

Sofia® 2 Flu + SARS Antigen FIA

Safety Data Sheet

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

Issue date: 09/04/2020

Revision date: 03/20/2023

Version: 2.0

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Sofia 2 Flu + SARS Antigen FIA
Product code : 20377, 20380, 20390

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@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
Reagent Tube (Extraction Reagent - Lyophilized)	Eye Dam. 1, H318

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
Reagent Tube (Extraction Reagent - Lyophilized)		Danger	H318 - Causes serious eye damage	P280 - Wear lab coat, safety glasses, and gloves. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a poison center or doctor. P321 - Specific treatment: Seek medical attention if ill effect develops.

SECTION 3: Composition/Information on ingredients

Name	Chemical name	CAS #	%	GHS US classification
Reagent Tube (Extraction Reagent - Lyophilized)	tetrasodium ethylenediaminetetracetate, dihydrate	10378-23-1	1 – 5	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318

Extraction solution is shipped as a lyophilized pellet and has a concentration of 3.067% EDTA, Tetrasodium Salt Dihydrate (10378-23-1). At this concentration H318 (Causes serious eye damage, Category 1) is applicable. When rehydrated following proper instructions, the EDTA concentration is 0.639%. At this concentration, H319 (Causes serious eye irritation, Category 2A) is applicable.

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

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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.
- 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 (acute and delayed)

- 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.

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

- 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. 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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- No additional information available

8.2. Appropriate engineering controls

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

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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	: Solid
Appearance	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: All reagents in this kit are neutral.
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

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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) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)	
LD50 oral rat	1780 – 2000 mg/kg body weight (Rat, Male / female, Experimental value, Oral, 14 day(s))
ATE US (oral)	1780 mg/kg body weight

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

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 : Not applicable

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.

12.2. Persistence and degradability

tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)	
Persistence and degradability	Not readily biodegradable in water.

12.3. Bioaccumulative potential

tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)	
BCF - Fish [1]	1.8 (28 day(s), Lepomis macrochirus, Flow-through system, Fresh water, Experimental value)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

12.4. Mobility in soil

No additional information available

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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

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

tetrasodium ethylenediaminetetracetate, dihydrate	CAS No 10378-23-1	1 – 5%
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This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)

Not listed on the Canadian DSL (Domestic Substances List)/NDL (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

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Indication of changes:

Regulatory Review. Updated SDS template. Composition/Information on ingredients.

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.