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 CICP EIA kit (Catalog #: 8003, 8005)
Intended Use: The MicroVue CICP assay provides a quantitative method for determining levels of CICP (C-Terminal of Type I Collagen) in serum.
Cat: #8003: For In Vitro Diagnostic use. For export only. Not for sale or use in the United States or Canada.
Cat. #8005: For Research Use Only in the United States. Not for use in diagnostic procedures.
Components: CICP Standards A → F, Low Control, High Control, Coated Strips, Stop Solution, 10X Wash Buffer, Assay Buffer, Substrate Buffer, Substrate Tablets, Enzyme Conjugate and Rabbit anti-CICP.

Section 2 – Hazards Identification

Classification of Substance or Mixture

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA Hazards</th>
<th>Target Organs</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop Solution (1.5% Sodium Hydroxide)</td>
<td>Irritant</td>
<td>Eyes and Skin</td>
<td>Skin Irritation (Category 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Irritation (Category 2)</td>
</tr>
<tr>
<td>Substrate Buffer (11.5% Diethanolamine)</td>
<td>Irritant</td>
<td>Eyes, Skin and Liver</td>
<td>Eye Irritation (Category 2B)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Irritation (Category 2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Specific Target Organ Toxicity (STOT RE2)</td>
</tr>
</tbody>
</table>

GHS Label Elements, Including Precautionary Statements

<table>
<thead>
<tr>
<th>Component</th>
<th>Pictogram</th>
<th>Hazard Statements</th>
<th>Precautionary Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop Solution (1.5% Sodium Hydroxide)</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>Substrate Buffer (11.5% Diethanolamine)</td>
<td>Warning</td>
<td>H302 Harmful if swallowed H315 Causes skin irritation. H319 Causes serious eye irritation. H373 May cause damage to the liver through prolonged or repeated exposure</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>
</tbody>
</table>
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 is used as a preservative (<0.1%) in various components within this kit. Avoid disposal of these buffers down sanitary or industrial plumbing systems.

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>Component Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop Solution (4702)</td>
<td>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>1.5</td>
<td>15 mL</td>
</tr>
<tr>
<td>Substrate Buffer (4705)</td>
<td>Diethanolamine</td>
<td>111-42-2</td>
<td>203-868-0</td>
<td>11.5</td>
<td>30 mL (3 x 10 mL)</td>
</tr>
</tbody>
</table>

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. 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.
**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 6 – Accidental Release Measures**

---

**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.
Section 8 – Exposure Controls and Personal Protection (cont’d)

**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 (4702)</th>
<th>Substrate Buffer (4705)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>&lt;13</td>
<td>9.9</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear liquid, mild odor</td>
<td>Clear liquid, mild ammonia like odor</td>
</tr>
</tbody>
</table>

Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Stop Solution (4702)</th>
<th>Substrate Buffer (4705)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</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>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</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>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>WB490000</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>Diethanolamine</td>
<td>111-42-2</td>
<td>KL2975000</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dermal LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&lt;12,200 mg/kg</td>
</tr>
</tbody>
</table>

Potential Health Effects:

Stop Solution (4702) and Substrate Buffer (4705) – Irritant

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


Reproductive Toxicity

No data available.

Teratogenicity

No data available.

Specified Target Organ General Toxicity (GHS)


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

Substrate Buffer: Liver Irregularities – Based on human evidence (Diethanolamine)

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.
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 (4702): Irritant
Substrate Buffer (4705): 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:
Diethanolamine CAS#: 111-42-2 Revision Date: 2011-07-01
Sodium Hydroxide CAS#: 1310-73-2 Acute Health Hazard
Diethanolamine CAS#: 111-42-2 Acute Health Hazard, Chronic Health Hazard

State Regulations
The following chemicals 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>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Diethanolamine</td>
<td>111-42-2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

California Prop 65: Substrate Buffer (4705) – WARNING – This component contains a chemical known to the State of California to cause birth defects or other reproductive harm.
Diethanolamine CAS#: 111-42-2 Revision Date: 2012-07-20
### Section 15 – Regulatory Information (cont’d)

#### Canadian - WHMIS Classification (Raw Material)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Hydroxide</td>
<td>1310-73-2</td>
<td>E  Corrosive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Corrosive to skin</td>
</tr>
<tr>
<td>Diethanolamine</td>
<td>111-42-2</td>
<td>D2A Very Toxic Material Causing Toxic Effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Chronic Toxicity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>D2B Toxic Material Causing Other Toxic Effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Carcinogen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Moderate skin irritant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Severe eye irritant</td>
</tr>
</tbody>
</table>

#### Additional Regulatory Information

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


**Chemical Safety Assessment:**

Not completed for the components contained within this kit.

**NFPA Kit Classification:**

- Health Hazard (blue): 2
- Fire Hazard (red): 0
- Reactivity Hazard (yellow): 0
- Special Hazards (white): None

### Section 16 – Other Information

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

**SUPERCEDES:** December 4, 2014

**REVISIONS:** Section 15, added EU Regulatory Reference.

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.