

**SECTION 1: Identification****1.1. Identification**

Product form : Mixture  
Product name : Sofia SARS Antigen FIA  
Product code : 20374, 20378, 20383

**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, 92121 - USA  
T 1.800.874.1517 - F 1.858.453.4338  
[gehs@quidel.com](mailto:gehs@quidel.com) - [quidel.com](http://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**

Not classified

**2.2. GHS Label elements, including precautionary statements**

According to the corresponding national regulations there is no labelling obligation for this product.

**2.4. Unknown acute toxicity (GHS US)**

Not applicable

**SECTION 3: Composition/Information on ingredients****3.1. Substances**

Not applicable

**3.2. Mixtures**

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of HazCom 2012

**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)**

No additional information available

**4.3. 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**

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.

**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.

**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.

**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	: In vitro diagnostic medical test kit.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
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 (solid, gas)	: 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
Viscosity, kinematic	: No data available
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****11.1. Information on toxicological effects**

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
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	: No data available

## 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

No additional information available

### 12.3. Bioaccumulative potential

No additional information available

### 12.4. Mobility in soil

No additional information available

### 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

No additional information available

### 15.2. International regulations

#### CANADA

##### Sofia 2 SARS Antigen FIA

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



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## Safety Data Sheet

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

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### 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

Other information : Please review product insert prior to using this product.

*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.*