

Section 1 – Product and Company Identification

Manufacturer Information

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Product Information

Product Name: Sofia S. pneumoniae FIA (Catalog #: 20292, 20293)

Intended Use: The Sofia S. pneumonia FIA employs immunofluorescence for qualitative detection of *Streptococcus pneumoniae* antigen in urine specimens of patients with pneumonia and in cerebral spinal fluid (CSF) specimens of patients with meningitis. Not for use by the general public.


Components: Kit is composed of individually pouched test cassettes, one *Streptococcus pneumonia* Positive Control Solution (*Streptococcus pneumonia* antigen) and one Negative Control Solution (*Streptococcus C* antigen).

Section 2 – Hazards Identification

Emergency Overview

Component	OSHA Hazards	Target Organs	GHS Classification
Positive Control (Microcide III, 0.3%)	Irritant, Sensitizer	Skin, eyes	Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)
Negative Control (Microcide III, 0.3%)	Irritant, Sensitizer	Skin, eyes	Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)

GHS Classification and Label Elements

Component	Pictogram	Hazard Statements	Precautionary Statements
Positive Control and Negative Control	 Warning	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P261 Avoid breathing mist or spray. 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. Avoid release to the environment.	

Section 3 – Composition / Information on Ingredients

Component	Chemical Name	CAS #	EINECS #	Concentration (%)	Component Volume
Positive Control, Negative Control	Microcide III	--	--	0.3	2.55 mL

Section 4 – First Aid Measures

General Advice

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

- 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.

- 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. Large spills of the Positive or Negative Controls contained within this kit are unlikely.

- Personal Precautions:* Use personal protective equipment, including protective gloves and safety glasses when cleaning up small spills. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.
- Materials and Methods for Clean-Up:* Wipe 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 sealed container for disposal. Refer to Section 13 for disposal guidance.
- Environmental Precautions:* Contain spill to prevent migration to public industrial / sanitary sewers or open water sources. Discharge into 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 instructions in the kit specific Package Insert.

Incompatibilities: None.

Section 8 – Exposure Controls and Personal Protection

Exposure Limits: No data available for the specific 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.

Section 9 – Physical and Chemical

Characteristic	Positive and Negative Controls
Boiling Point (°C)	No data available
Melting Point (°C)	No data available
Specific Gravity (H ₂ O = 1)	No data available
Vapor Pressure (mm Hg)	No data available
Vapor Density (Air = 1)	No data available
Evaporation Rate (Ether = 1)	No data available
pH	7.2 to 8.5
Solubility in Water	Soluble
Appearance and Odor	Clear, odorless

Section 10 – Stability and Reactivity

Characteristic	Positive and Negative Controls
Component Stability	Stable
Hazard Reaction Potential	Will not occur
Conditions to Avoid	None
Materials to Avoid	None
Hazardous Decomposition Products	No data available
Additional Information:	
Not applicable	

Section 11 – Toxicological Information

Acute Toxicity
Component Analysis – LD50 / LC50

Chemical Name	CAS #	RTECS #	Information
Microcide III	--	--	Oral LD ₅₀ Rat >5000 mg/kg
			Inhalation LC ₅₀ Rat (4-hr) 0.33 mg/L (dust/mist)
			Dermal LD ₅₀ Rabbit >5000 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.

Carcinogenicity

The chemicals in the Positive and Negative Controls 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
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 Positive and Negative Controls 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 Positive or Negative 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 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	Positive and Negative Controls: Irritant, Skin Sensitizer
SARA 302	No chemicals in this kit are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
SARA 311/312	No SARA Hazards.

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
Microcide III	--	No	No	No	No	No

Section 15 – Regulatory Information (cont'd)
California Proposition 65

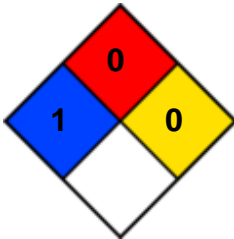
This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

Canadian - WHMIS IDL

Chemical Name	CAS #	Minimum Concentration
Microcide III	--	No data available

Additional Regulatory Information

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

NFPA 704 Rating

HMIS Classification

Section 16 – Other Information

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SUPERCEDES: December 15, 2015

REVISIONS: Updated OSHA hazard classification in Section 15.

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