

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

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

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


The hazards associated with this product are related to the **Reagent Solution** that contains a 0.4N Hydrochloric Acid (1.2%) glass ampoule inside of a plastic bottle containing a 4M Sodium Nitrite (27.6%) solution. The Reagent Solution contains approximately 0.475 mL of Sodium Nitrite and 0.475 mL of Hydrochloric 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 (Part #: 1263700) within this kit is considered hazardous as defined by the Occupational Safety and Health Administration (OSHA), the Canadian Workplace Materials Information System (WHMIS), or the European Union (EU) Directives 1999/45/EC, 67/548/EEC and/or 1272/2008/EC.

Component	OSHA Hazards	Target Organs	GHS Classification
Reagent Solution	Oxidizer, Target Organ Effect, Toxic by Ingestion, Irritant	Blood, cardiovascular system, smooth muscle	Oxidizing liquids (Category 3) Acute Toxicity, Oral (Category 4) Eye Irritation (Category 2A) 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. H319 Causes serious eye irritation. H401 Toxic to aquatic life.	P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements			Follow Universal Precautions when working with this kit. Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Reagent Solution (Part #: 1263700)

Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume	Chemical Classification
Sodium Nitrite	7632-00-0	231-555-9	27.6	<0.5	Ox. Sol. 3; H400 Acute Tox. 3; H272 Aquatic Acute 1; H301
Hydrochloric Acid	7647-01-0	231-5957	1.2	<0.5	Skin Corr.1B; H314 STOT SE 3; 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.

- 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. Seek medical advice if irritation develops.
- Note to Physicians:* Treat symptomatically.

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.
- 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.

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 (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 clean-up supplies and place in a sealed container for disposal. Refer to Section 13 for disposal guidance.
- Materials and Methods for Clean-Up:* Wipe up with absorbent (e.g. paper towel, etc.). Thoroughly wash the area with soap and water after a spill or release clean-up.
- Environmental Precautions:* Contain spill to prevent migration to drains, 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 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 None.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: Contains no components with occupational exposure limit values.

Exposure Controls:

Engineering Measures Use with adequate ventilation to minimize potential for worker exposure.

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.

***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 Nitrogen Dioxide and Nitric Oxide as reaction products.*

Section 9 – Physical and Chemical Properties

Characteristic	Reagent Solution (Part #: 1263700)	
	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 ₂ 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 vinegar like odor

Section 10 – Stability and Reactivity

Characteristic	Reagent Solution (Part #: 1263700)	
	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	None	None
Materials to Avoid	None	None
Hazardous Decomposition Products	No data available	No data available

Section 11 – Toxicological Information

Acute Toxicity

Component Analysis – LD50 / LC50 / Irritation (No data available for specific kit components)

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

Potential Health Effects: Reagent Solution (Part #: 1263700)

<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.

Carcinogenicity

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

None anticipated under product use conditions.

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.

Synergistic Effects No data available.

Additional Information No data available.

Section 12 – Ecological Information

Ecotoxicity	No data available.	Mobility in Soil	No data available.
Persistence / Degradability	No data available.	PBT and vPvB Assessment	No data available.
Bioaccumulation	No data available.		
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 buffers, solutions, reagents or controls 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.

Section 14 – Transportation Information

U.S. Department of Transportation (DOT)	This kit is not regulated as a hazardous material.
International Air Transportation (IATA)	This kit is not regulated as a dangerous good.
International Maritime Dangerous Goods (IMDG)	This kit is not regulated as a dangerous good.

Section 15 – Regulatory Information

Regulatory Information

U.S. Federal Regulations

OSHA Hazards	Reagent Solution: Oxidizer, Target Organ Effect, Toxic by Ingestion, Irritant		
SARA 302	The following chemicals are subject to reporting levels established by SARA Title III, Section 302: <i>No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.</i>		
SARA 313	The following chemicals are subject to reporting levels established by SARA Title III, Section 313:		
	<i>Sodium Nitrite</i>	<i>CAS#: 7632-00-0</i>	<i>Revision Date: 2007-07-01</i>
	<i>Hydrochloric Acid</i>	<i>CAS#: 7647-01-0</i>	<i>Revision Date: 1993-04-24</i>
SARA 311/312	<i>Sodium Nitrite</i>	<i>CAS#: 7632-00-0</i>	<i>Reactivity Hazard, Acute and Chronic Health Hazard</i>
	<i>Hydrochloric Acid</i>	<i>CAS#: 7664-93-9</i>	<i>Acute Health Hazard, Chronic Health Hazard</i>

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

Section 15 – Regulatory Information (cont'd)

California Prop 65: This product 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

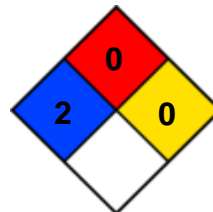
Safety, Health and Environmental regulations/legislation specific for the mixture: No data available

Chemical Safety Assessment: No data available

HMIS Classification:



NFPA Classification:



Section 16 – Other Information

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

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

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REVISIONS: Update kit name – Addition of “+.”

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.