

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

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

**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

**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
Specimen Diluent	Skin Sens. 1, H317
Positive and Negative Controls	Skin Sens. 1, H317



Full text of H- and EUH-statements: see section 16

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

Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

**2.2. Label elements**

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

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.

**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
Specimen Diluent	<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
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

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. 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, both acute and delayed**

Symptoms/effects after skin contact	: Irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Eye irritation.

**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. Avoid contact with skin and eyes.

**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**

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.

**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):**

**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

**mixture of: 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)**

LD50 oral rat	53 mg/kg (Rat, Literature study)
LD50 dermal	200 – 1000 mg/kg body weight (Literature study)

**1H-imidazole (288-32-4)**

LD50 oral rat	970 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Experimental value)
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**polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)**

LD50 oral rat	1800 mg/kg (Rat, Literature study)
LD50 dermal rabbit	8000 mg/kg (Rabbit, Literature study)

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

**Sofia 2 Campylobacter FIA**

Viscosity, kinematic	Not applicable
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**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

**mixture of: 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)**

LC50 - Fish [1]	0.28 mg/l (96 h, Lepomis macrochirus, Literature)
EC50 - Crustacea [1]	0.16 mg/l (48 h, Daphnia magna, Literature)
EC50 72h - Algae [1]	0.018 mg/l (Pseudokirchneriella subcapitata, Literature)

**1H-imidazole (288-32-4)**

LC50 - Fish [1]	283.6 mg/l (Other, 48 h, Leuciscus idus, Static system, Fresh water, Experimental value)
EC50 - Crustacea [1]	341.5 mg/l (EU Method C.2, 48 h, Daphnia magna, Static system, Fresh water, Experimental value)

ErC50 algae	133 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value)
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### polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

LC50 - Fish [1]	8.9 mg/l (96 h, Pimephales promelas, Literature study)
EC50 - Crustacea [1]	26 mg/l (48 h, Daphnia magna, Literature study)

### 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

Component	
polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	This substance/mixture does not meet the PBT criteria of REACH, annex XIII This substance/mixture does not meet the vPvB criteria of REACH, annex XIII
1H-imidazole (288-32-4)	This substance/mixture does not meet the PBT criteria of REACH, annex XIII This substance/mixture does not meet the vPvB criteria of REACH, annex XIII

### 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 / IMDG / IATA / ADN

### 14.1. UN number

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

### 14.2. UN proper shipping name

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

### 14.3. Transport hazard class(es)

#### ADR

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

#### IMDG

Transport hazard class(es) (IMDG) : Not regulated

**IATA**

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

**ADN**

Transport hazard class(es) (ADN) : Not regulated

**14.4. Packing group**

Packing group (ADR) : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : Not regulated

Packing group (ADN) : Not regulated

**14.5. Environmental hazards**

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

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

Not regulated

**Transport by sea**

Not regulated

**Air transport**

Not regulated

**Inland waterway 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 substance on the candidate list in concentration  $\geq 0.1\%$  or with a lower specific limit: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9002-93-1)

Contains REACH Annex XIV substances: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9002-93-1)

**15.1.2. National regulations**

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

**Germany**

Regulatory reference : WGK 1, slightly 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 : 1H-imidazole is listed

**Denmark**

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

Pregnant/breastfeeding women working with the product must not be in direct contact with 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:**

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H360D	May damage the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Repr. 1B	Reproductive toxicity Category 1B
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation Category 2
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.*