

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Solana C. difficile Assay
Product code : M307
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 : Professional Use of Medical Devices

1.3. Details of the supplier of the safety data sheet

Manufacturer

Quidel Corporation
2005 East State Street, Suite 100
45701 Athens - USA
T 1.800.874.1517 - F 1.740.592.9820
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
Lysis Buffer, C.difficile	Eye Irrit. 2, H319
Dilution Buffer, C. difficile	Not classified (CLP)


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

Adverse physicochemical, human health and environmental effects

Causes serious eye irritation.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
Lysis Buffer, C.difficile		Warning	H319 - Causes serious eye irritation.	P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, safety glasses and lab coat. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 - If eye irritation persists: Get medical advice/attention.	No additional information available
Dilution Buffer, C. difficile	-	-	-	-	EUH210 - Safety data sheet available on request.

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
Dilution Buffer, C. difficile	glycerol	56-81-5 -	10-15	Acute Tox. 4 (Inhalation:dust,mist), H332
	sodium azide	26628-22-8 -	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Chronic 1, H410
Lysis Buffer, C.difficile	polyethyleneglycolmono(para-(1,1,3,3-tetramethylbutyl)phenyl)ether	9002-93-1 -	1 – 5	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
	sodium azide	26628-22-8 -	< 0.1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 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. 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, both acute and delayed

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. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

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.

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 : Take up liquid spill into absorbent material.
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. 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

sodium azide (26628-22-8)		
EU	IOEL TWA	0.1 mg/m ³
EU	IOEL STEL	0.3 mg/m ³
Belgium	OEL TWA	0.1 mg/m ³ (La mention "M" indique que lors d'une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d'intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l'exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d'échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d'échantillonnage.)
Belgium	OEL STEL	0.3 mg/m ³ (La mention "M" indique que lors d'une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d'intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l'exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d'échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d'échantillonnage.)
France	VME (OEL TWA)	0.1 mg/m ³
France	VLE (OEL C/STEL)	0.3 mg/m ³
Netherlands	TGG-8u (OEL TWA)	0.1 mg/m ³
Netherlands	TGG-8u (OEL TWA) [ppm]	0.037 ppm
Netherlands	TGG-15min (OEL STEL)	0.3 mg/m ³
Netherlands	TGG-15min (OEL STEL) [ppm]	0.084 ppm
United Kingdom	WEL TWA (OEL TWA) [1]	0.1 mg/m ³
United Kingdom	WEL STEL (OEL STEL)	0.3 mg/m ³
USA - ACGIH	ACGIH OEL C	0.29 mg/m ³
USA - ACGIH	ACGIH OEL C [ppm]	0.11 ppm

sodium azide (26628-22-8)		
EU	IOEL TWA	0.1 mg/m ³
EU	IOEL STEL	0.3 mg/m ³
Belgium	OEL TWA	0.1 mg/m ³ (La mention "M" indique que lors d'une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d'intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l'exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d'échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d'échantillonnage.)
Belgium	OEL STEL	0.3 mg/m ³ (La mention "M" indique que lors d'une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d'intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l'exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d'échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d'échantillonnage.)
France	VME (OEL TWA)	0.1 mg/m ³
France	VLE (OEL C/STEL)	0.3 mg/m ³
Netherlands	TGG-8u (OEL TWA)	0.1 mg/m ³
Netherlands	TGG-8u (OEL TWA) [ppm]	0.037 ppm
Netherlands	TGG-15min (OEL STEL)	0.3 mg/m ³
Netherlands	TGG-15min (OEL STEL) [ppm]	0.084 ppm
United Kingdom	WEL TWA (OEL TWA) [1]	0.1 mg/m ³
United Kingdom	WEL STEL (OEL STEL)	0.3 mg/m ³
USA - ACGIH	ACGIH OEL C	0.29 mg/m ³
USA - ACGIH	ACGIH OEL C [ppm]	0.11 ppm

glycerol (56-81-5)		
Belgium	OEL TWA	10 mg/m ³
France	VME (OEL TWA)	10 mg/m ³
United Kingdom	WEL TWA (OEL TWA) [1]	10 mg/m ³
USA - OSHA	Local name	Glycerin (mist)
USA - OSHA	OSHA PEL TWA [1]	15 mg/m ³ (Total dust) 5 mg/m ³ (Respirable fraction)

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

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
Appearance	: Molecular Test Kit.
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: Lysis and Dilution Buffers are neutral
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability	: Not applicable
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	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 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

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg bodyweight (Rat, Experimental value, Oral)
LD50 dermal rabbit	19 – 48 mg/kg bodyweight (Rabbit, Inconclusive, insufficient data, Dermal)
LC50 Inhalation - Rat	0.054 – 0.52 mg/l air Animal: rat, Guideline: EPA OPPTS 870.1300 (Acute inhalation toxicity)

sodium azide (26628-22-8)	
LD50 oral rat	27 mg/kg bodyweight (Rat, Experimental value, Oral)
LD50 dermal rabbit	19 – 48 mg/kg bodyweight (Rabbit, Inconclusive, insufficient data, Dermal)
LC50 Inhalation - Rat	0.054 – 0.52 mg/l air Animal: rat, Guideline: EPA OPPTS 870.1300 (Acute inhalation toxicity)

glycerol (56-81-5)	
LD50 oral rat	27200 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value, Oral, 10 day(s))
LD50 dermal	56750 mg/kg (4 day(s), Guinea pig, Male / female, Experimental value, Dermal, 14 day(s))
LC50 Inhalation - Rat	> 5.85 mg/l (Equivalent or similar to OECD 412, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol), 14 day(s))
LC50 Inhalation - Rat (Vapours)	> 2.75 mg/l Source: ECHA

Skin corrosion/irritation : Not classified
 pH: Lysis and Dilution Buffers are neutral

Serious eye damage/irritation : Causes serious eye irritation.
 pH: Lysis and Dilution Buffers are neutral

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

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

sodium azide (26628-22-8)	
LC50 - Fish [1]	2.75 – 3.28 mg/l (Equivalent or similar to OECD 203, 96 h, Oncorhynchus mykiss, Flow-through system, Fresh water, Experimental value)
EC50 - Other aquatic organisms [1]	5 mg/l Test organisms (species): Gammarus fasciatus
EC50 96h - Algae [1]	0.35 mg/l (Equivalent or similar to OECD 201, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Cell numbers)

sodium azide (26628-22-8)	
LC50 - Fish [1]	2.75 – 3.28 mg/l (Equivalent or similar to OECD 203, 96 h, Oncorhynchus mykiss, Flow-through system, Fresh water, Experimental value)
LC50 - Other aquatic organisms [1]	1 (1 – 10) mg/l (96 h)
EC50 - Crustacea [1]	4.2 mg/l Source: NCIS
EC50 - Other aquatic organisms [1]	5 (5 – 14) mg/l (Protozoa; TOXICITY TEST)
EC50 96h - Algae [1]	0.35 mg/l (Equivalent or similar to OECD 201, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Cell numbers)

glycerol (56-81-5)	
LC50 - Fish [1]	54000 mg/l (96 h, Oncorhynchus mykiss, Static system, Fresh water, Experimental value, Lethal)
EC50 - Crustacea [1]	> 10000 mg/l (24 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect)

12.2. Persistence and degradability

polyethyleneglycolmono(para-(1,1,3,3-tetramethylbutyl)phenyl)ether (9002-93-1)	
Persistence and degradability	Biodegradability in water: no data available.

sodium azide (26628-22-8)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)

sodium azide (26628-22-8)	
Persistence and degradability	Biodegradability: not applicable.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

glycerol (56-81-5)	
Persistence and degradability	Readily biodegradable in water.

12.3. Bioaccumulative potential

polyethyleneglycolmono(para-(1,1,3,3-tetramethylbutyl)phenyl)ether (9002-93-1)	
Bioaccumulative potential	No bioaccumulation data available.
sodium azide (26628-22-8)	
Bioaccumulative potential	Not bioaccumulative.
sodium azide (26628-22-8)	
Partition coefficient n-octanol/water (Log Pow)	0.16 Source: NIOSH
Bioaccumulative potential	not bioaccumulable.
glycerol (56-81-5)	
Partition coefficient n-octanol/water (Log Pow)	-1.75 (Experimental value, Equivalent or similar to OECD 107, 25 °C)
Bioaccumulative potential	Not bioaccumulative.

12.4. Mobility in soil

sodium azide (26628-22-8)	
Surface tension	No data available (test not performed)
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.63 (log Koc, Calculated value)
Ecology - soil	Low potential for adsorption in soil.
sodium azide (26628-22-8)	
Surface tension	No data available (test not performed)
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.63 (log Koc, Calculated value)
Ecology - soil	Low potential for adsorption in soil.
glycerol (56-81-5)	
Surface tension	63 mN/m (20 °C, 1000 g/l)
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Highly mobile in soil.

12.5. Results of PBT and vPvB assessment

Component	
polyethyleneglycolmono(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
sodium azide (26628-22-8)	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
sodium azide (26628-22-8)	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
glycerol (56-81-5)	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.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number

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

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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14.4. Packing group

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

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 United States TSCA (Toxic Substances Control Act) inventory

Germany

Regulatory reference	: WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)
Employment restrictions	: Observe restrictions according Act on the Protection of Working Mothers (MuSchG) Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)
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

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:	
New EU SDS template.	
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. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
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
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H410	Very toxic to aquatic life with long lasting effects.

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.