

**SECTION 1: Identification**
**1.1. Identification**

Product form : Mixture  
 Product name : Sofia Legionella FIA  
 Product code : 20244

**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**
**Manufacturer**

Quidel Corporation  
 10165 McKellar Court  
 San Diego, 92121 - USA  
 T 1.800.874.1517 - F 1.858.453.4338  
[gehs@quidel.com](mailto:gehs@quidel.com) - [quidel.com](http://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
Legionella Negative Control	Skin Sens. 1, H317
Legionella Positive Control	Skin Sens. 1, H317

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Legionella Negative Control		Warning	H317 - May cause an allergic skin reaction	P280 - Wear protective gloves, safety glasses, and lab coat 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. P501 - Dispose of contents: Dispose in a safe manner in accordance with local, regional, or national regulations
Legionella Positive Control		Warning	H317 - May cause an allergic skin reaction	P280 - Wear protective gloves, safety glasses, and lab coat 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. P501 - Dispose of contents: Dispose in a safe manner in accordance with local, regional, or national regulations

**SECTION 3: Composition/Information on ingredients**

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

#### 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 dust/fume/gas/mist/vapors/spray. 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:**

Incidental contact with the Positive or Negative Control may be encountered. Approximately, 2.55 mL of solution per Control.

**Hand protection:**

Type	Material	Permeation	Thickness (mm)	Permeation
Medical Grade Disposable Gloves (powder-free) recommended	Nitrile rubber (NBR)	5 (> 240 minutes)	0.12	-

**Eye protection:**

Safety glasses

**Skin and body protection:**

Wear suitable protective clothing

**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
Appearance	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: Positive and Negative Controls - 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 (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: 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.
-------------------	--

**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****Microcide III**

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

**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

*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.*