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

1.1. Product identifier

Product form : Mixture

Product name : Solana Strep Complete Assay

Product code : M305

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
qehs@quidel.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
Solana GAS Dilution Buffer	Not classified (CLP)
Solana GAS+ CG Lysis Buffer	Eye Irrit. 2, H319

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
Solana GAS Dilution Buffer	None	--	None	None	EUH210 Safety data sheet available on request.
Solana GAS+ CG Lysis Buffer		Warning	H319 - Causes serious eye irritation.	P264 - Wash hands thoroughly after handling. P280 - Wear eye protection 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 attention.	No additional information available

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
Solana GAS+ CG Lysis Buffer	Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether	9002-93-1 -	1	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
	Sodium azide	26628-22-8 -	< 0.01	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Solana GAS Dilution Buffer	Glycerol	56-81-5 -	5.5	Acute Tox. 4 (Inhalation:dust,mist), H332
	Sodium azide	26628-22-8 -	< 0.01	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-phrases: 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, both acute and delayed

No additional information available

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.

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. 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	IOELV TWA (mg/m³)	0.1 mg/m³
EU	IOELV STEL (mg/m³)	0.3 mg/m³
Belgium	Limit value (mg/m³)	0.1 mg/m³
Belgium	Short time value (mg/m³)	0.3 mg/m³
France	VME (mg/m³)	0.1 mg/m³
France	VLE (mg/m³)	0.3 mg/m³
Netherlands	Grenswaarde TGG 8H (mg/m³)	0.1 mg/m³
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	0.3 mg/m³
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m³
USA - ACGIH	ACGIH Ceiling (mg/m³)	0.29 mg/m³
USA - ACGIH	ACGIH Ceiling (ppm)	0.11 ppm

Glycerol (56-81-5)		
Belgium	Limit value (mg/m³)	10 mg/m³
France	VME (mg/m³)	10 mg/m³
United Kingdom	WEL TWA (mg/m³)	10 mg/m³
USA - OSHA	Local name	Glycerin (mist)
USA - OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ (Total dust) 5 mg/m³ (Respirable fraction)

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

Lab coat

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	: Liquid
Appearance	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
pH solution	: Buffers are neutral.
Relative evaporation rate (butyl acetate=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 (solid, gas)	: Not applicable
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	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion 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 body weight (Rat, Inconclusive, insufficient data)
LD50 dermal rabbit	19 – 48 mg/kg body weight (Rabbit, Inconclusive, insufficient data)

Glycerol (56-81-5)	
LD50 oral rat	27200 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value)
LD50 dermal	56750 mg/kg (4 day(s), Guinea pig, Male/female, Experimental value)
LC50 inhalation rat (mg/l)	> 2.75 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male, Converted value)

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 : Causes serious eye irritation.
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

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

Sodium azide (26628-22-8)	
LC50 fish 1	0.8 mg/l (Equivalent or similar to OECD 203, 96 h, Gasterosteus aculeatus, Fresh water, Experimental value)
LC50 other aquatic organisms 1	1 (1 – 10) mg/l (96 h)
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)

Glycerol (56-81-5)	
LC50 fish 1	54000 mg/l (96 h, Salmo gairdneri, Static system, Fresh water, Experimental value)
EC50 Daphnia 1	> 10000 mg/l (24 h, Daphnia magna, Static system, Fresh water, Experimental value)

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 Daphnia 1	26 mg/l (48 h, Daphnia magna, Literature study)

12.2. Persistence and degradability

Sodium azide (26628-22-8)	
Persistence and degradability	Biodegradability in soil: not applicable. 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.
Biochemical oxygen demand (BOD)	0.87 g O_2/g substance
Chemical oxygen demand (COD)	1.16 g O_2/g substance
ThOD	1.217 g O_2/g substance
BOD (% of ThOD)	0.71

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

Sodium azide (26628-22-8)	
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.

Polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
Partition coefficient n-octanol/water (Log Pow)	4.86 (Estimated value)
Bioaccumulative potential	Potential for bioaccumulation (4 ≥ Log Kow ≤ 5).

12.4. Mobility in soil

Sodium azide (26628-22-8)	
Ecology - soil	Highly mobile in soil.

Glycerol (56-81-5)	
Surface tension	0.0634 N/m (20 °C, 1000 g/l)
Ecology - soil	No (test)data on mobility of the substance available.

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	
Gycerol (56-81-5)	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
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

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 / IATA / IMDG

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

IMDG

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

IATA

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

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 REACH substances with Annex XVII restrictions

Contains substance on the candidate list in concentration ≥ 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

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
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige 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

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-phrases:	
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 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
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.
H400	Very toxic to aquatic life.
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.