# Safety Data Sheet

## Section 1 – Product and Company Identification

### 1.1 Manufacturer Information

Quidel Corporation  
Phone: 1.800.874.1517  
Web: [quidel.com](http://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 Legionella FIA (Cat. #: 20244)  
**Intended Use:** The Sofia Legionella FIA employs immunofluorescence for qualitative detection of *Legionella pneumophila* serogroup 1 antigen in human urine specimens. It is designed to test specimens from patients with symptoms of pneumonia. Test results are to be used as an aid in diagnosis of *Legionella pneumophila* serogroup 1 infection.  
**Components:** Kit is composed of individually pouched test cassettes, fixed volume pipettes, Legionella positive control (2.6 mL reagent contains buffer with non-infectious Legionella) and negative control (2.6 mL reagent contains buffer with non-infectious *Streptococcus C* antigen).

## 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>
</table>
| Positive Control and Negative Control (0.3% Microcide III) | Irritant, Sensitizer | Eyes, skin | Eye Irritation (Category 2A)  
Skin Irritation (Category 2)  
Skin Sensitizer (Category 1) |

### 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>
</table>
| Positive Control Negative Control (0.3% Microcide III) | ![Warning] | H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation. | 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. |

**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>Positive Control</td>
<td>Mixture for Microcide III: 2-Methyl-4-isothiazolin-3-one (&lt;1%); Magnesium nitrate (&lt;2%)</td>
<td>--</td>
<td>--</td>
<td>0.3</td>
<td>2.6 mL</td>
</tr>
<tr>
<td>Negative Control</td>
<td>Mixture for Microcide III: 2-Methyl-4-isothiazolin-3-one (&lt;1%); Magnesium nitrate (&lt;2%)</td>
<td>--</td>
<td>--</td>
<td>0.3</td>
<td>2.6 mL</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: 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.
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.

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 Legionella FIA kit 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.

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>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>
</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>Neutral</td>
<td>Neutral</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
<td>Soluble</td>
</tr>
<tr>
<td>Appearance and Odor</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>Positive Control</th>
<th>Negative Control</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

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>RTECS #</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture for Microcide III:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Methyl-4-isothiazolin-3-one (&lt;1%); Magnesium nitrate (&lt;2%)</td>
<td>--</td>
<td>Oral LD50 No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inhalation LC50 No data available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dermal LD50 No data available</td>
</tr>
</tbody>
</table>

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

- **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:** May act as a sensitizer
  - Eyes: May cause serious eye irritation.
- **Generative Cell Mutagenicity:** No data available
  - Ingestion: May be harmful if swallowed.

Carcinogenicity

No component of the Sofia 2 Legionella FIA kit 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 Legionella FIA components.

11.3 Additional Information

- **Sensitization:** The Reagent Solution contains a small volume of a very dilute, sensitizing preservative (Microcide III). 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.
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
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
No SARA hazards

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>Mixture for Microcide III:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Methyl-4-isothiazolin-3-one</td>
<td>&lt;1%</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Magnesium nitrate (&lt;2%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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><em>Mixture for Microcide III:</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Methyl-4-isothiazolin-3-one (&lt;1%);</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium nitrate (&lt;2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>--</td>
<td>D2B  Toxic Material Causing Other Toxic Effects</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 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

---

Section 16 – Other Information

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

SUPERCEDES: October 7, 2013

REVISIONS: Updated template to 16-Section format.

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.