1.1 Manufacturer Information
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121
Phone: 1.800.874.1517
Fax: 1.858.453.4338
Web: quidel.com
E-mail: gehs@quidel.com

1.2 Product Information
Product Name: InflammaDry (Catalog #: RPS-ID-20-U)
Intended Use: A rapid, immunoassay test for the visual, qualitative, \textit{in vitro} detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye. For \textit{in vitro} diagnostic use only. For prescription use. Single use only.

Components: Sample Collector, Test Cassette, Buffer Vial

2.1 Classification of the Substance or Mixture
Not a hazardous substance or mixture.

2.2 GHS Label Elements, including Precautionary Statements
Not a hazardous substance or mixture.

2.3 Supplemental Hazard Statements
- Refer to Universal Precautions information in Section 7, Handling and Storage.
- Avoid disposal of the Buffer solution down the sanitary or industrial plumbing systems. Refer to Section 13, Disposal Considerations for further guidance.
  - Sodium azide is used as a preservative (0.1%).
  - Tergitol (0.8%) – Contains various components that are listed on the California Prop 65 list. Refer to Section 15.
  - Gentamycin (0.0126%) – May act as a skin sensitizer in some individuals. Refer to Section 8 for appropriate personal protection recommendations.
- The Dacron material used in the sampling fleece may cause allergic reactions for some people upon contact with the eye.

3.1 Mixtures
Contains non-hazardous quantities of proprietary ingredients according to OSHA (29 CFR 1910.1200).
Not a hazardous mixture according to Regulation (EC) No. 1272/2008.

3.2 No chemicals need to be disclosed according to the applicable regulations for the components in this kit.

4.1 Description of First Aid Measures
\textit{If inhaled}: Move the person to fresh air and support breathing as required.
\textit{In case of skin contact}: Wash affected area with soap and water. Seek medical advice if irritation develops.
\textit{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.
\textit{If swallowed}: Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

4.2 Most Important Symptoms and Effects (both acute and delayed)
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed
No specific measures identified.
### Section 5 – Fire Fighting Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

5.1 **Suitable Extinguishing Media**
For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 **Special Hazards Arising from the Substance or Mixture**
Nature of decomposition products not known.

5.3 **General Fire Hazards**
The components within this kit will not significantly contribute to the intensity of a fire.

5.4 **Fire Fighting Equipment**
Firefighters should wear full protective gear when responding to fires.

### Section 6 – Accidental Release Measures

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release. A large spill of any of the components listed in this SDS is unlikely.

6.1 **Personal Precautions**
Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the sample diluent. Avoid breathing vapors, mist or gas. Keep all unnecessary personnel away from the spill area.

6.2 **Methods and Materials 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.

6.3 **Recovery and Neutralization**
Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.

6.4 **Environmental Precautions**
Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

### Section 7 – Handling and Storage

7.1 **Specific Use**
For *in vitro* diagnostic use only. For prescription use.

7.2 **Precautions for Safe Handling**
As with all chemical and biological substances, avoid getting these components ON YOU or IN YOU. Wash exposed areas thoroughly after using these components. Do not eat or drink while using these components. These components should be handled only by qualified clinical or laboratory employees trained on the use of these antibodies and proteins and who are familiar with the potential hazards. Universal Precautions should be followed when handling and working with these components. Keep out of reach of the general public.

7.3 **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.

7.4 **Conditions for Safe Storage (including any incompatibilities)**
To maintain efficacy, store according to the Package Insert instructions.

7.5 **Incompatibilities**
To maintain efficacy, store according to the Package Insert instructions.
# Section 8 – Exposure Controls and Personal Protection

## 8.1 Exposure Limits
No data available for the specific components within this kit.

## 8.2 Exposure Controls

### Engineering Measures
Use with adequate ventilation.

### Personal Protective Equipment

#### Respiratory Protection
None needed under normal conditions of use.

#### Skin 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 these components.

#### Eye Protection
Wear safety glasses with side shields or goggles to prevent eye contact.

#### Body Protection
Use body protection appropriate for the task. A laboratory coat is recommended.

#### Hygiene Measures
Wash hands before use, after use and at the end of the workday.

## 8.3 Environmental Exposure Controls
No special environmental controls are required.

## 8.4 Special Notes
No data available.

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# Section 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Buffer Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (mm Hg)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Ether = 1)</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>9.5</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Clear, colorless, odorless</td>
</tr>
</tbody>
</table>

# Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Buffer Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazard Reaction Potential</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Section 11 – Toxicological Properties

11.1 Information on Toxicological Effects

**Acute Toxicity**
No data available

**Skin Corrosion / Irritation**
May cause irritation of eyes.

**Respiratory or Skin Sensitization**
No data available

**Generative Cell Mutagenicity**
No data available

**Carcinogenicity**
No component of this kit is present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, IARC, NTP or OSHA.

**Reproductive Toxicity**
No data available

**Teratogenicity**
No data available

**Specified Target Organ Toxicity**

<table>
<thead>
<tr>
<th>Exposure Type</th>
<th>Acute</th>
<th>Repeated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Aspiration Hazard**
No data available

**Potential Health Effects**

<table>
<thead>
<tr>
<th>Route</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>May be harmful if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May cause skin irritation upon contact.</td>
</tr>
<tr>
<td>Eyes</td>
<td>May cause eye irritation.</td>
</tr>
</tbody>
</table>

11.2 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 within this kit.

11.3 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the components within this kit.

Section 12 – Ecological Information

12.1 Toxicity
No data available

12.2 Persistence and Degradability
No data available

12.3 Bioaccumulative Potential
No data available

12.4 Mobility in Soil
No data available

12.5 PBT and vPvB Assessment
No data available

12.6 Other Adverse Effects
An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid disposal to the environment.

Section 13 – Disposal Considerations

13.1 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 control stocks into drains, water courses or onto the ground.

13.2 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

14.1 U.S Department of Transportation (DOT) These components are not regulated for transport.

14.2 International Air Transportation Association (IATA) These components are not regulated for transport.

14.3 International Maritime Dangerous Goods (IMDG) These components are not regulated for transport.

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards None

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:
No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 313.

SARA311/312 Hazards No SARA hazards.

15.2 State Regulations

The following chemicals appear on one or more of the following state hazardous substance 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>α-(4-Nonylphenyl)-ω-hydroxy-poly(oxy-1,2-ethanediyl) branched</td>
<td>127087-87-0</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

California Prop 65: Buffer Vial (Tergitol 0.8%) – WARNING! – This component contains a chemical known to the State of California to cause cancer. *Used in the manufacturing process of the Tergitol component.

- Ethylene Oxide CAS#: 75-21-8 Revision Date: 2009-02-01
- 1,4-Dioxane CAS#: 123-91-1 Revision Date: 2007-09-28
- Formaldehyde CAS#: 50-00-0 Revision Date: 2007-09-28
- Acetaldehyde CAS#: 75-07-0 Revision Date: 2007-09-29

California Prop 65: Buffer Vial (Tergitol 0.8%) – WARNING! – This component contains a chemical known to the State of California to cause birth defects or other reproductive harm. *Used in the manufacturing process of the Tergitol component.

- Ethylene Oxide CAS#: 75-21-8 Revision Date: 2009-02-01

15.3 Canadian – WHMIS Classification

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

15.4 Additional Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Mixture No data available

Chemical Safety Assessment Not completed for the components contained within this kit.

NFPA Kit Classification:
- Health Hazard (blue): 1
- Fire Hazard (red): 0
- Reactivity (yellow): 0
- Special Hazards (white): None
Section 16 – Other Information

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

SUPERSEDES: --

REVISIONS: New

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