

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 medical 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@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 |
|---------------------------------|--|
| 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 | P264 - Wash hands thoroughly after handling 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. 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 P330 - Rinse mouth. P332+P313 - If skin irritation occurs: Get medical attention. P337+P313 - If eye irritation persists: Get medical attention. 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 | <28 | Ox. Sol. 3, H272 Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400 |
| | Hydrochloric acid (%) | | 1.2 | Skin Corr. 1B, H314 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. Carbon dioxide.

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 : 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.

SECTION 8: Exposure controls/personal protection
8.1. Control parameters

| Hydrochloric acid (%) | | |
|-----------------------|--------------------------------|--------------------------|
| OSHA | OSHA PEL (Ceiling) | 7 mg/m ³ |
| OSHA | OSHA PEL (Ceiling) (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

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

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 : Solid
- Appearance : EIA Kit.
- Color : Not applicable
- Odor : Not applicable
- Odor threshold : No data available
- pH : **Reagent Solution:** Sodium Nitrite solution pH 8.6; Hydrochloric Acid pH <2 (glass ampule)
- 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 (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 |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, 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 |
| 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 |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |

| Hydrochloric acid (%) | |
|-------------------------------------|-----------------------------------|
| STOT-single exposure | May cause respiratory irritation. |
| 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 : 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) |
| EC50 - Daphnia [1] | 15.4 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP) |
| Erc50 algae | > 100 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, GLP) |

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 (%) | |
|-------------------------------|-----------------------------------|
| 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 (%) | |
|------------------------------|--|
| Bioaccumulative potential | Does not contain bioaccumulative component(s). |

12.4. Mobility in soil

| Sodium nitrite (7632-00-0) | |
|-----------------------------------|---|
| Ecology - soil | No (test)data on mobility of the substance available. |

| Hydrochloric acid (%) | |
|------------------------------|--|
| 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 regulated

Transport by sea (IMDG)

Not regulated

Air transport (IATA)

Not regulated

SECTION 15: Regulatory information
15.1. US Federal regulations
Sofia Strep A+ FIA

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory except for:

| | | |
|-----------------------|--------|--------|
| Hydrochloric acid (%) | CAS No | 1 – 2% |
|-----------------------|--------|--------|

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% |
|----------------|------------------|----------|

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
Sodium nitrite (7632-00-0)

Listed on the Canadian DSL (Domestic Substances List)

Hydrochloric acid (%)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-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

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.