

SECTION 1: Identification
1.1. Identification

Product form : Mixture
 Product name : Sofia Lyme FIA / Sofia 2 Lyme FIA
 Product code : 20298, 20319

1.2. Recommended use and restrictions on use

Recommended use : For medical diagnostic use.
 Restrictions on use : Professional Use of Medical Devices

1.3. Supplier

Quidel Corporation
 10165 McKellar Court
 San Diego, CA 92121 - U.S.A
 T 1.800.874.1517 - F 1.858.453.4338
gehs@quidel.com - quidel.com



1.4. Emergency telephone number

Emergency number : 1.866.519.4752

SECTION 2: Hazard(s) identification
2.1. Classification of the substance or mixture
GHS US classification

Components	GHS US classification
Positive Control	Skin Sens. 1, H317
Negative Control	Skin Sens. 1, H317

2.2. GHS Label elements, including precautionary statements
GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Positive Control		Warning	H317 - May cause an allergic skin reaction	P280 - Wear lab coat, safety glasses, and gloves. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.
Negative Control		Warning	H317 - May cause an allergic skin reaction	P280 - Wear lab coat, safety glasses, and gloves. P302+P352 - If on skin: Wash skin thoroughly with mild soap and water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations.

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Positive Control	Microcide III	-	0.3	Skin Sens. 1, H317
Negative Control	Microcide III	-	0.3	Skin Sens. 1, H317

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
- First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
- First-aid measures after eye contact : Rinse eyes with water as a precaution.
- First-aid measures after ingestion : Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects after skin contact : May cause an allergic skin reaction.
- Immediate medical attention and special treatment, if necessary : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

No additional information available

5.3. Special protective equipment and precautions for fire-fighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist/vapors.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

- Environmental precautions : Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material.
- Other information : Dispose of materials or solid residues at an authorized site.
- Reference to other sections : For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing mist/vapors. Wear personal protective equipment.
- Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station.
- Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment
Materials for protective clothing:

Lab coat

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Clear (Positive Control), clear (Negative Control), slight blue (Reagent Solution)
Odor	: Odorless
Odor threshold	: No data available
pH	: Neutral
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: Soluble
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
No data available Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects after skin contact	: May cause an allergic skin reaction.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information
Department of Transportation (DOT)

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information
15.1. US Federal regulations
Sofia 2 Lyme

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

Microcide III	CAS No	< 1%
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This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations
CANADA
Microcide III

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Indication of changes:

Regulatory Review.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.