

SECTION 1: Identification

1.1. Identification

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

1.2. Recommended use and restrictions on use

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

1.3. Supplier

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


2.1. Classification of the substance or mixture

GHS US classification

Components	GHS US classification
Extraction Solution (ERDs)	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Extraction Solution (ERDs)		Warning	H302 - Harmful if swallowed H315 - Causes skin irritation H319 - Causes serious eye irritation	P280 - Wear lab coat, safety glasses, and gloves. P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell. P302+P352 - If on skin: Wash skin thoroughly with mild soap and 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. P321 - Specific treatment: Seek medical attention if ill effect develops P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Extraction Solution (ERDs)	acetic acid	64-19-7	1.2	Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318
	sodium nitrite	7632-00-0	27.6	Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2A, H319

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. Carbon dioxide.
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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.
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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.
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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".
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6.2. Environmental precautions

Environmental precautions	: Avoid release to the environment.
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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.
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.
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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

acetic acid (64-19-7)		
ACGIH	ACGIH OEL TWA [ppm]	10 ppm
ACGIH	ACGIH OEL STEL [ppm]	15 ppm

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:

Protective gloves

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
Appearance : Liquid.
Color : clear
Odor : acidic
Odor threshold : No data available
pH : 2.4
Melting point : Not applicable
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available
Flammability : 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
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
No data availableViscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
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
acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg body weight (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)
ATE US (oral)	180 mg/kg body weight
ATE US (vapors)	5.5 mg/l/4h
ATE US (dust, mist)	5.5 mg/l/4h

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

STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects after skin contact	: Irritation.
Symptoms/effects after eye contact	: Eye irritation.

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.
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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. 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 regulated

Transport by sea

Not regulated

Air transport

Not regulated

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

acetic acid	CAS No 64-19-7	1 – 5%
sodium nitrite	CAS No 7632-00-0	25 – 30%
Contains chemical(s) subject to TSCA 12b export notification if product is shipped outside the U.S		
sodium nitrite	CAS No 7632-00-0	25 – 30%
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	25 – 30%
acetic acid (64-19-7)		
CERCLA RQ	5000 lb	
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	

15.2. International regulations

CANADA

acetic acid (64-19-7)

Listed on the Canadian DSL (Domestic Substances List)

sodium nitrite (7632-00-0)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

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:

Regulatory Review.

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.