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

1.1. Product identifier

Product form : Mixture
Product name : Sofia Strep A FIA
Product code : 20231, 20253
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

Quidel Corporation
10165 McKellar Court
92121 San Diego, CA - U.S.A
T 1.800.874.1517 - F 1.858.453.4338
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
Extraction Solution (ERDs)	Acute Tox. 4 (Oral), H302 Eye Irrit. 2, H319 Aquatic Acute 1, H400

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

Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Causes serious eye irritation. Very toxic to aquatic life.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements	Extra phrases
Extraction Solution (ERDs)		Warning	H302 - Harmful if swallowed. H319 - Causes serious eye irritation. H400 - Very toxic to aquatic life.	P270 - Do not eat, drink or smoke when using this product. P273 - Avoid release to the environment. P280 - Wear protective gloves, safety glasses, and lab coat.. P301+P312 - IF SWALLOWED: Call a doctor if you feel unwell. P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water . 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. P370+P378 - In case of fire: Use media other than water to extinguish.	No additional information available

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 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
Extraction Solution (ERDs)	sodium nitrite	7632-00-0 -	27.6	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400
	acetic acid	64-19-7 -	1.2	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318

Specific concentration limits:

Name	Product identifier	Specific concentration limits
acetic acid	(CAS No) 64-19-7 (EC-No.) 200-580-7 (EC Index-No.) 607-002-00-6	(10 ≤C < 25) Skin Irrit. 2, H315 (10 ≤C < 25) Eye Irrit. 2, H319 (25 ≤C < 90) Skin Corr. 1B, H314 (90 ≤C < 100) Skin Corr. 1A, H314

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 general : Call a poison center or a doctor if you feel unwell.

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 : Rinse mouth. 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

For containment : Collect spillage.

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

acetic acid (64-19-7)		
EU	IOEL TWA	25 mg/m³
EU	IOEL TWA [ppm]	10 ppm
EU	IOEL STEL	50 mg/m³
EU	IOEL STEL [ppm]	20 ppm
Belgium	OEL TWA	25 mg/m³
Belgium	OEL TWA [ppm]	10 ppm
Belgium	OEL STEL	38 mg/m³
Belgium	OEL STEL [ppm]	15 ppm
France	VME (OEL TWA)	25 mg/m³
France	VME (OEL TWA) [ppm]	10 ppm
France	VLE (OEL C/STEL)	50 mg/m³
France	VLE (OEL C/STEL) [ppm]	20 ppm
Netherlands	TGG-8u (OEL TWA)	25 mg/m³
Netherlands	TGG-8u (OEL TWA) [ppm]	10 ppm
Netherlands	TGG-15min (OEL STEL)	50 mg/m³
Netherlands	TGG-15min (OEL STEL) [ppm]	20 ppm
United Kingdom	WEL TWA (OEL TWA) [1]	25 mg/m³
United Kingdom	WEL TWA (OEL TWA) [2]	10 ppm
United Kingdom	WEL STEL (OEL STEL)	50 mg/m³
United Kingdom	WEL STEL (OEL STEL) [ppm]	20 ppm
USA - ACGIH	ACGIH OEL TWA [ppm]	10 ppm

acetic acid (64-19-7)		
USA - ACGIH	ACGIH OEL STEL [ppm]	15 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	: Liquid
Colour	: Clear
Odour	: Acidic
Odour threshold	: No data available
pH	: 2.4
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) : Harmful if swallowed.
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

ATE CLP (oral)	652.174 mg/kg bodyweight

acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg bodyweight (Rat, Male / female, Experimental value, Oral, 6 day(s))
LC50 Inhalation - Rat	11.4 mg/l (Equivalent or similar to OECD 403, 4 h, Rat, Female, Experimental value, Inhalation (vapours), 14 day(s))

sodium nitrite (7632-00-0)	
LD50 oral rat	180 mg/kg (Rat; Other; Experimental value)
LC50 Inhalation - Rat	5.5 mg/l/4h (Rat; Literature study)

Skin corrosion/irritation : Not classified
pH: 2.4
Serious eye damage/irritation : Causes serious eye irritation.
pH: 2.4
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 : Very toxic to aquatic life.

Hazardous to the aquatic environment, short–term (acute) : Very toxic to aquatic life.

Hazardous to the aquatic environment, long–term (chronic) : Not classified

acetic acid (64-19-7)	
LC50 - Fish [1]	> 1000 mg/l (Equivalent or similar to OECD 203, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value, GLP)
EC50 - Crustacea [1]	> 1000 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)
ErC50 algae	> 1000 mg/l (ISO 10253, 72 h, Skeletonema costatum, Static system, Salt water, Experimental value, Nominal concentration)

12.2. Persistence and degradability

acetic acid (64-19-7)	
Persistence and degradability	Readily biodegradable in the soil. Readily biodegradable in water.
Biochemical oxygen demand (BOD)	0.6 – 0.74 g O_2/g substance
Chemical oxygen demand (COD)	1.03 g O_2/g substance
ThOD	1.07 g O_2/g substance

sodium nitrite (7632-00-0)	
Persistence and degradability	Biodegradable in water. Autooxidation in water. No (test)data on mobility of the substance available.

12.3. Bioaccumulative potential

acetic acid (64-19-7)	
BCF - Fish [1]	3.16 (Pisces, Fresh water, QSAR)
Partition coefficient n-octanol/water (Log Pow)	-0.17 (Experimental value, 25 °C)
Bioaccumulative potential	Not bioaccumulative.

sodium nitrite (7632-00-0)	
Partition coefficient n-octanol/water (Log Pow)	-3.7 (Experimental value; OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method; 25 °C)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

12.4. Mobility in soil

acetic acid (64-19-7)	
Surface tension	26 mN/m (30 °C)
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.062 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Highly mobile in soil. May be harmful to plant growth, blooming and fruit formation.

12.5. Results of PBT and vPvB assessment

Component	
acetic acid (64-19-7)	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 applicable
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 applicable
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 applicable

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 applicable
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	: Yes
Marine pollutant	: Yes
Other information	: No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

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 no substance(s) listed on the REACH Candidate List
Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

15.1.2. National regulations

Germany

Regulatory reference	: WGK 2, Significantly 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:
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. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
H226	Flammable liquid and vapour.
H272	May intensify fire; oxidiser.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
Ox. Sol. 3	Oxidising Solids, Category 3
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2

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.