

SECTION 1: Identification

1.1. Identification

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

1.2. Recommended use and restrictions on use

Recommended use : For medical diagnostic use.
 Restrictions on use : Restricted to professional users, Professional Use of Medical Devices

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

Components	GHS US classification
C. difficile FIA, Specimen Diluent	Eye Irrit. 2A, H319

2.2. GHS Label elements, including precautionary statements

GHS US labelling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
C. difficile FIA, Specimen Diluent		Warning	H319 - Causes serious eye irritation.	P264 - Wash hands thoroughly after handling P280 - Wear gloves and safety glasses when handling this component. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 - Specific treatment: Seek medical attention if ill effect develops. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.

SECTION 3: Composition/information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
C. difficile FIA, Specimen Diluent	ProClin 300	55965-84-9	0.05	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
C difficile FIA, Positive and Negative Control	ProClin 300	55965-84-9	0.05	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330 Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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 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 or a doctor if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- 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.

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. 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

- 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. Avoid contact with skin and eyes. 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

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.
- Colour : No data available
- Odour : No data available
- Odour threshold : No data available

pH	: Neutral - Specimen Diluent
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butylacetate=1)	: 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
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
No data available Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosive limits	: Not applicable
Explosive properties	: No data available
Oxidising 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	: Causes serious eye irritation.
Respiratory or skin sensitisation	: 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 eye contact : Eye irritation.

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.

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

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 C. difficile 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, except for:

C. difficile FIA, Specimen Diluent	CAS No	100%
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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

C. difficile FIA, Specimen Diluent

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

Indication of changes:
Regulatory Review. Updated SDS template.

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.