

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Product name : Sofia® Strep A+ FIA
 Product code : 20274, 20276, 20290, 20323

1.2. Recommended use and restrictions on use

Recommended use : For in vitro diagnostic use.
 Restrictions on use : Professional Use of Medical Devices.

1.3. Supplier

Manufacturer

Quidel Corporation
 10165 McKellar Court
 San Diego, CA 92121 - 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: Hazard(s) identification



2.1. Classification of the substance or mixture

GHS US classification

Components	GHS US classification
Sofia Strep A+ Reagent Solution	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Aquatic Acute 1, H400

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Sofia Strep A+ Reagent Solution	 	Warning	H302 - Harmful if swallowed H315 - Causes skin irritation H319 - Causes serious eye irritation H400 - Very toxic to aquatic life	P280 - Wear lab coat, safety glasses, and gloves. P321 - Specific treatment: Seek medical attention if ill effect develops P330 - Rinse mouth. P501 - Dispose of contents/container: Dispose in a safe manner in accordance with local/national regulations

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Sofia Strep A+ Reagent Solution	sodium nitrite	7632-00-0	27.6	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400
	hydrochloric acid	7647-01-0	1.2	Met. Corr. 1, H290 Skin Corr. 1, H314 Eye Dam. 1, H318 STOT SE 3, H335

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures
4.1. Description of first aid measures

- First-aid measures general : Call a poison center/doctor/physician 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. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
- 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/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects after skin contact : Irritation.
- Symptoms/effects after eye contact : Eye irritation.
- Immediate medical attention and special treatment, if necessary : Treat symptomatically.

SECTION 5: Fire-fighting measures
5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Specific hazards arising from the chemical

No additional information available

5.3. Special protective equipment and precautions for fire-fighters

- 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

- 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.
- 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 : Wash contaminated clothing before reuse. 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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

hydrochloric acid (7647-01-0)		
OSHA	OSHA PEL C	7 mg/m ³
OSHA	OSHA PEL C [ppm]	5 ppm
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

8.2. Appropriate engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station.
- Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

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):



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.
- Color : Not applicable
- Odor : Not applicable
- Odor threshold : No data available
- pH : Sodium Nitrite solution pH 8.6; Hydrochloric Acid pH <2 (glass ampule within Reagent Solution bottle)
- Melting point : No data available

Freezing point	:	Not applicable
Boiling point	:	No data available
Flash point	:	Not applicable
Relative evaporation rate (butyl acetate=1)	:	No data available
Flammability	:	Non flammable.
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
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	No data available
No data availableViscosity, kinematic	:	Not applicable
Viscosity, dynamic	:	No data available
Explosion limits	:	Not applicable
Explosive properties	:	No data available
Oxidizing properties	:	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

Acute toxicity (oral)	:	Harmful if swallowed.
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified

Sofia Strep A+ FIA	
ATE US (oral)	652.174 mg/kg body weight
sodium nitrite (7632-00-0)	
LD50 oral rat	180 mg/kg (Rat, Male, Experimental value, Oral)
ATE US (oral)	180 mg/kg body weight

Skin corrosion/irritation	:	Causes skin irritation.
Serious eye damage/irritation	:	Causes serious eye irritation.
Respiratory or skin sensitization	:	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
hydrochloric acid (7647-01-0)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
sodium nitrite (7632-00-0)	
NOAEL (subchronic,oral,animal/male,90 days)	220 mg/kg body weight Animal: mouse, Animal sex: male
NOAEL (subchronic,oral,animal/female,90 days)	165 mg/kg body weight Animal: mouse, Animal sex: female
Aspiration hazard	: Not classified
Viscosity, kinematic	: Not applicable
Symptoms/effects after skin contact	: Irritation.
Symptoms/effects after eye contact	: Eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Very toxic to aquatic life.

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)

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 components available. May be harmful to plant growth, blooming and fruit formation.

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal 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

Department of Transportation (DOT)

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Sofia Strep A+ FIA

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

sodium nitrite	CAS No 7632-00-0	27.6%
hydrochloric acid	CAS No 7647-01-0	1 - 2%
Contains chemical(s) subject to TSCA 12b export notification if product is shipped outside the U.S		
sodium nitrite	CAS No 7632-00-0	27.6%

Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.

sodium nitrite	CAS No 7632-00-0	27.6%
hydrochloric acid ... %	CAS No 7647-01-0	1 - 2%

sodium nitrite (7632-00-0)

EPA TSCA Regulatory Flag	S - S - indicates a substance that is identified in a final Significant New Use Rule.
CERCLA RQ	100 lb

hydrochloric acid (7647-01-0)

Listed on EPA Hazardous Air Pollutant (HAPS)	
CERCLA RQ	5000 lb
RQ (Reportable quantity, section 304 of EPA's List of Lists)	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb

15.2. International regulations

CANADA

sodium nitrite (7632-00-0)

Listed on the Canadian DSL (Domestic Substances List)

hydrochloric acid (7647-01-0)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

sodium nitrite (7632-00-0)Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active
Listed on INSQ (Mexican National Inventory of Chemical Substances)**hydrochloric acid (7647-01-0)**Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active
Listed on INSQ (Mexican National Inventory of Chemical Substances)**15.3. US State regulations**

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Indication of changes:

Updated SDS template.

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.