

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 : 20274, 20276, 20290, 20323
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, CA - U.S.A
T 1.800.874.1517 - F 1.858.453.4338
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
Sofia Strep A+ Reagent Solution	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. 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
Sofia Strep A+ Reagent Solution		Warning	H302 - Harmful if swallowed. H319 - Causes serious eye irritation. H400 - Very toxic to aquatic life.	P280 - Wear protective gloves, safety glasses, and lab coat. P321 - Specific treatment: Seek medical attention if ill effect develops P330 - Rinse mouth. P501 - Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.	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
Sofia Strep A+ Reagent Solution	hydrochloric acid	7647-01-0 -	1.2	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335
	sodium nitrite	7632-00-0 -	27.6	Ox. Sol. 2, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400

Specific concentration limits:

Name	Product identifier	Specific concentration limits
hydrochloric acid	(CAS No) 7647-01-0 (EC-No.) 231-595-7 (EC Index-No.) 017-002-01-X	(10 ≤ C < 25) Skin Irrit. 2, H315 (10 ≤ C < 25) Eye Irrit. 2, H319 (10 ≤ C ≤ 100) STOT SE 3, H335 (25 ≤ C ≤ 100) Skin Corr. 1B, 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 eyes with water as a precaution.
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

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.

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

For containment : Collect spillage.
 Methods for cleaning up : Mechanically recover the product.
 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

hydrochloric acid (7647-01-0)		
USA - OSHA	Local name	Hydrogen chloride
USA - OSHA	OSHA PEL C	7 mg/m ³
USA - OSHA	OSHA PEL C [ppm]	5 ppm

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

Lab coat

Hand protection:

Wear protective gloves. Wash your hands

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 (Sofia Strep A+ Reagent Solution)
Appearance	: EIA Kit.
Colour	: Not applicable.
Odour	: Not applicable.
Odour threshold	: No data available
pH	: Sodium Nitrite solution pH 8.6; Hydrochloric Acid pH <2 (glass ampule within Reagent Solution bottle)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Flammability	: Non flammable.
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	: Not applicable
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: Not applicable

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
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sodium nitrite (7632-00-0)	
LD50 oral rat	180 mg/kg (Rat, Male, Experimental value, Oral)

Skin corrosion/irritation	: Not classified pH: Sodium Nitrite solution pH 8.6; Hydrochloric Acid pH <2 (glass ampule within Reagent Solution bottle)
Serious eye damage/irritation	: Not classified pH: Sodium Nitrite solution pH 8.6; Hydrochloric Acid pH <2 (glass ampule within Reagent Solution bottle)
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

hydrochloric acid (7647-01-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

sodium nitrite (7632-00-0)	
NOAEL (subchronic, oral, animal/male, 90 days)	220 mg/kg bodyweight Animal: mouse, Animal sex: male
NOAEL (subchronic, oral, animal/female, 90 days)	165 mg/kg bodyweight Animal: mouse, Animal sex: female

Aspiration hazard	: Not classified
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Sofia Strep A+ FIA	
Viscosity, kinematic	Not applicable

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

sodium nitrite (7632-00-0)	
LC50 - Fish [1]	0.54 mg/l (96 h, Oncorhynchus mykiss, Flow-through system, Fresh water, Experimental value, Lethal)
EC50 - Crustacea [1]	15.4 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect)
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)

12.2. Persistence and degradability

sodium nitrite (7632-00-0)	
Persistence and degradability	Biodegradable in water.
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

hydrochloric acid (7647-01-0)	
Persistence and degradability	Biodegradability: not applicable.

12.3. Bioaccumulative potential

sodium nitrite (7632-00-0)	
BCF - Fish [1]	11.3 (Salmo gairdneri, Pure substance)
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	Not bioaccumulative.

hydrochloric acid (7647-01-0)	
Bioaccumulative potential	Does not contain bioaccumulative component(s).

12.4. Mobility in soil

sodium nitrite (7632-00-0)	
Surface tension	No data available in the literature
Ecology - soil	No (test)data on mobility of the substance available.

hydrochloric acid (7647-01-0)	
Ecology - soil	No (test)data on mobility of the component(s) available. May be harmful to plant growth, blooming and fruit formation.

12.5. Results of PBT and vPvB assessment

Component	
sodium nitrite (7632-00-0)	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
hydrochloric acid (7647-01-0)	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 applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable

14.3. Transport hazard class(es)
ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

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

IATA

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

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

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 applicable

Air transport

Not applicable

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 3, Highly 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. 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
H272	May intensify fire; oxidiser.
H290	May be corrosive to metals.
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.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
Met. Corr. 1	Corrosive to metals, Category 1
Ox. Sol. 2	Oxidising Solids, Category 2
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
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

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.