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: qehs@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

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

GHS Classification and Label Elements

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop Solution (4% Hydrochloric Acid)</td>
<td>Warning</td>
<td>H315 Causes skin irritation. H319 Causes serious eye irritation.</td>
<td>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.</td>
</tr>
<tr>
<td>20X Wash Solution, Complement Specimen Diluent, Factor H Standards and Controls (0.035% Proclin 300)</td>
<td>Warning</td>
<td>H317 May cause an allergic skin reaction.</td>
<td>P264 Wash hands thoroughly after handling. P303+P361+P338: 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.</td>
</tr>
</tbody>
</table>
## Section 2 – Hazards Identification (cont’d)

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
</table>
| **TMB Substrate**  
(Proprietary Mixture) | ![Danger]  
H225  | Highly flammable liquid and vapor. | P202  
Do not handle until all safety precautions have been read and understood. |
|  | H315  | Causes skin irritation. | P210  
Keep way from heat/sparks/open flames/hot surfaces – no smoking. |
|  | H319  | Causes serious eye irritation. | P264  
Wash hands thoroughly after handling. |
|  | H335  | May cause respiratory irritation. | P280  
Wear protective gloves and safety glasses. |
|  | H360  | May damage fertility or the unborn child. | 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

<table>
<thead>
<tr>
<th>Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Conc. (%)</th>
<th>Componen t Volume</th>
<th>Chemical Classification</th>
</tr>
</thead>
</table>
| 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  
(S059) | Proprietary Mixture | -- | -- | <20 | 12 mL | Flam. Liq. 2; Skin Irrit. 2; Eye Dam. 1; Repr. 1B; STOT SE 3; H225, H315, H318, H335, H360 |
|  | **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 |

1. 20X Wash Solution (A9957)  
2. Complement Specimen Diluent (A9784)  
3. Factor H Standards and Controls
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. 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: 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.
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: 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stop Solution (A9947)</th>
<th>20X Wash Solution (A9957)</th>
<th>Complement Specimen Diluent (A9784)</th>
<th>TMB Substrate (5059)</th>
<th>Factor H Standards and Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>pH</td>
<td>&lt;1</td>
<td>6.1 to 6.6</td>
<td>Neutral</td>
<td>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear liquid, mild odor</td>
<td>Clear liquid, odorless</td>
<td>Slightly brown liquid, odorless</td>
<td>Clear liquid, mild odor</td>
<td>Clear Liquid, mild odor</td>
</tr>
</tbody>
</table>

N/A = Do data available
### Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stop Solution (A9947)</th>
<th>20X Wash Solution (A9957)</th>
<th>Complement Specimen Diluent (A9784)</th>
<th>TMB Substrate (5059)</th>
<th>Factor H Standards and Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>Heat, flames, sparks</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>Bases, amines, alkali metals, metals, fluorine, permanganates</td>
<td>Strong oxidizing agents, reducing agents, amines</td>
<td>Strong oxidizing agents, reducing agents, amines</td>
<td>Bases, strong oxidizing agents, reducing agents, acid chlorides</td>
<td>Strong oxidizing agents</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### Section 11 – Toxicological Information

#### Acute Toxicity

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>RTECS #</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>MW4025000</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt; Oral LC&lt;sub&gt;50&lt;/sub&gt;, Inhalation LC&lt;sub&gt;50&lt;/sub&gt;, Dermal LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Rabbit</td>
<td>900 mg/kg</td>
<td>Mouse 1108 PPM/1H</td>
</tr>
<tr>
<td>Inhalation</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixture for Proclin 300:</td>
<td>55965-84-9</td>
<td>Not available</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;, Inhalation LC&lt;sub&gt;50&lt;/sub&gt;, Dermal LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</td>
<td></td>
<td></td>
<td>Rat 53 mg/kg</td>
</tr>
<tr>
<td>Ingestion</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proprietary Mixture</td>
<td>--</td>
<td>Not available</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;, Inhalation LC&lt;sub&gt;50&lt;/sub&gt;, Dermal LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
</tbody>
</table>

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

- **Skin Corrosion/ Irritation:** No data available
- **Inhalation:** May cause respiratory tract irritation.
- **Serious Eye Damage / Irritation:** No data available
- **Skin:** May cause skin irritation upon contact.
- **Respiratory or Skin Sensitization:** No data available
- **Eyes:** May cause serious eye irritation.
- **Generative Cell Mutagenicity:** No data available
- **Ingestion:** 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.

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

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.

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.

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.
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>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Revision Date</th>
<th>CA</th>
<th>MA</th>
<th>MN</th>
<th>NJ</th>
<th>PA</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Proprietary Mixture</td>
<td>872-50-4</td>
<td>2007-07-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SARA 311/312

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Minimum Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>1%</td>
</tr>
<tr>
<td>Proprietary Mixture</td>
<td>55965-84-9</td>
<td>No data available</td>
</tr>
</tbody>
</table>

State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>CA</th>
<th>MA</th>
<th>MN</th>
<th>NJ</th>
<th>PA</th>
<th>RI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Mixture for Procllin 300:</td>
<td>55965-84-9</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</td>
<td>--</td>
<td>No data available</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proprietary Mixture</td>
<td>--</td>
<td>No data available</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Minimum Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>1310-73-2</td>
<td>1%</td>
</tr>
<tr>
<td>Mixture for Procllin 300:</td>
<td>55965-84-9</td>
<td>No data available</td>
</tr>
<tr>
<td>5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</td>
<td>--</td>
<td>No data available</td>
</tr>
<tr>
<td>Proprietary Mixture</td>
<td>--</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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.  
H290 May be corrosive to metals.  
H314 Causes severe skin burns and eye damage.  
H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H334 Causes severe skin burns and eye damage.  
H335 May cause respiratory irritation.  
H360 May damage fertility or the unborn child.  
H301+H311+H331 Toxic if swallowed, in contact with skin or inhaled.  
H410 Very toxic to aquatic life with long lasting effects.

Met. Corr. Metal corrosion  
Skin. Corr. Skin corrosion  
Eye. Dam. Eye damage  
Flam. Liq. Flammable liquid  
Skin Irrit. Skin irritation  
Resp. Sens. Respiratory sensitizer  
Repr. Reproductive toxicity  
Acute Tox. Acute toxicity  
Acute Aq. Acute aquatic  
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.