

### SECTION 1: Identification

#### 1.1. Identification

Product form	: Article
Product name	: Sofia Fluorescent Immunoassay Analyzer, Generation 1 and 2
Product code	: 20221, 20299, 20300

#### 1.2. Recommended use and restrictions on use

Recommended use	: For medical diagnostic use.
Restrictions on use	: Restricted to professional users

#### 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
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### 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.

#### 2.3. Other hazards which do not result in classification

Other hazards not contributing to the classification : Lithium ion battery may be contained or packed with the Sofia 2 instrument. These batteries are sealed units which are not hazardous when used according to the recommendations of the manufacturer. SDS available upon request.

#### 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	: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
First-aid measures after skin contact	: Wash with water and soap.
First-aid measures after eye contact	: Not expected to present a significant eye contact hazard under anticipated conditions of normal use.
First-aid measures after ingestion	: Not applicable.

#### 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 : Dry chemical powder. Foam.

### 5.2. Specific hazards arising from the chemical

Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

### 5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Depending on nature/size of load: consider extinguishment. Evacuate area.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Other information : This product is made up of hard plastic parts that will give off carbon monoxide and other toxic gases when burned. Use self-contained breathing apparatus (SCBA) when fighting fires with this product involved.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Protective equipment : Wear suitable protective clothing.

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment.

### 6.2. Environmental precautions

Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

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 : Wear personal protective equipment. Ensure good ventilation of the work station.

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 as directed in product literature.

## 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

#### Personal protective equipment:

Gloves. Safety glasses.

**Hand protection:**

Gloves

**Eye protection:**

Safety glasses

**Skin and body protection:**

Wear suitable protective clothing

**Respiratory protection:**

Not required for normal conditions of use

**Personal protective equipment symbol(s):**



**Thermal hazard protection:**

No data available.

**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	: Instrument.
Colour	: No data available
Odour	: No data available
Odour 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 (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	: Not applicable
Solubility	: No data available
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
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

None known.

### 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 sensitisation	: 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 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.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT when lithium ion batteries are packed with the Sofia Fluorescent Immunoassay Analyzer.

Transport document description	: UN3481 Lithium ion batteries, contained in equipment including lithium ion polymer batteries, 9
UN-No.(DOT)	: UN3481
Proper Shipping Name (DOT)	: Lithium ion batteries, contained in equipment including lithium ion polymer batteries
Class (DOT)	: 9 - Class 9 - Miscellaneous hazardous material 49 CFR 173.140
Hazard labels (DOT)	: 9 - Class 9 (Miscellaneous dangerous materials)



DOT Packaging Non Bulk (49 CFR 173.xxx)	: 185
DOT Packaging Bulk (49 CFR 173.xxx)	: 185
DOT Special Provisions (49 CFR 172.102)	: A54 - Lithium batteries or lithium batteries contained or packed with equipment that exceed the maximum gross weight allowed by Column (9B) of the 172.101 Table may only be transported on cargo aircraft if approved by the Associate Administrator.
DOT Packaging Exceptions (49 CFR 173.xxx)	: 185
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27)	: 5 kg
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75)	: 35 kg
DOT Vessel Stowage Location	: A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel.
Emergency Response Guide (ERG) Number	: 147
Other information	: No supplementary information available.

#### Transport by sea

Transport document description (IMDG)	: UN 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT, 9
UN-No. (IMDG)	: 3481
Proper Shipping Name (IMDG)	: LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT
Class (IMDG)	: 9 - Miscellaneous dangerous substances and articles

#### Air transport

Transport document description (IATA)	: UN 3481 Lithium ion batteries contained in equipment, 9
UN-No. (IATA)	: 3481
Proper Shipping Name (IATA)	: Lithium ion batteries contained in equipment
Class (IATA)	: 9 - Miscellaneous Dangerous Goods



# Sofia Fluorescent Immunoassay Analyzer, Generation 1 and 2

## Safety Data Sheet

A safety data sheet is not required for this product. This Safety Information Sheet has been created on a voluntary basis.

Date of issue: 05/17/2019

Revision date: 05/17/2019

### 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

A safety data sheet is not required for this product. This Product Safety Information Sheet has been created on a voluntary basis

Revision date : 05/17/2019

Indication of changes:

Section	Changed item	Change	Comments
			New Safety Data Sheet.

SDS US Quidel

*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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