quidel Corporation
 12544 High Bluff Drive, Suite 200
 San Diego, CA 92130

SUPERCEDES: New

REVISIONS: --

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.

SDA040000EN00 (02/16)