

Section 1 – Product and Company Identification

Manufacturer Information

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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.

Section 2 – Hazards Identification

Emergency Overview

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

GHS Label Elements and Precautionary Statements

Component	Pictogram	Signal Word	Hazard Statements	Precautionary Statements
Reagent Solution (Sodium Nitrite, 27.6%)		Warning	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.
Supplemental Hazard Statements			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

Reagent Solution

Chemical Name	CAS #	EINECS #	Concentration (%)	Component Volume	Chemical Classification
Sodium Nitrite	7632-00-0	231-555-9	27.6	<0.4 mL	Ox. Sol.3; Acute Tox. 3; Eye Irrit. 2A, Acute Aq. 1; H272, H301, H319, H400
Acetic Acid	64-19-7	200-580-7	1.2	<0.5 mL	Flam. Liq. 3; Skin Corr. 1A; Eye Dam. 1; H226, H314, H318

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 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.

- 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.

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. A large spill of the Reagent Solution contained within this kit is 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.

Section 6 – Accidental Release Measures (cont'd)

Materials and Methods for Clean-Up: 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.

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.

Environmental Precautions: 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 the 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. 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 use, 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% 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 9 – Physical and Chemical Properties

Characteristic	Reagent Solution	
	Sodium Nitrite (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 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	2.4
Solubility in Water	Soluble	Soluble
Appearance and Odor	Liquid, yellow with no odor	Liquid, clear with vinegar like odor

Section 10 – Stability and Reactivity

Characteristic	Reagent Solution	
	Sodium Nitrite (27.6%)	Acetic 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 – 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	<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)

These solutions, reagents or controls do not contain chemicals present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the ACGIH, NTP or OSHA.

Reproductive Toxicity No data available**Teratogenicity** No data available**Specified Target Organ General Toxicity**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 within this kit.

Additional Information

Liver – irregularities – Based on Human Evidence (Sodium Nitrite).

Section 12 – Ecological Information**Toxicity** 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. Toxic to aquatic life.**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 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 a licensed professional waste disposal service to dispose of this material.

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

SARA 311/312 Sodium Nitrite CAS#: 7632-00-0 Acute Health Hazard / Chronic Health Hazard
 Acetic Acid CAS#: 64-19-7 Fire Hazard, 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
Acetic Acid	64-19-7	Yes	Yes	Yes	Yes	Yes	Yes

California Prop 65: This kit does 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

Not completed for the components contained within this kit.

HMIS Kit Classification:

Health Hazard: 2
 Chronic Health Hazard: *
 Flammability: 0
 Physical Hazard: 0

NFPA Kit Classification:

Health Hazard (blue): 2
 Fire Hazard (red): 0
 Reactivity (yellow): 0
 Special Hazards (white): None

**Use additional care when handling this kit.*

Section 16 – Other Information

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

H226	Flammable liquid and vapor.	Flam. Liq.	Flammable liquid
H272	May intensify fire; oxidizer.	Acute Tox.	Acute toxicity
H301	Toxic if swallowed.	Eye Irrit.	Eye irritation
H302	Harmful if swallowed.	Acute Aq.	Acute aquatic
H314	Causes severe skin burns and eye damage.	Ox. Solid	Oxidizing solid
H318	Causes serious eye damage.	Eye Dam.	Eye damage
H319	Causes serious eye irritation.		
H400	Very toxic to aquatic life.		
H401	Toxic to aquatic life.		

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REVISIONS: Updated template, updated to Acute Aquatic Toxicity (Category 1), added environmental hazard pictogram, updated supplemental hazard statements in Section 2; updated Section 3 with chemical classification for raw material; removed specific exposure limit data in Section 8; updated to include IARC 2A and Additional Information in Section 11; removed reference to EU Directive 67/548/EEC danger symbols, risk phrases and safety phrases, and included HMIS and NFPA ratings in Section 15; added text of H-codes and removed legend in Section 16.

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