

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

Product form : Mixture
 Product name : Sofia S. pneumoniae FIA
 Product code : 20293
 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
 10165 McKellar Court
 92121 San Diego - USA
 T 1.800.874.1517 - F 1.858.453.4338
gehs@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
Positive Control, Streptococcus pneumoniae	Skin Sens. 1, H317
Negative Control, Strep pneumo	Skin Sens. 1, H317



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.
 May cause an allergic skin reaction.

2.2. Label elements

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

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Positive Control, Strep pneumo		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear protective gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of mild soap and water. P333+P313 - If skin irritation or rash occurs: Get medical advice. P501 - Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, and/or national regulation.
Negative Control, Strep pneumo		Warning	H317 - May cause an allergic skin reaction.	P280 - Wear protective gloves, safety glasses, and lab coat. P302+P352 - IF ON SKIN: Wash with plenty of mild soap and water. P333+P313 - If skin irritation or rash occurs: Get medical advice. P501 - Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, and/or national regulation.

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
Negative Control, Strep pneumo	Microcide III	- -	0.3	Skin Sens. 1, H317
	Sodium azide	26628-22-8 -	< 0.02	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Positive Control, Strep pneumo	Microcide III	- -	0.3	Skin Sens. 1, H317
	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

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Microcide III	-	(0.1 ≤ C < 100) Skin Sens. 1, H317

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. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
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

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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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.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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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.
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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. Avoid breathing dust/fume/gas/mist/vapors/spray.

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. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapors/spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

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/m ³)	0.1 mg/m ³
EU	IOELV STEL (mg/m ³)	0.3 mg/m ³
Belgium	Limit value (mg/m ³)	0.1 mg/m ³
Belgium	Short time value (mg/m ³)	0.3 mg/m ³
France	VME (mg/m ³)	0.1 mg/m ³
France	VLE (mg/m ³)	0.3 mg/m ³
Netherlands	Grenswaarde TGG 8H (mg/m ³)	0.1 mg/m ³
Netherlands	Grenswaarde TGG 15MIN (mg/m ³)	0.3 mg/m ³
United Kingdom	WEL TWA (mg/m ³)	0.1 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	0.3 mg/m ³
USA - ACGIH	ACGIH Ceiling (mg/m ³)	0.29 mg/m ³
USA - ACGIH	ACGIH Ceiling (ppm)	0.11 ppm

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

Incidental contact with the Positive and Negative Control may be encountered. Approximately, 2.55 mL of solution per Control.

Eye protection:

Safety glasses

Hand protection:

Type	Material	Permeation	Thickness (mm)	Permeation	Standard
Medical Grade Disposable Gloves (powder-free) recommended	Nitrile rubber (NBR)	5 (> 240 minutes)	0.12	--	EN 420

Skin and body protection:

Wear suitable protective clothing, such as a lab coat

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	: Positive and Negative Control = 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)

Skin corrosion/irritation : Not classified
 Serious eye damage/irritation : Not classified
 Respiratory or skin sensitization : May cause an allergic skin reaction.
 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)

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

12.3. Bioaccumulative potential
Sodium azide (26628-22-8)

Bioaccumulative potential	not bioaccumulable.
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12.4. Mobility in soil
Sodium azide (26628-22-8)

Ecology - soil	Highly mobile in soil.
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12.5. Results of PBT and vPvB assessment

No additional information available

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 no REACH candidate substance
 Contains no REACH Annex XIV substances.

15.1.2. National regulations
Germany

Regulatory reference	: WGK 2, significant 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

Denmark

Danish National Regulations	: Young people below the age of 18 years are not allowed to use the product
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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
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Skin Sens. 1	Skin sensitization, Category 1
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H317	May cause an allergic skin reaction.
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.