

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**
**1.1. Product identifier**

Product form : Mixture  
 Product name : Sofia 2 C. difficile FIA  
 Product code : 20328, 20329

**1.2. Relevant identified uses of the substance or mixture and uses advised against**
**1.2.1. Relevant identified uses**

Industrial/Professional use spec : For in vitro diagnostic use

**1.2.2. Uses advised against**

Restrictions on use : Restricted to professional users, Professional Use of Medical Devices

**1.3. Details of the supplier of the safety data sheet**
**Manufacturer**

Quidel Corporation  
 10165 McKellar Court  
 92121 San Diego, CA - 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



**SECTION 2: Hazards identification**
**2.1. Classification of the substance or mixture**
**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Components	CLP classification
C. difficile FIA, Specimen Diluent	Skin Sens. 1, H317
C. difficile FIA, Positive and Negative Control	Skin Sens. 1, H317

**Adverse physicochemical, human health and environmental effects**

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

**2.2. Label elements**
**Labeling according to Regulation (EC) No. 1272/2008 [CLP]**

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
<b>C. difficile FIA, Specimen Diluent</b>		Warning	H317 - May cause an allergic skin reaction.	P264 - Wash hands thoroughly after handling. P280 - Wear gloves and safety glasses when handling this component. 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.
<b>C. difficile FIA, Positive and Negative Control</b>		Warning	H317 - May cause an allergic skin reaction.	P264 - Wash hands thoroughly after handling. P280 - Wear gloves and safety glasses when handling this component. 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.

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/Information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Chemical name	CAS No EC-No.	%	CLP classification
1. C. difficile FIA, Specimen Diluent 2. C. difficile FIA, Positive and Negative Control	<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	1. 0.05 2. 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

Full text of H- and EUH-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.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes.
First-aid measures after ingestion	: Call a poison center/doctor/physician if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: Irritation. May cause an allergic skin reaction.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam.
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### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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### 5.3. Advice for firefighters

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.
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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

Avoid release to the environment.

### 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.

#### 6.4. 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.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station.

##### 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):



##### Environmental exposure controls:

Avoid release to the environment.

##### 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  
 Relative evaporation rate (butyl acetate=1) : No data available  
 Melting point : No data available

Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: 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
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: Not applicable

## 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

### 11.1. Information on toxicological effects

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

**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.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

**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. Results of PBT and vPvB assessment**

No additional information available

**12.6. Other adverse effects**

No additional information available

**SECTION 13: Disposal considerations**
**13.1. Waste treatment 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.
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**

In accordance with ADR / IATA

**14.1. UN number**

UN-No. (ADR)	: Not regulated
UN-No. (IATA)	: Not regulated

**14.2. UN proper shipping name**

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated

**14.3. Transport hazard class(es)**
**ADR**

Transport hazard class(es) (ADR)	: Not regulated
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**IATA**

Transport hazard class(es) (IATA)	: Not regulated
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**14.4. Packing group**

Packing group (ADR)	: Not regulated
Packing group (IATA)	: Not regulated

**14.5. Environmental hazards**

Dangerous for the environment	: No
Other information	: No supplementary information available

**14.6. Special precautions for user**
**Overland transport**

Not regulated

**Air transport**

Not regulated

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable

**SECTION 15: Regulatory information**
**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**
**15.1.1. EU-Regulations**

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

**15.1.2. National regulations**
**Germany**

Regulatory reference : WGK nwg, non-hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

**Netherlands**

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

**Denmark**

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**
**Indication of changes:**

Composition/Information on ingredients.

Other information : Please review product insert prior to using this product.

**Full text of H- and EUH-phrases:**

H317	May cause an allergic skin reaction.
Skin Sens. 1	Skin sensitization, Category 1

*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.*