

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
Product group : Kit

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@quidelortho.com - 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, Sofia 2 Campylobacter FIA	Skin Sens. 1, H317
Campy FIA, 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

May cause an allergic skin reaction.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
Specimen Diluent, Sofia 2 Campylobacter FIA		Warning	H317 - May cause an allergic skin reaction.	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.	No additional information available

Campy FIA, Positive and Negative Controls		Warning	H317 - May cause an allergic skin reaction.	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.	No additional information available
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2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS No EC-No.	%	CLP classification
Campy FIA, Positive and Negative Controls	Triton X-100 polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether	9002-93-1 -	0.22	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Chronic 2, H411
Campy FIA, Positive and Negative Controls	1H-imidazole	288-32-4 -	0.15	Acute Tox. 4 (Oral), H302 Skin Corr. 1C, H314 Eye Dam. 1, H318 Repr. 1B, H360D

Specific concentration limits:

Name	Product identifier	Specific concentration limits
ProClin® 300 reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	(CAS No) 55965-84-9 (EC Index-No.) 613-167-00-5	(0.0015 \leq C \leq 100) Skin Sens. 1A, H317 (0.06 \leq C < 0.6) Eye Irrit. 2, H319 (0.06 \leq C < 0.6) Skin Irrit. 2, H315 (0.6 \leq C \leq 100) Eye Dam. 1, H318 (0.6 \leq C \leq 100) Skin Corr. 1C, H314

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. 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 or a doctor if you feel unwell.

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

Symptoms/effects after skin contact	: 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.

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 dust/fume/gas/mist/vapours/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

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. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/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.

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:

Wear protective gloves. Wash your hands

Eye protection:

Safety glasses

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	: Liquid (Specimen Diluent, Positive and Negative Controls)
Appearance	: In vitro diagnostic medical test kit.
Colour	: No data available
Odour	: Odorless.
Odour threshold	: No data available
pH	: Neutral - Specimen Diluent, Positive and Negative Controls
Relative evaporation rate (butylacetate=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	: Non flammable.
Vapour pressure	: No data available
Relative vapour 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
Oxidising properties	: No data available
Explosive 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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50 oral rat	66 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Calculated by reference to active substance, Oral, 14 day(s))
LD50 dermal rat	> 141 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s))
LC50 Inhalation - Rat	0.17 mg/l air (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Calculated by reference to active substance, Inhalation (dust), 14 day(s))

1H-imidazole (288-32-4)	
LD50 oral rat	970 mg/kg bodyweight (Equivalent or similar to OECD 401, Rat, Experimental value, Oral, 7 day(s))

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
LD50 oral rat	1800 mg/kg (Rat, Literature study, Oral)
LD50 dermal rabbit	8000 mg/kg (Rabbit, Literature study, Dermal)

Skin corrosion/irritation : Not classified
pH: Neutral - Specimen Diluent, Positive and Negative Controls

Serious eye damage/irritation : Not classified
pH: Neutral - Specimen Diluent, Positive and Negative Controls

Respiratory or skin sensitisation : 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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LOAEL (dermal, rat/rabbit, 90 days)	0.525 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: EPA OPP 82-3 (Subchronic Dermal Toxicity 90 Days)

Aspiration hazard : Not classified

Sofia 2 Campylobacter FIA	
Viscosity, kinematic	Not applicable

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor 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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LC50 - Fish [1]	0.19 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
LC50 - Fish [2]	0.28 mg/l Test organisms (species): Lepomis macrochirus
EC50 - Crustacea [1]	0.007 mg/l (48 h, Acartia tonsa, Salt water, Experimental value, GLP)
NOEC (chronic)	0.1 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	0.098 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '28 d'

1H-imidazole (288-32-4)	
LC50 - Fish [1]	283.6 mg/l (48 h, Leuciscus idus, Static system, Fresh water, Experimental value, Nominal concentration)
EC50 - Crustacea [1]	341.5 mg/l (EU Method C.2, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect)
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, Nominal concentration)

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

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Persistence and degradability	Not readily biodegradable in water.
Biochemical oxygen demand (BOD)	Not applicable.
Chemical oxygen demand (COD)	Not applicable.
ThOD	Not applicable.
BOD (% of ThOD)	Not applicable.

1H-imidazole (288-32-4)	
Persistence and degradability	Readily biodegradable in the soil. Readily biodegradable in water.

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
Persistence and degradability	Not readily biodegradable in water.
Chemical oxygen demand (COD)	2.19 mg/g
ThOD	2.16 g O ₂ /g substance

12.3. Bioaccumulative potential

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
BCF - Fish [1]	41 – 54 (OECD 305: Bioconcentration: Flow-Through Fish Test, 28 day(s), Lepomis macrochirus, Flow-through system, Fresh water, Experimental value, Fresh weight)
Partition coefficient n-octanol/water (Log Pow)	0.75 (24 °C)
Bioaccumulative potential	Not established.

1H-imidazole (288-32-4)	
Partition coefficient n-octanol/water (Log Pow)	-0.02 (Weight of evidence approach, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 25 °C)
Bioaccumulative potential	Not bioaccumulative.

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
Partition coefficient n-octanol/water (Log Pow)	4.86 (Estimated value, KOWWIN)
Bioaccumulative potential	Potential for bioaccumulation ($4 \leq \text{Log Kow} \leq 5$).

12.4. Mobility in soil

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Surface tension	No data available in the literature
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.81 – 1 (log Koc, Calculated value)
Ecology - soil	Highly mobile in soil.

1H-imidazole (288-32-4)	
Surface tension	No data available in the literature
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.36 – 2.32 (log Koc, Calculated value)
Ecology - soil	Low potential for adsorption in soil.

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
Ecology - soil	No (test) data on mobility of the substance available.

12.5. Results of PBT and vPvB assessment

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
1H-imidazole (288-32-4)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, 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
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IMDG

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

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

Transport hazard class(es) (ADN)	: Not regulated
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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 substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains substance(s) listed on the REACH Candidate List in concentrations \geq 0.1 % or SCL: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (CAS 9002-93-1)

Contains substance(s) listed on REACH Annex XIV: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (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 3, Highly 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.	
Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BLV	Biological limit value
CAS No	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration

REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

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

Full text of H- and EUH-statements:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
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 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
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.
H310	Fatal 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.
H330	Fatal if inhaled.
H360D	May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
Repr. 1B	Reproductive toxicity, 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 sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A
STOT RE 1	Specific target organ toxicity – Repeated exposure, 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.