

Section 1 - Product and Company Identification

Manufacturer Information

Quidel Corporation	Phone: 1-800-874-1517	Web: www.quidel.com
10165 McKellar Court	Fax: 1-858-453-4338	
San Diego, CA 92121	Emergency #: 1-800-222-1222 (Poison)	

Product Information

Product Name: Sofia Strep A FIA (Catalog #: 20253 and 20231) **For in vitro diagnostic use only**

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.

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.

Section 2 – Hazards Identification

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 the 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 and 67/548/EEC.

OSHA Hazards

Target Organ Effect, Toxic by Ingestion, Irritant

Label Elements, including Risk and Safety Phrases

EU Labeling Classification

<p>Reagent Solution (1 mL) <i>Sodium Nitrite (27.6%)</i> <i>Acetic Acid (1.2%)</i></p> <p> Toxic</p> <p> Environmentally Dangerous</p>	<p>Risk Phrases (for Sodium Nitrite):</p> <p>R25: Toxic if swallowed. R50: Very toxic to aquatic organisms.</p> <p>Safety Phrases:</p> <p>S1/2: Keep locked up and out of the reach of children. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection S45: In case of accident or if you feel unwell, seek medical advice immediately S61: Avoid release to the environment. Refer to special instructions/safety data sheets.</p>
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Section 3 – Composition / Information on Ingredients

Reagent Solution

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

***Acetic Acid ampoule is within plastic reagent bottle containing Sodium Nitrite.*

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.

- 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

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, carbon dioxide or alcohol-resistant foam
- Unsuitable Extinguishing Media:* None
- General Fire Hazards:* The components within this kit will not significantly contribute to the intensity of a fire
- Hazardous Combustion Products:* Not determined
- Fire Fighting Equipment:* Firefighters should wear full protective gear when responding to fires

Additional Considerations

- Flash Point:* Non Combustible
- Auto-Ignition Temperature:* Not Applicable
- Upper / Lower Explosion Limits:* Not Applicable

Section 6 – Accidental Release Measures

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:* 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 sealed container for disposal.

Section 6 – Accidental Release Measures (continued)

Materials and Methods for Clean-Up: Thoroughly wash the area with soap and water after a spill or release clean-up

Environmental Precautions: No environmental hazard is anticipated provided that the material is handled and disposed of with due care. Contain spill to prevent migration to public industrial / sanitary sewers or open water sources

Section 7 – Handling and Storage

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.

Incompatibilities None

Section 8 – Exposure Controls and Personal Protection

Exposure Limits:

Chemical Name	CAS #	Exposure Limits (US)	Exposure Limits (EU)	Exposure Limits (EU)
Acetic Acid	64-19-7	ACGIH: 10 ppm TWA 15 ppm STEL	Austria: 10 ppm STEL 5 ppm MAK	Ireland: 10 PPM STEL 5 ppm TWA
		OSHA: 10 ppm TWA	Belgium: 10 ppm STEL 5 ppm TWA	Italy: 5 ppm TWA Netherlands: 15 mg/m ³ STEL 8 mg/m ³ TWA
		NIOSH: 10 ppm TWA 15 ppm STEL	Denmark: 5 ppm Ceiling Finland: 5 ppm STEL France: 5 ppm VLCT Germany: 2 ppm TWA 2 ppm MAK 4 ppm Peak	Spain: 10 ppm VLA-EC 5 ppm VLA-EC Sweden: 5 ppm CLV Greece: 5 ppm STEL/TWA
				Exposure Limits (Japan)
				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.

Section 8 – Exposure Controls and Personal Protection (continued)

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 gloves (nitrile or equivalent). 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

Section 9 – Physical and Chemical Properties

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

Section 10 – Stability and Reactivity

Characteristic	Sodium Nitrite Solution (27.6%)	Acetic Acid Ampoule (1.2%)
Component Stability	Stable	Stable
Hazard Reaction Potential	Will not occur	Will not occur
Conditions to Avoid	None	None
Materials to Avoid	None	None
Hazardous Decomposition Products	Not determined	Not determined

Section 11 – Toxicological Information

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 Oral LD50 Rat = 85 mg/kg
Acetic Acid	64-19-7	AF1225000	Inhalation LC50 Rat = 11.4 mg/L 4 hr Oral LD50 Rat = 3310 mg/kg Dermal LD50 Rabbit = 1060 mg/kg

Potential Health Effects

<i>Skin Corrosion/ Irritation:</i>	No data available. General irritation at point of exposure may be experienced
<i>Serious Eye Damage / Irritation:</i>	Causes eye irritation
<i>Ingestion:</i>	Harmful if swallowed
<i>Inhalation:</i>	None anticipated under normal product use conditions
<i>Respiratory Organ or Skin Sensitization:</i>	No data available
<i>Generative Cell Mutagenicity:</i>	This product is not reported to produce mutagenic effects in humans

Carcinogenicity

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

Reproductive Toxicity

This product is not reported to cause reproductive effects in humans.

Specified Target Organ General Toxicity

Single Exposure	May cause damage to organs (blood, cardiovascular system)
Repeated Exposure	May cause damage to organs through prolonged or repeated exposure (blood)

Aspiration Respiratory Organs Hazard

None anticipated under product use conditions.

Section 12 – Ecological Information

Ecotoxicity

Chemical Name	CAS #	Test & Species	
Sodium Nitrite	7632-00-0	96-hr LC50 Oncorhynchus mykiss	0.19 mg/L [flow-through] -- Juvenile
		96-hr LC50 Oncorhynchus mykiss	0.092-0.13 mg/L [flow-through]
		96-hr LC50 Oncorhynchus mykiss	0.4-0.6 mg/L [semi-static]
		96-hr LC50 Oncorhynchus mykiss	0.65-1 mg/L [static]
		96-hr LC50 Pimephales promelas	2.3 mg/L [flow-through]
Acetic Acid	64-19-7	96-hr LC50 Pimephales promelas	20 mg/L [static]
		96-hr LC50 Pimephales promelas	79 mg/L [static]
		96-hr LC50 Lepomis macrochirus	75 mg/L [static]
		24-hr EC50 Daphnia magna	47 mg/L
		48-hr EC50 Daphnia magna	65 mg/L [static]

Section 12 – Ecological Information (continued)

Persistence / Degradability	No information available for this product
Bioaccumulation	No information available for this product
Mobility in Soil	No information available for this product
PBT and vPvB Assessment	No information available for this product
Other adverse effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13 – Disposal Considerations

Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit.

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.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)

This kit is not regulated for transport.

Canadian Transportation

This kit is not regulated for transport.

International Air Transportation

This kit is not regulated for transport.

Section 15 – Regulatory Information

Regulatory Information

US 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

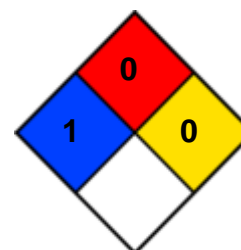
Chemical Name	CAS #	Minimum Concentration
Sodium Nitrite	7632-00-0	1%
Acetic Acid	64-19-7	1%

Additional Regulatory Information

HMIS Classification:



NFPA Classification:



***Classifications based on the chemicals and volume within the Reagent Solution*

Inventory reporting requirements:

Chemical Name	CAS #	TSCA	CAN	EEC
Sodium Nitrite	7632-00-0	Yes	DSL	EINECS
Acetic Acid	64-19-7	Yes	DSL	EINECS

Section 16 – Other Information

This MSDS has been prepared in accordance with ANSI Z400.1 format and the guidance provided under the Globally Harmonized System (GHS). Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using the Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 Program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks (Refer to Definitions of Terms at the end of this MSDS). Chronic (long-term) health effects are indicated in the HMIS by an asterisk (*). HMIS is a registered trade and service mark of the NPCA. For details on HMIS ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.

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

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Key / Legend

ACGIH = American Conference of Governmental Industrial Hygienists
 BAT = Biological Tolerance Values (Germany)
 CAS# = Chemical Abstract Service Number
 CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)
 CLV = Ceiling Limit Value (Sweden)
 DOT = Department of Transportation
 DSL = Domestic Substances List
 EEC = European Economic Community
 EINECS = European Inventory of Existing Commercial Chemical Substances
 ELINCS = European List of Notified Chemical Substances
 EPA = Environmental Protection Agency
 EU = European Union
 GHS = Globally Harmonized System
 HMIS = Hazardous Materials Identification System
 IARC = International Agency for Research on Cancer
 IMO = International Maritime Organization
 IATA = International Air Transport Association
 LLV = Level Limit Value (Sweden)
 MAK = Maximum Concentration Value in the Workplace
 NDSL = Non-Domestic Substances List

NFPA = National Fire Protection Association
 NIOSH = National Institute of Occupational Safety and Health
 NOHSC = National Occupational Health & Safety Commission
 NTP = National Toxicology Program
 OEL = Occupational Exposure Limit
 OSHA = Occupational Safety and Health Administration
 PEL = Permissible Exposure Limit
 PPE = Personal Protective Equipment
 RTECS = Registry of Toxic Effects of Chemical Substances
 SARA = Superfund Amendments and Reauthorization Act
 STEL = Short-term Exposure Limit
 STV = Short Term Value (Sweden)
 TDG = Transportation of Dangerous Goods
 TLV = Threshold Limit Value
 TSCA = Toxic Substances Control Act
 TWA = Time Weighted Average
 VLA-EC = Valor Límite Ambiental Exposición de Corta Duración (Spain): The limit for short-term exposure concentration
 VLA-ED = Valor Límite Ambiental Exposición Diaria (Spain): The limit for the daily average concentration
 VLCT = VALEUR LIMITE D EXPOSITION A COURT TERME (Limit Value Exposure is Short Term (France))