

Section 1 – Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name: Sofia Lyme FIA, Sofia 2 Lyme FIA, Sofia 2 Lyme+ FIA (Cat. #: 20298, 20319, 20309)

Intended Use: This qualitative test is intended for use as an aid in the diagnosis of Lyme disease.



Components: Individually pouched Test Cassettes, Blood Collection and Preparation Kit (contains Reagent Solution), Positive Control, and Negative Control

Section 2 – Hazards Identification

2.1 Classification of Substance or Mixture

Kit Component	OSHA Hazards	Target Organs	GHS Classification
Reagent Solution (0.03% Proclin 300)	Sensitizer	Skin	Skin Sensitizer (Category 1)
Positive Control and Negative Control (0.3% Microcide III)	Irritant, Sensitizer	Eyes, skin	Eye Irritation (Category 2A) Skin Irritation (Category 2) Skin Sensitizer (Category 1)

2.2 GHS Label Elements, Including Precautionary Statements

Component	Pictogram	Hazard Statements	Precautionary Statements
Reagent Solution (0.03% Proclin 300)	 Warning	H317 May cause an allergic skin reaction.	P264 Wash hands thoroughly after handling. P303+P361+P353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water. P333+P313: If skin irritation or rash occurs: Get medical attention.
Positive Control Negative Control (0.3% Microcide III)	 Warning	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.	P264 Wash hands thoroughly after handling. 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. P302+P352 IF ON SKIN: Rinse skin with water.
Supplemental Hazard Statements		1. Avoid release to the environment (P273). 2. Follow Universal Precautions when working with this kit. Refer to additional information in Section 7, Handling and Storage.	

Section 3 – Composition / Information on Ingredients

3.1 Mixtures

Kit Component	Chemical Name	CAS #	EINECS #	Conc. (%)	Component Volume
Reagent Solution	Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	0.03	0.3 mL
Positive Control	Mixture for Microcide III: 2-Methyl-4-isothiazolin-3-one (<1%); Magnesium nitrate (<2%)	--	--	0.30	2.55 mL 2.55 mL
Negative Control	1. Mixture for Microcide III: 2-Methyl-4-isothiazolin-3-one (<1%); Magnesium nitrate (<2%) 2. Lyme Negative Serum	--	--	1. 0.3 2. 10	2.55 mL

Section 4 – First Aid Measures

4.1 Description of First Aid Measures

Move out of 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: Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water (do not swallow). Seek medical advice if irritation develops.

4.2 Most Important Symptoms and Effects (both acute and delayed)

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

No specific measures identified.

Section 5 – Fire Fighting Measures

5.1 General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to extinguish a fire.

5.2 Suitable Extinguishing Media

For small fires, use dry chemical, water spray, carbon dioxide or alcohol-resistant foam.

Section 5 – Fire Fighting Measures (cont'd)

5.3 Special Hazards Arising from the Substance of Mixture

Nature of decomposition products not known

5.4 General Fire Hazards

The components within this kit will not significantly contribute to the intensity of a fire.

5.5 Fire Fighting Equipment

Firefighters should wear full protective gear when responding to fires.

Section 6 – Accidental Release Measures

6.1 General Advice

Only individuals properly trained and issued appropriate personal protective equipment should respond and attempt to clean up a spill or release.

6.2 Personal Precautions

Use personal protective equipment, including protective gloves and safety glasses when cleaning up spills associated with the components of this kit. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Keep all unnecessary personnel away from the spill area.

6.3 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.

6.4 Recovery and Neutralization

Collect spilled material and clean-up supplies and place in sealed container for disposal. Refer to Section 13 for disposal guidance.

6.5 Environmental Precautions

Contain spill to prevent migration to drains, sewers or open water sources. Discharge into the environment must be avoided.

Section 7 – Handling and Storage

7.1 Specific Use

Refer to product specific Package Insert. Not for use by the public.

7.2 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 working with the components of this kit. Do not eat or drink while handling this kit. The Sofia 2 Lyme FIA and Sofia Lyme FIA kits should be handled only by qualified individuals who are familiar with the potential hazards. Keep out of reach of the public.

7.3 Universal Precautions

No known test method can offer complete assurance that product(s) derived from human blood, serum or plasma used in components of this kit will not transmit infectious agents. All blood products should be treated as potentially infectious; use universal precautions. Users should ensure the use of proper personal protective equipment (PPE), covering of any cuts or abrasions on the skin (hands), and follow standard protocols for the decontamination of work surfaces when testing has been completed. Always wash hands thoroughly after handling the components within this kit.

Section 7 – Handling and Storage (cont'd)

7.4 Conditions for Safe Storage

To maintain efficacy, store according to the kit specific Package Insert instructions.

7.5 Incompatibilities

To maintain efficacy, store according to the kit specific Package Insert instructions.

Section 8 – Exposure Controls and Personal Protection

8.1 Exposure Limits

No data available for the components contained within this kit.

8.2 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 in 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.

8.3 Environmental Exposure Controls

No special environmental controls are required.

8.4 Special Notes

No data available

Section 9 – Physical and Chemical Properties

Characteristic	Reagent Solution	Positive Control	Negative Control
Boiling Point (°C)	No data available	No data available	No data available
Melting Point (°C)	No data available	No data available	No data available
Specific Gravity (H ₂ O = 1)	No data available	No data available	No data available
Vapor Pressure (mm Hg)	No data available	No data available	No data available
Vapor Density (Air = 1)	No data available	No data available	No data available
Evaporation Rate (Ether = 1)	No data available	No data available	No data available
pH	Neutral	Neutral	Neutral
Solubility in Water	Soluble	Soluble	Soluble
Appearance and Odor	Slight blue liquid, odorless	Clear liquid, odorless	Clear liquid, odorless

Section 10 – Stability and Reactivity

Characteristic	Reagent Solution	Positive Control	Negative Control
Component Stability	Stable	Stable	Stable
Hazard Reaction Potential	No data available	No data available	No data available
Conditions to Avoid	No data available	No data available	No data available
Materials to Avoid	No data available	No data available	No data available
Hazardous Decomposition Products	No data available	No data available	No data available

Section 11 – Toxicological Information

11.1 Information on Toxicological Effects

Acute Toxicity

Component Analysis – LD50 / LC50 / Irritation (No specific data available for the Reagent Solution)

Chemical Name	CAS #	RTECS #	Information
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	--	Oral LD ₅₀ Rat 862 mg/kg Inhalation LC ₅₀ No data available Dermal LD ₅₀ Rabbit 2,800 mg/kg
Mixture for Microcide III: 2-Methyl-4-isothiazolin-3-one (<1%); Magnesium nitrate (<2%)	--	--	Oral LD ₅₀ No data available Inhalation LC ₅₀ No data available Dermal LD ₅₀ No data available

Potential Health Effects – Reagent Solution, Positive Control, Negative Control – Irritant, Sensitizer

<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>	May act as a sensitizer	<i>Eyes:</i>	May cause serious eye irritation.
<i>Generative Cell Mutagenicity:</i>	No data available	<i>Ingestion:</i>	May be harmful if swallowed.

Carcinogenicity

No component of the Sofia 2 Lyme FIA and Sofia Lyme FIA kits present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by the 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 Hazard None anticipated under product use conditions.

Synergistic Effects No data available

11.2 Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated for the Sofia 2 Lyme FIA and Sofia Lyme FIA components.

11.3 Additional Information

Sensitization: The Reagent Solution contains a small volume of a very dilute, sensitizing preservative (Proclin 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

Section 12 – Ecological Information

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|---|-------------------|
| 12.1 Ecotoxicity | No data available |
| 12.2 Persistence / Degradability | No data available |
| 12.3 Bioaccumulation | No data available |
| 12.4 Mobility in Soil | No data available |
| 12.5 PBT and vPvB Assessment | No data available |
| 12.6 Other Adverse Effects | |

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Avoid reease to the environment.

Proclin 300 is very toxic to aquatic life with long lasting effects.

Section 13 – Disposal Considerations

13.1 Waste Disposal Instructions

Utilize appropriate personal protective equipment and spill control when handling wastes generated from using this kit. Do not discharge the solution or controls into drains, water courses or onto the ground.

13.2 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

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|---|--|
| 14.1 U.S. Department of Transportation (DOT) | This kit is not regulated for transport. |
| 14.2 International Air Transportation (IATA) | This kit is not regulated for transport. |
| 14.3 International Maritime Dangerous Goods (IMDG) | This kit is not regulated for transport. |

Section 15 – Regulatory Information

15.1 U.S. Federal Regulations

OSHA Hazards Reagent Solution, Positive Control, Negative Control: Irritant, Sensitizer

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:
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 Proclin 300 CAS#: 55965-84-9 Acute Health Hazard

Section 15 – Regulatory Information (cont'd)

15.2 State Regulations

The following chemical(s) appear on one or more of the following state hazardous substances lists:

Chemical Name	CAS #	CA	MA	MN	NJ	PA	RI
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	No	No	No	Yes	Yes	No
Mixture for Microcide III: 2-Methyl-4-isothiazolin-3-one (<1%); Magnesium nitrate (<2%)	--	No	No	No	No	No	No

California Prop 65

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

15.3 Canadian – WHMIS Classification

Chemical Name	CAS #	Classification
Mixture for Proclin 300: 5-Chloro-2-methyl-2, 3-dihydroisothiazol-3-one; 2-Methyl-2, 3-dihydroisothiazol-3-one (3:1)	55965-84-9	D2B Toxic Material Causing Other Toxic Effects - Sensitizer
Mixture for Microcide III: 2-Methyl-4-isothiazolin-3-one (<1%); Magnesium nitrate (<2%)	--	D2B Toxic Material Causing Other Toxic Effects - Sensitizer

15.4 Additional Regulatory Information

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

European Union – Regulation (EC) 1907/2006.

Chemical Safety Assessment:

Not completed for the components contained within this kit.

NFPA Kit Classification:

Health Hazard (blue): 1
 Fire Hazard (red): 0
 Reactivity Hazard (yellow): 0
 Special Hazards (white): None





Section 16 – Other Information

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