

SECTION 1: Identification of the substance/mixture and of the company/undertaking
1.1. Product identifier

Product form : Mixture
 Product name : Solana GAS Assay
 Product code : M301

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

Diagnostic Hybrids, Inc. a subsidiary of 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 |
|----------------------------|----------------------|
| Solana GAS Dilution Buffer | 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 |
|----------------------------|------------|-------------|-------------------|--------------------------|--|
| Solana GAS Dilution Buffer | - | - | - | - | 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 |
|-------------------------|---------------|----------------|-----|---|
| Solana GAS Lysis Buffer | Triton X-100 | 9002-93-1 - | 1.0 | Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 |

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 |

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 | : Clear, colorless liquid. |
| Colour | : Colourless. |
| Odour | : mild. |
| Odour threshold | : No data available |
| pH | : 7 – 7.6 |
| 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 | : Soluble. |
| 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) |

Skin corrosion/irritation : Not classified
pH: 7 – 7.6
Serious eye damage/irritation : Causes serious eye irritation.
pH: 7 – 7.6
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) |
| 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) |

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. |
| Biochemical oxygen demand (BOD) | Not applicable |
| Chemical oxygen demand (COD) | Not applicable |
| ThOD | Not applicable |
| BOD (% of ThOD) | Not applicable |

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)

| | |
|---|--------------------|
| Partition coefficient n-octanol/water (Log Pow) | 0.16 Source: NIOSH |
|---|--------------------|

| | |
|---------------------------|---------------------|
| Bioaccumulative potential | not bioaccumulable. |
|---------------------------|---------------------|

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. |
|----------------|---------------------------------------|

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 |
|---------------------------|---|

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 / ADN / RID

14.1. UN number

| | |
|---------------|-----------------|
| UN-No. (ADR) | : Not regulated |
| UN-No. (IMDG) | : Not regulated |
| UN-No. (IATA) | : Not regulated |
| UN-No. (ADN) | : Not regulated |
| UN-No. (RID) | : 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 |
| Proper Shipping Name (RID) | : 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

ADN

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

RID

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

14.4. Packing group

Packing group (ADR) : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : Not regulated

Packing group (ADN) : Not regulated

Packing group (RID) : 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

Rail 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

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 |

Denmark

| | |
|-----------------------------|--|
| Danish National Regulations | : 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:

New EU SDS template. Regulatory Review.

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 (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. |
| 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.