

**Manufacturer Information**

|                      |                        |                |        |  |
|----------------------|------------------------|----------------|--------|--|
| Quidel Corporation   | Phone:                 | 1.800.874.1517 | Web:   | <a href="http://quidel.com">quidel.com</a> |
| 10165 McKellar Court | Fax:                   | 1.858.453.4338 | email: | qehs@quidel.com                            |
| San Diego, CA 92121  | Emergency # (24-Hour): | 1.866.519.4752 |        |  |

**Product Information**

Product Name: Sofia Strep A FIA (Catalog #: 20231 and 20253)

Intended Use: The Sofia Strep A FIA employs immunofluorescence technology to detect Group A Streptococcal antigens from throat swabs or for confirmation of presumptive Group A Streptococcal colonies recovered from culture. The test is intended for professional and laboratory use as an aid in the diagnosis of Group A Streptococcal infection. This kit shall be used for in vitro diagnostic use only.

Components: Kit is composed of individually pouched test cassettes, reagent tubes, reagent solution (contains Sodium Nitrite and Acetic Acid), reagent dropper tips, sterile rayon throat swabs, positive control swab and negative control swab.


The hazards associated with this product are related to the **Reagent Solution** that contains a 0.2M Acetic Acid (1.2%) glass ampoule inside of a plastic bottle containing a 4M Sodium Nitrite (27.6%) solution. The Reagent Solution contains approximately 0.4 mL of Sodium Nitrite and 0.5 mL of Acetic Acid and is considered as single use only.

**Emergency Overview**

Significant health effects are not anticipated from routine use of this kit when following the precautions listed within this SDS and the kit specific package insert. The Reagent Solution within this kit is considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), and the European Union (EU) Directives 1999/45/EC, 67/548/EEC and/or 1272/2008/EC.

| OSHA Hazards  | Target Organs                               | GHS Classification   |
|---|---|--|
| Oxidizer, Target Organ Effect, Toxic by Ingestion, Irritant | Blood, cardiovascular system, smooth muscle | Oxidizing liquids (Category 3)<br>Acute Toxicity, Oral (Category 4)<br>Eye Irritation (Category 2A)<br>Acute Aquatic Toxicity (Category 2) |

**GHS Label Elements & Precautionary Statements**

| Component                             | Pictogram   | Signal Word | Hazard Statements  | Precautionary Statements   |
|---------------------------------------|---|-------------|--|--|
| Reagent Solution                      |  | Warning     | H302 Harmful if swallowed.<br>H319 Causes serious eye irritation.<br>H401 Toxic to aquatic life. | P305+P351+P338<br>If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| <b>Supplemental Hazard Statements</b> |   |             | Avoid release to the environment.  |  |

**Reagent Solution**

| Chemical Name  | CAS #     | EINECS #  | Index #      | Concentration (%) | Component Volume (mL) |
|----------------|-----------|-----------|--------------|-------------------|-----------------------|
| Sodium Nitrite | 7632-00-0 | 231-555-9 | 007-010-00-4 | 27.6              | <0.4                  |
| Acetic Acid    | 64-19-7   | 200-580-7 | 607-002-00-6 | 1.2               | <0.5                  |

**General Advice**

Move out of exposure area. Consult a physician. Show this safety data sheet to the doctor in attendance.

- 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. Seek medical advice.

**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.

**Indication of any immediate medical attention and special treatment needed**

No data available

**General Advice**

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

- Suitable Extinguishing Media:* For small fires, use dry chemical, 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 reagent solution contained within this kit are unlikely.

- Personal Precautions (e.g., PPE):* Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills of the reagent solution. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from spill area.
- Recovery and Neutralization:* Collect spilled material and place in a sealed container for disposal.
- Materials and Methods for Clean-Up:* Thoroughly wash the area with soap and water after a spill or release clean-up.
- Environmental Precautions:* Contain spill to prevent migration to public industrial / sanitary sewers or open water sources.

**Specific Use:** For *in vitro* diagnostic use only – Not for use by 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 using this kit.

**Conditions for Safe Storage:** To maintain efficacy, store according to the package insert instructions. Keep out of reach of the general public.

**Incompatibilities** None

### Exposure Limits:

| Chemical Name  | CAS #     | Exposure Limits (US)             | Exposure Limits (EU)   | Exposure Limits (EU)   |
|----------------|-----------|----------------------------------|--|--|
| Acetic Acid    | 64-19-7   | ACGIH: 10 ppm TWA<br>15 ppm STEL | Austria: 10 ppm STEL<br>5 ppm MAK  | Ireland: 10 PPM STEL<br>5 ppm TWA  |
|                |           | OSHA: 10 ppm TWA                 | Belgium: 10 ppm STEL<br>5 ppm TWA  | Italy: 5 ppm TWA   |
|                |           | NIOSH: 10 ppm TWA<br>15 ppm STEL | Denmark: 5 ppm Ceiling<br>Finland: 5 ppm STEL<br>France: 5 ppm VLCT<br>Germany: 2 ppm TWA<br>2 ppm MAK<br>4 ppm Peak | Netherlands: 15 mg/m <sup>3</sup> STEL<br>8 mg/m <sup>3</sup> TWA<br>Spain: 10 ppm VLA-EC<br>5 ppm VLA-EC<br>Sweden: 5 ppm CLV<br>Greece: 5 ppm STEL/TWA |
|                |           |                                  |  | <b>Exposure Limits (Japan)</b>   |
|                |           |                                  |  | JSOH: 10 ppm OEL   |
| Sodium Nitrite | 7632-00-0 | None Established                 | None Established   | None Established   |

\*\* Refer to OSHA IMIS Code Number S236 for general information on the monitoring methods used by OSHA for Sodium Nitrite.

\*\* When activating the Reagent Solution (by breaking the glass ampoule of 1.2% Acetic Acid and mixing with the 27.6% Sodium Nitrite) the initial chemical reaction will create Nitrogen Dioxide and Nitric Oxide as reaction products.

### Exposure Controls

#### Engineering Measures

Use with adequate ventilation to maintain worker exposure below limits listed above.

#### 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:* Handle in accordance with good industrial hygiene and safety practice. Wash hands before and at the end of the workday.

**Environmental Exposure Controls**

No special environmental controls are required

| Characteristic                          | Reagent Solution                |                              |
|---|---------------------------------|------------------------------|
|   | Sodium Nitrite Solution (27.6%) | Acetic Acid Ampoule (1.2%)   |
| Boiling Point (°C)                      | No data available               | No data available            |
| Melting Point (°C)                      | No data available               | No data available            |
| Specific Gravity (H <sub>2</sub> O = 1) | No data available               | No data available            |
| Vapor Pressure (mm Hg)                  | No data available               | No data available            |
| Vapor Density (Air = 1)                 | No data available               | No data available            |
| Evaporation Rate (Ether = 1)            | No data available               | No data available            |
| pH                                      | 8.6                             | 2.4                          |
| Solubility in Water                     | Soluble                         | Soluble                      |
| Appearance and Odor                     | Yellow with no odor             | Clean with vinegar like odor |

| Characteristic                   | Reagent Solution                |                            |
|----------------------------------|---------------------------------|----------------------------|
|                                  | Sodium Nitrite Solution (27.6%) | Acetic Acid Ampoule (1.2%) |
| Component Stability              | Stable                          | Stable                     |
| Hazard Reaction Potential        | No data available               | No data available          |
| Conditions to Avoid              | None                            | None                       |
| Materials to Avoid               | None                            | None                       |
| Hazardous Decomposition Products | No data available               | No data available          |

**Acute Toxicity**
**Component Analysis – LD50 / LC50**

| Chemical Name  | CAS #     | RTECS #   | Information   |
|----------------|-----------|-----------|---|
| Sodium Nitrite | 7632-00-0 | RA1225000 | Inhalation LC50 Rat = 5.5 mg/L 4 hr<br>Oral LD50 Rat = 85 mg/kg                                       |
| Acetic Acid    | 64-19-7   | AF1225000 | Inhalation LC50 Rat = 11.4 mg/L 4 hr<br>Oral LD50 Rat = 3310 mg/kg<br>Dermal LD50 Rabbit = 1060 mg/kg |

**Potential Health Effects**

|   |                   |                    |                   |
|---|-------------------|--------------------|-------------------|
| <i>Skin Corrosion/ Irritation:</i>      | No data available | <i>Inhalation:</i> | No data available |
| <i>Serious Eye Damage / Irritation:</i> | No data available | <i>Ingestion:</i>  | No data available |
| <i>Respiratory Organ or</i>             |                   |                    |                   |
| <i>Skin Sensitization:</i>              | No data available |                    |                   |
| <i>Generative Cell Mutagenicity:</i>    | No data available |                    |                   |

**Carcinogenicity**

The chemicals in the Reagent Solution are not listed as carcinogens by any of the following: ACGIH, IARC, NTP or OSHA.

**Reproductive Toxicity**

No data available

**Specified Target Organ General Toxicity**

**Single Exposure** No data available      **Repeated Exposure** No data available

**Aspiration Respiratory Organs Hazard**

None anticipated under product use conditions.

**Toxicity**

No data available

**Mobility in Soil**

No data available

**Persistence / Degradability**

No data available

**Other adverse effects**

Toxic to aquatic life.

**Bioaccumulation**

No data available

**PBT and vPvB Assessment**

No data available

**Waste Disposal Instructions**

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge the Reagent Solution 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 the authorities for information.

**U.S. Department of Transportation (DOT)**

Not regulated as a hazardous material.

**Canadian Transportation**

Not regulated as a hazardous material.

**International Air Transportation**

Not regulated as a dangerous good.

**Regulatory Information**
**U.S. Federal Regulations**

The Reagent Solution contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

**Sodium Nitrite (7632-00-0)**

SARA 313: 1.0% de minimis concentration

CERCLA: 100 lb. final RQ; 45.4 kg final RQ

**Acetic Acid (64-19-7)**

CERCLA: 5000 lb. final RQ; 2270 kg final RQ

**State Regulations**

The following chemicals appear on one or more of the following state hazardous substances lists:

| Chemical Name  | CAS #     | CA  | MA  | MN  | NJ  | PA  | RI  |
|----------------|-----------|-----|-----|-----|-----|-----|-----|
| Sodium Nitrite | 7632-00-0 | Yes | Yes | No  | Yes | Yes | No  |
| Acetic Acid    | 64-19-7   | Yes | Yes | Yes | Yes | Yes | Yes |

*\*\* The components contained within this kit do not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm.*

**Canadian - WHMIS IDL**

| Chemical Name  | CAS #     | Minimum Concentration |
|----------------|-----------|-----------------------|
| Sodium Nitrite | 7632-00-0 | 1%                    |
| Acetic Acid    | 64-19-7   | 1%                    |



**Additional Regulatory Information**
**Safety, Health and Environmental regulations/legislation specific for the mixture**

No data available

**Chemical Safety Assessment**

No data available

**European Directive 67/548/EEC as amended**

| Danger Symbol   | Risk Phrases  | Safety Phrases  |
|---|---|---|
| <br><b>T</b> Toxic                     | R25: Toxic if swallowed.<br>R50: Very toxic to aquatic organisms. | S36/37/39: Wear suitable protective clothing, gloves and eye/face protection<br>S45: In case of accident or if you feel unwell, seek medical advice immediately<br>S61: Avoid release to the environment. Refer to special instructions/safety data sheets. |
| <br><b>N</b> Environmentally Dangerous |   |   |

**PREPARED BY:** Quidel Corporation  
 10165 McKellar Court  
 San Diego, CA 92121  
 (858)-552-1100

**SUPERCEDES:** June 12, 2013

**REVISIONS:** New branding and brand format; addition of GHS specific hazard pictograms.

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.

### Key / Legend

|  |   |
|--|---|
| ACGIH = American Conference of Governmental Industrial Hygienists                          | NFPA = National Fire Protection Association   |
| BAT = Biological Tolerance Values (Germany)  | NIOSH = National Institute of Occupational Safety and Health  |
| CAS# = Chemical Abstract Service Number  | NOHSC = National Occupational Health & Safety Commission  |
| CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act (Superfund) | NTP = National Toxicology Program   |
| CLV = Ceiling Limit Value (Sweden)   | OEL = Occupational Exposure Limit   |
| DOT = Department of Transportation   | OSHA = Occupational Safety and Health Administration  |
| DSL = Domestic Substances List   | PEL = Permissible Exposure Limit  |
| EEC = European Economic Community  | PPE = Personal Protective Equipment   |
| EINECS = European Inventory of Existing Commercial Chemical Substances                     | RTECS = Registry of Toxic Effects of Chemical Substances  |
| ELINCS = European List of Notified Chemical Substances                                     | SARA = Superfund Amendments and Reauthorization Act   |
| EPA = Environmental Protection Agency  | STEL = Short-term Exposure Limit  |
| EU = European Union  | STV = Short Term Value (Sweden)   |
| GHS = Globally Harmonized System   | TDG = Transportation of Dangerous Goods   |
| HMIS = Hazardous Materials Identification System   | TLV = Threshold Limit Value   |
| IARC = International Agency for Research on Cancer   | TSCA = Toxic Substances Control Act   |
| IMO = International Maritime Organization  | TWA = Time Weighted Average   |
| IATA = International Air Transport Association   | VLA-EC = Valor Límite Ambiental Exposición de Corta Duración (Spain): The limit for short-term exposure concentration |
| LLV = Level Limit Value (Sweden)   | VLA-ED = Valor Límite Ambiental Exposición Diaria (Spain): The limit for the daily average concentration              |
| MAK = Maximum Concentration Value in the Workplace   | VLCT = VALEUR LIMITE D EXPOSITION A COURT TERME (Limit Value Exposure is Short Term (France))                         |
| NDSL = Non-Domestic Substances List  |   |

6RA1111D-3 (10/13)