

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

Product form	: Mixture
Product name	: Sofia 2 Campylobacter FIA
Product code	: 20352, 20353

**1.2. Recommended use and restrictions on use**

Recommended use	: For medical diagnostic use.
Restrictions on use	: Restricted to professional users

**1.3. Supplier**
**Manufacturer**

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](mailto:gehs@quidel.com) - [quidel.com](http://quidel.com)



**1.4. Emergency telephone number**

Emergency number	: 1.866.519.4752
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**SECTION 2: Hazard(s) identification**
**2.1. Classification of the substance or mixture**
**GHS US classification**

Components	GHS US classification
Specimen Diluent	Skin Sens. 1, H317
Positive and Negative Controls	Skin Sens. 1, H317

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Specimen Diluent		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Positive and Negative Controls		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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

Name	Chemical name	CAS #	%	GHS US classification
Specimen Diluent	Mixture for ProClin 300: 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9 -	0.05	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Positive and Negative Controls	polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether	9002-93-1 -	0.22	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
	1H-imidazole	288-32-4 -	0.15	Acute Tox. 4 (Oral), H302 Skin Corr. 1C, H314 Repr. 1B, H360D
	<i>Mixture for ProClin 300:</i> 5-chloro-2-methyl-2H-isothiazol-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	55965-84-9 -	0.05	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

## 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. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after 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 advice/attention.
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.
Symptoms/effects after eye contact	: Eye irritation.
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.
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### 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.
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## 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.
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#### 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".
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### 6.2. Environmental precautions

Environmental precautions	: Avoid release to the environment.
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### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Mechanically recover the product.
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. Wear personal protective equipment.
Hygiene measures	: 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

#### Personal protective equipment:

Gloves. Safety glasses.

#### Materials for protective clothing:

Lab coat

#### Hand protection:

Protective gloves

#### 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 : Solid  
 Appearance : In vitro diagnostic medical test kit.  
 Color : No data available  
 Odor : No data available  
 Odor threshold : No data available  
 pH : Neutral - Specimen Diluent, Positive and Negative Controls  
 Melting point : No data available  
 Freezing point : Not applicable  
 Boiling point : No data available  
 Flash point : Not applicable  
 Relative evaporation rate (butyl acetate=1) : No data available  
 Flammability (solid, gas) : Non flammable.  
 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	: Not applicable
Decomposition temperature	: No data available
No data available	Viscosity, kinematic : Not applicable
Viscosity, dynamic	: No data available
Explosion limits	: Not applicable
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	: Not classified
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	: Not applicable
Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Eye irritation.

**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**

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|--|--|
| 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.   |
| Product/Packaging disposal recommendations | : Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations. |
| Ecology - waste materials                  | : Avoid release to the environment.  |

**SECTION 14: Transport information****Department of Transportation (DOT)** : Not regulated**International Maritime Dangerous Goods (IMDG)** : Not regulated**International Air Transportation Association (IATA)** : Not regulated**SECTION 15: Regulatory information****15.1. US Federal regulations****Sofia 2 Campylobacter FIA**

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

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****Sofia 2 Campylobacter FIA**

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.*