

## Section 1 – Product and Company Identification

### Manufacturer Information

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### Product Information

Product Name: Sofia Strep A+ FIA (Cat. #: 20274, 20276, 20290, and 20323)

Intended Use: The Sofia Strep A+ FIA employs immunofluorescence technology to detect Group A Streptococcal antigens from throat swabs of symptomatic patients. 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 Hydrochloric Acid), Fixed Volume Pipettes, sterile rayon Throat Swabs, Positive Control Swab and Negative Control Swab.

## Section 2 – Hazards Identification

### Emergency Overview

Component	OSHA Hazards	Target Organs	GHS Classification
Reagent Solution (Sodium Nitrite, 27.6%)	Toxic, Irritant	Eyes, Skin	Acute Toxicity, Oral (Category 4) Eye Irritation (Category 2A) Acute Aquatic Toxicity (Category 1)

### GHS Label Elements & Precautionary Statements

Component	Pictogram	Signal Word	Hazard Statements	Precautionary Statements
Reagent Solution (Sodium Nitrite, 27.6%)		<b>Warning</b>	H302 Harmful if swallowed. H319 Causes serious eye irritation. H400 Very toxic to aquatic life.	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.
<b>Supplemental Hazard Statements</b>				1. Follow Universal Precautions when working with the components within this kit. 2. Wash skin thoroughly after handling. (P264) 3. Do not eat, drink or smoke when using this kit. (P270) 4. Avoid release to the environment. (P273)

### Section 3 – Composition / Information on Ingredients

Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
Sodium Nitrite	7632-00-0	231-555-9	27.6	<0.5	Ox. Sol. 3; Acute Tox. 3; Eye Irrit. 2A; Acute Aq. 1; H272, H301, H319, H400
Hydrochloric Acid	7647-01-0	231-5957	1.2	<0.5	Met. Corr. 1; Skin Corr. 1B; Eye Dam. 1; STOT SE 3; H290, H314, H335

### 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.

<i>If inhaled:</i>	Move the person to fresh air and support breathing as required.
<i>In case of skin contact:</i>	Wash affected area with soap and water. Seek medical advice if irritation develops.
<i>In case of eye contact:</i>	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.
<i>If swallowed:</i>	Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Seek medical advice if irritation develops.

#### Most important symptoms and effects, both acute and delayed

Symptoms after ingestion: Harmful if swallowed.

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

No specific measures identified.

### 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.

<i>Suitable Extinguishing Media:</i>	For small fires, use dry chemical, carbon dioxide or alcohol-resistant foam.
<i>General Fire Hazards:</i>	The components within this kit will not significantly contribute to the intensity of a fire.
<i>Hazardous Combustion Products:</i>	No data available
<i>Fire Fighting Equipment:</i>	Firefighters should wear full protective gear when responding to fires.

### 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.

<i>Personal Precautions (e.g. PPE):</i>	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.
<i>Materials and Methods for Clean-Up:</i>	Soak 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.

## Section 6 – Accidental Release Measures (cont'd)

<i>Recovery and Neutralization:</i>	Collect spilled material and clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.
<i>Environmental Precautions:</i>	Contain spill to prevent migration to drains, sewers or open water sources. Discharge to the environment must be avoided.

## 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 handling and working with this kit. Keep out of reach of the general public.

**Conditions for Safe Storage:** To maintain efficacy, store according to the Package Insert instructions.

**Incompatibilities** To maintain efficacy, store according to the Package Insert instructions.

## Section 8 – Exposure Controls and Personal Protection

**Exposure Limits:** No data available for the components within this kit.

### 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 (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:* Wash hands before and after use and at the end of the workday.

### Environmental Exposure Controls

No special environmental controls are required.

### Special Notes

When activating the Reagent Solution (by breaking the glass ampoule of 1.2% Hydrochloric Acid and mixing with the 27.6% Sodium Nitrite) the initial chemical reaction will create nitrous acid (unstable), sodium chloride, nitric oxide and nitric acid.

## Section 9 – Physical and Chemical Properties

Characteristic	Reagent Solution	
	Sodium Nitrite Solution (27.6%)	Hydrochloric Acid (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
Solubility in Water	Soluble	Soluble
Appearance and Odor	Yellow with no odor	Clear with chlorine like odor

## Section 10 – Stability and Reactivity

Characteristic	Reagent Solution	
	Sodium Nitrite Solution (27.6%)	Hydrochloric Acid Ampoule (1.2%)
Component Stability	Stable	Stable
Hazard Reaction Potential	No data available	No data available
Conditions to Avoid	No data available	No data available
Materials to Avoid	No data available	No data available
Hazardous Decomposition Products	No data available	No data available

## Section 11 – Toxicological Information

### Acute Toxicity

**Component Analysis – LD<sub>50</sub> / LC<sub>50</sub> / Irritation** (No data available for specific kit components)

Chemical Name	CAS #	RTECS #	Information
Sodium Nitrite	7632-00-0	RA1225000	Oral LD <sub>50</sub> Rat 85 mg/kg
			Inhalation LC <sub>50</sub> Rat 5.5 mg/L 4 hr
			Dermal LD <sub>50</sub> No data available
Hydrochloric Acid	7647-01-0	MW4025000	Oral LD <sub>50</sub> Rat 900 mg/kg
			Inhalation LC <sub>50</sub> Rat (1h) 3124 ppm
			Dermal LD <sub>50</sub> Rabbit <5010 mg/kg

### Potential Health Effects:

<i>Skin Corrosion/ Irritation:</i>	No data available	<i>Inhalation:</i>	May cause respiratory tract irritation.
<i>Serious Eye Damage / Irritation:</i>	No data available	<i>Skin:</i>	May cause skin irritation upon contact.
<i>Respiratory or Skin Sensitization:</i>	No data available	<i>Eyes:</i>	May cause eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May be harmful if swallowed.

## Section 11 – Toxicological Information (cont'd)

### Carcinogenicity

IARC: Reagent Solution: 2A – Group 2A: Probably carcinogenic to humans (Sodium Nitrite)

The chemicals contained in this kit are not listed as carcinogens by any of the following: ACGIH, 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 Respiratory Organs Hazard

None anticipated under product use conditions.

**Synergistic Effects** No data available

### 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 contained within this kit.

**Additional Information** Liver – Irregularities – Based on Human Evidence (Sodium Nitrite)

## Section 12 – Ecological Information

**Ecotoxicity** No data available

**Persistence / Degradability** No data available

**Bioaccumulation** No data available

**Mobility in Soil** No data available

**PBT and vPvB Assessment** Not available as chemical safety assessment not required / not conducted.

**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. Do not discharge the any of 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 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.

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

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

## Section 15 – Regulatory Information

### Regulatory Information

#### U.S. Federal Regulations

**OSHA Hazards** Reagent Solution: Toxic, Irritant

**SARA 302** The following chemicals are subject to reporting levels established by SARA Title III, Section 302:  
*No chemicals in this material 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:

Sodium Nitrite CAS#: 7632-00-0 Revision Date: 2007-07-01

Hydrochloric Acid CAS#: 7647-01-0 Revision Date: 1993-04-24

**SARA 311/312** Sodium Nitrite CAS#: 7632-00-0 Reactivity Hazard, Acute and Chronic Health Hazard

Hydrochloric Acid CAS#: 7664-93-9 Acute Health Hazard, Chronic Health Hazard

#### 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
Hydrochloric Acid	7647-01-0	Yes	Yes	Yes	Yes	Yes	Yes

**California Prop 65:** This kit does not contain any chemicals known to 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%
Hydrochloric Acid	7647-01-0	1%

#### Additional Regulatory Information

**Safety, Health and Environmental regulations/legislation specific for the mixture:**

No data available

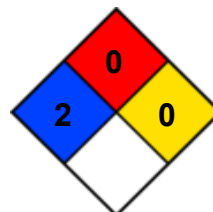
**Chemical Safety Assessment:**

Not completed for the components contained within this kit.

**HMIS Classification:**



**NFPA Classification:**



## Section 16 – Other Information

**Text of H-code(s) mentioned in Section 3:**

H272	May intensify fire; oxidizer.	Eye Dam.	Serious eye damage
H290	May be corrosive to metals.	Met. Corr.	Corrosive to metals
H301	Toxic if swallowed.	Acute Tox.	Acute toxicity
H314	Causes severe skin burns and eye damage.	Aquatic Acute	Acute aquatic toxicity
H335	May cause respiratory irritation.	Ox. Sol.	Oxidizing solids
H400	Very toxic to aquatic life.	Skin Corr.	Skin corrosion
		STOT SE	Specific target organ toxicity – single exposure

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**REVISIONS:** Additional SKU, Cat. #20323

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.