

Safety Data Sheet

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

Version: 1.0

## **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, 92121 - USA

T 1.800.874.1517 - F 1.858.453.4338 qehs@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** 

Not classified

## 2.2. GHS Label elements, including precautionary statements

**GHS US labelling** 

No labelling applicable

## **SECTION 3: Composition/information on ingredients**

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 or a doctor if you feel unwell.

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

Immediate medical attention and special treatment, : Treat symptomatically.

if necessary

## **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.

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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".

### 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.

### 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.

Colour : No data available
Odour : No data available
Odour threshold : No data available

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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 (butylacetate=1) No data available Flammability (solid, gas) Non flammable. Vapour pressure No data available Relative vapour density at 20 °C No data available Relative density No data available Solubility : No data available : No data available Partition coefficient n-octanol/water (Log Pow) Auto-ignition temperature : Not applicable Decomposition temperature : No data available Viscosity, kinematic : No data available Viscosity, dynamic No data available **Explosive limits** Not applicable **Explosive properties** : No data available Oxidising 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) : Not classified : Not classified Acute toxicity (dermal) Acute toxicity (inhalation) : Not classified Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified Respiratory or skin sensitisation : Not classified : Not classified Germ cell mutagenicity 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

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### **SECTION 12: Ecological information**

### 12.1. Toxicity

Ecology - general

: The product is not considered harmful to aquatic organisms nor 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

No additional information available

**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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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.

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