Section 1 – Product and Company Identification

1.1 Manufacturer Information
Quidel Corporation Phone: 1.800.874.1517 Web: quidel.com
10165 McKellar Court Fax: 1.858.453.4338 E-mail: qehs@quidel.com
San Diego, CA 92121 Emergency #: 1.866.519.4752

1.2 Product Information
Product Name: Sofia Lyme FIA, Sofia 2 Lyme FIA, Sofia 2 Lyme+ FIA (Cat. #: 20298, 20319, 20309)
Intended Use: This qualitative test is intended for use as an aid in the diagnosis of Lyme disease.
Components: Individually pouched Test Cassettes, Blood Collection and Preparation Kit (contains Reagent Solution), Positive Control, and Negative Control

Section 2 – Hazards Identification

2.1 Classification of Substance or Mixture

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>OSHA Hazards</th>
<th>Target Organs</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Solution (0.03% Proclin 300)</td>
<td>Sensitizer</td>
<td>Skin</td>
<td>Skin Sensitizer (Category 1)</td>
</tr>
<tr>
<td>Positive Control and Negative Control (0.3% Microcide III)</td>
<td>Irritant, Sensitizer</td>
<td>Eyes, skin</td>
<td>Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)</td>
</tr>
</tbody>
</table>

2.2 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>Reagent Solution (0.03% Proclin 300)</td>
<td>![Warning]</td>
<td>H317 May cause an allergic skin reaction.</td>
<td>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.</td>
</tr>
<tr>
<td>Positive Control Negative Control (0.3% Microcide III)</td>
<td>![Warning]</td>
<td>H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.</td>
<td>P264 Wash hands thoroughly after handling. P280 Wear protective gloves and eye protection. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352 If ON SKIN: Rinse skin with water.</td>
</tr>
</tbody>
</table>

Supplemental Hazard Statements
1. Avoid release to the environment (P273).
2. Follow Universal Precautions when working with this kit. Refer to additional information in Section 7, Handling and Storage.
Section 3 – Composition / Information on Ingredients

3.1 Mixtures

<table>
<thead>
<tr>
<th>Kit Component</th>
<th>Chemical Name</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>Conc. (%)</th>
<th>Component Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Solution</td>
<td><em>Mixture for Proclin 300:</em> 5-Chloro-2-methyl-2, 3-</td>
<td>55965-84-9</td>
<td>--</td>
<td>0.03</td>
<td>0.3 mL</td>
</tr>
<tr>
<td></td>
<td>dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive Control</td>
<td><em>Mixture for Microside III:</em> 2-Methyl-4-isothiazolin-3-one (&lt;1%); Magnesium nitrate (&lt;2%)</td>
<td>--</td>
<td>--</td>
<td>0.30</td>
<td>2.55 mL 2.55 mL</td>
</tr>
<tr>
<td>Negative Control</td>
<td>1. <em>Mixture for Microside III:</em> 2-Methyl-4-isothiazolin-3-one (&lt;1%); Magnesium nitrate (&lt;2%)</td>
<td>--</td>
<td>--</td>
<td>1. 0.3</td>
<td>2.55 mL</td>
</tr>
<tr>
<td></td>
<td>2. Lyme Negative Serum</td>
<td></td>
<td></td>
<td>2. 10</td>
<td></td>
</tr>
</tbody>
</table>

Section 4 – First Aid Measures

4.1 Description of First Aid Measures

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:* Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). 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

5.1 General Advice

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

5.2 Suitable Extinguishing Media

For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.
5.3 **Special Hazards Arising from the Substance of Mixture**
Nature of decomposition products not known

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

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

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**Section 6 – Accidental Release Measures**

6.1 **General Advice**
Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release.

6.2 **Personal Precautions**
Use personal protective equipment, including protective gloves and safety glasses when cleaning up spills associated with the components of this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.

6.3 **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.

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

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

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**Section 7 – Handling and Storage**

7.1 **Specific Use**
Refer to product specific Package Insert. Not for use by the public.

7.2 **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 working with the components of this kit. Do not eat or drink while handling this kit. The Sofia 2 Lyme FIA and Sofia Lyme FIA kits should be handled only by qualified individuals who are familiar with the potential hazards. Keep out of reach of the 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.
Section 7 – Handling and Storage (cont’d)

7.4 Conditions for Safe Storage
To maintain efficacy, store according to the kit specific Package Insert instructions.

7.5 Incompatibilities
To maintain efficacy, store according to the kit specific Package Insert instructions.

Section 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits
No data available for the components contained 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.
  - *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 in 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.

8.3 Environmental Exposure Controls
No special environmental controls are required.

8.4 Special Notes
No data available

Section 9 – Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Reagent Solution</th>
<th>Positive Control</th>
<th>Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity (H₂O = 1)</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (Air = 1)</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>pH</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>
</tr>
<tr>
<td>Appearance and Odor</td>
<td>Slight blue liquid, odorless</td>
<td>Clear liquid, odorless</td>
<td>Clear liquid, odorless</td>
</tr>
</tbody>
</table>
Section 10 – Stability and Reactivity

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Reagent Solution</th>
<th>Positive Control</th>
<th>Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component Stability</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>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>No data available</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>
<td>No data available</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Section 11 – Toxicological Information

11.1 Information on Toxicological Effects

Acute Toxicity

Component Analysis – LD50 / LC50 / Irritation (No specific data available for the Reagent Solution)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>RTECS #</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mixture for Proclin 300:</strong></td>
<td>55965-84-9</td>
<td>--</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>5-Chloro-2-methyl-2, 3-</td>
<td></td>
<td></td>
<td>Rat</td>
</tr>
<tr>
<td>dihydroisothiazol-3-one; 2-Methyl-2,</td>
<td></td>
<td></td>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>3-dihydroisothiazol-3-one (3:1)</td>
<td></td>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Mixture for Microcide III:</strong></td>
<td>--</td>
<td>--</td>
<td>Oral LD&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>2-Methyl-4-isothiazolin-3-one (&lt;1%);</td>
<td></td>
<td></td>
<td>Inhalation LC&lt;sub&gt;50&lt;/sub&gt;</td>
</tr>
<tr>
<td>Magnesium nitrate (&lt;2%)</td>
<td></td>
<td></td>
<td>No data available</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>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2,800 mg/kg</td>
</tr>
</tbody>
</table>

Potential Health Effects – Reagent Solution, Positive Control, Negative Control – Irritant, Sensitizer

- **Skin Corrosion/ Irritation:** No data available
- **Serious Eye Damage / Irritation:** No data available
- **Respiratory or Skin Sensitization:** May act as a sensitizer
- **Generative Cell Mutagenicity:** No data available
- **Ingestion:** May be harmful if swallowed.

Carcinogenicity

No component of the Sofia 2 Lyme FIA and Sofia Lyme FIA kits 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 General Toxicity (GHS)

- **Single Exposure (GHS):** No data available
- **Repeated Exposure (GHS):** No data available
- **Aspiration Hazard:** None anticipated under product use conditions.
- **Synergistic Effects:** No data available

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 Sofia 2 Lyme FIA and Sofia Lyme FIA components.

11.3 Additional Information

- **Sensitization:** The Reagent Solution 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

12.1 Ecotoxicity
No data available

12.2 Persistence / Degradability
No data available

12.3 Bioaccumulation
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 release to the environment.

*Proclin 300 is very toxic to aquatic life with long lasting effects.*

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 the solution or controls 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)
This kit is not regulated for transport.

14.2 International Air Transportation (IATA)
This kit is not regulated for transport.

14.3 International Maritime Dangerous Goods (IMDG)
This kit is not regulated for transport.

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards
Reagent Solution, Positive Control, Negative Control: Irritant, Sensitizer

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:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312
Proclin 300 CAS#: 55965-84-9 Acute Health Hazard
15.2 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><strong>Mixture for Proclin 300:</strong> 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</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><strong>Mixture for Microcide III:</strong> 2-Methyl-4-isothiazolin-3-one (&lt;1%); Magnesium nitrate (&lt;2%)</td>
<td>--</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

California Prop 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

15.3 Canadian – WHMIS Classification

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS #</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mixture for Proclin 300:</strong> 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)</td>
<td>55965-84-9</td>
<td>D2B Toxic Material Causing Other Toxic Effects - Sensitizer</td>
</tr>
<tr>
<td><strong>Mixture for Microcide III:</strong> 2-Methyl-4-isothiazolin-3-one (&lt;1%); Magnesium nitrate (&lt;2%)</td>
<td>--</td>
<td>D2B Toxic Material Causing Other Toxic Effects - Sensitizer</td>
</tr>
</tbody>
</table>

15.4 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): 1
- Fire Hazard (red): 0
- Reactivity Hazard (yellow): 0
- Special Hazards (white): None
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.