

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 in vitro 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@quidelortho.com - 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

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

No labeling applicable

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Campy FIA, Positive and Negative Controls	1H-imidazole	288-32-4	<0.5	Acute Tox. 4 (Oral), H302 Skin Corr. 1C, H314 Eye Dam. 1, H318 Repr. 1B, H360

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.
 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)

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.

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.

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 : 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. Wear protective gloves. Wash your hands

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 (Specimen Diluent, Positive and Negative Controls)
Appearance	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: Odorless
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	: 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
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

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

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

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.

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)

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

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.

12.4. Mobility 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.

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.
- 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

Transport by sea

Not regulated

Air transport

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

1H-imidazole	CAS No 288-32-4	0.15%
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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)

1H-imidazole (288-32-4)

Listed on the Canadian DSL (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

Indication of changes:

Composition/Information on ingredients.

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.