

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Product name : Sofia 2 SARS Antigen FIA  
Product code : 20374  
Product group : Kit

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Industrial/Professional use spec : For in vitro diagnostic use

##### 1.2.2. Uses advised against

Restrictions on use : Professional Use of Medical Devices

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

Quidel Corporation  
10165 McKellar Court  
92121 San Diego, CA - U.S.A  
T 1.800.874.1517 - F 1.858.453.4338  
[gehs@quidelortho.com](mailto:gehs@quidelortho.com) - [quidel.com](http://quidel.com)

#### 1.4. Emergency telephone number

Emergency number : 1.866.519.4752

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

| Components                 | CLP classification |
|----------------------------|--------------------|
| Influenza, Extraction Soln | Eye Dam. 1, H318   |


##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

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

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

| Components                 | Pictograms  | Signal word | Hazard statements                 | Precautionary statements  | Extra phrases                       |
|----------------------------|---|-------------|-----------------------------------|---|-------------------------------------|
| Influenza, Extraction Soln |  | Danger      | H318 - Causes serious eye damage. | P280 - Wear lab coat, safety glasses, and gloves.<br>P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P310 - Immediately call a poison center or doctor.<br>P321 - Specific treatment: Seek medical attention if ill effect develops. | No additional information available |

#### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

| Name                       | Chemical name                                     | CAS No<br>EC-No. | %     | CLP classification                            |
|----------------------------|---|------------------|-------|---|
| Influenza, Extraction Soln | tetrasodium ethylenediaminetetracetate, dihydrate | 10378-23-1<br>-  | 1 – 5 | Acute Tox. 4 (Oral), H302<br>Eye Dam. 1, H318 |

Extraction solution is shipped as a lyophilized pellet and has a concentration of 5% 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 1.25%. At this concentration, H319 (Causes serious eye irritation, Category 2A) is applicable.

Full text of H- and EUH-statements: see section 16

### 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, both acute and delayed

No additional information available

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

#### 5.3. Advice for firefighters

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.

**7.3. Specific end use(s)**

No additional information available

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

No additional information available

**8.2. Exposure controls**

**Appropriate engineering controls:**

Ensure good ventilation of the work station.

**Materials for protective clothing:**

Lab coat

**Hand protection:**

Protective gloves

**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):**



**Environmental exposure controls:**

Avoid release to the environment.

**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 : White  
Odour : No data available  
Odour threshold : No data available  
pH : 9.4 (once rehydrated)  
Relative evaporation rate (butylacetate=1) : No data available  
Melting point : No data available  
Freezing point : Not applicable  
Boiling point : No data available

|   |                     |
|---|---------------------|
| Flash point                                     | : Not applicable    |
| Auto-ignition temperature                       | : Not applicable    |
| Decomposition temperature                       | : No data available |
| Flammability                                    | : 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 |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Viscosity, kinematic                            | : Not applicable    |
| Viscosity, dynamic                              | : No data available |
| Explosive properties                            | : No data available |
| Oxidising properties                            | : No data available |
| Explosive limits                                | : Not applicable    |

### 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 |

#### **tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1)**

|               |  |
|---------------|--|
| LD50 oral rat | 1780 – 2000 mg/kg bodyweight (Rat, Male / female, Experimental value, Oral, 14 day(s)) |
|---------------|--|

|                                   |                  |
|-----------------------------------|------------------|
| 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 |

| Sofia 2 SARS Antigen FIA |                |
|--------------------------|----------------|
| Viscosity, kinematic     | Not applicable |

### 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. |
| Hazardous to the aquatic environment, short-term (acute)  | : Not classified  |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified  |

#### 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

#### 12.5. Results of PBT and vPvB assessment

| Component  |   |
|--|---|
| tetrasodium ethylenediaminetetracetate, dihydrate (10378-23-1) | This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII<br>This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII |

#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment 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

In accordance with ADR / IMDG / IATA / ADN / RID

#### 14.1. UN number

|               |                 |
|---------------|-----------------|
| UN-No. (ADR)  | : Not regulated |
| UN-No. (IMDG) | : Not regulated |
| UN-No. (IATA) | : Not regulated |
| UN-No. (ADN)  | : Not regulated |
| UN-No. (RID)  | : Not regulated |

#### 14.2. UN proper shipping name

|                             |                 |
|-----------------------------|-----------------|
| Proper Shipping Name (ADR)  | : Not regulated |
| Proper Shipping Name (IMDG) | : Not regulated |
| Proper Shipping Name (IATA) | : Not regulated |

Proper Shipping Name (ADN) : Not regulated  
Proper Shipping Name (RID) : Not regulated

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR) : Not regulated

#### IMDG

Transport hazard class(es) (IMDG) : Not regulated

#### IATA

Transport hazard class(es) (IATA) : Not regulated

#### ADN

Transport hazard class(es) (ADN) : Not regulated

#### RID

Transport hazard class(es) (RID) : Not regulated

### 14.4. Packing group

Packing group (ADR) : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : Not regulated

Packing group (ADN) : Not regulated

Packing group (RID) : Not regulated

### 14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Contains no substance(s) listed on the REACH Candidate List

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### 15.1.2. National regulations

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

#### Germany

Regulatory reference : WGK nwg, Non-hazardous to water (Classification according to AwSV, Annex 1)

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG)  
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

### Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

| Abbreviations and acronyms: |   |
|-----------------------------|---|
| ADN                         | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways   |
| ADR                         | European Agreement concerning the International Carriage of Dangerous Goods by Road               |
| ATE                         | Acute Toxicity Estimate   |
| BLV                         | Biological limit value  |
| CAS No                      | Chemical Abstract Service number  |
| CLP                         | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008                       |
| DMEL                        | Derived Minimal Effect level  |
| DNEL                        | Derived-No Effect Level   |
| EC50                        | Median effective concentration  |
| EC-No.                      | European Community number   |
| EN                          | European Standard   |
| IATA                        | International Air Transport Association   |
| IMDG                        | International Maritime Dangerous Goods  |
| LC50                        | Median lethal concentration   |
| LD50                        | Median lethal dose  |
| LOAEL                       | Lowest Observed Adverse Effect Level  |
| NOAEC                       | No-Observed Adverse Effect Concentration  |
| NOAEL                       | No-Observed Adverse Effect Level  |
| NOEC                        | No-Observed Effect Concentration  |
| OEL                         | Occupational Exposure Limit   |
| PBT                         | Persistent Bioaccumulative Toxic  |
| PNEC                        | Predicted No-Effect Concentration   |
| REACH                       | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID                         | Regulations concerning the International Carriage of Dangerous Goods by Rail                      |
| SDS                         | Safety Data Sheet   |
| vPvB                        | Very Persistent and Very Bioaccumulative  |
| WGK                         | Water Hazard Class  |

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

| <b>Full text of H- and EUH-statements:</b> |   |
|--|---|
| Acute Tox. 4 (Oral)                        | Acute toxicity (oral), Category 4   |
| EUH401                                     | To avoid risks to human health and the environment, comply with the instructions for use. |
| Eye Dam. 1                                 | Serious eye damage/eye irritation, Category 1   |
| H302                                       | Harmful if swallowed.   |
| H318                                       | Causes serious eye damage.  |

*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.*