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

1.1. Product identifier
- **Product form**: Mixture
- **Product name**: Sofia SARS Antigen FIA
- **Product code**: 20374, 20378, 20383
- **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 - USA
T 1.800.874.1517 - F 1.858.453.4338
gehs@quidel.com - 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]**
Not classified

**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]**
No labelling applicable

2.3. Other hazards

No additional information available

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 REACH Annex II

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

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

Eye protection:
Safety glasses

Skin and body protection:
Wear suitable protective clothing

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment
SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Appearance</td>
<td>In vitro diagnostic medical test kit.</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Non flammable.</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Pow)</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>Not classified</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>Not classified</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>Not classified</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

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
No additional information available

12.3. Bioaccumulative potential
No additional information available

12.4. Mobility in soil
No additional information available

12.5. Results of PBT and vPvB assessment
No additional information available

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 / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR): Not regulated

UN-No. (IMDG): Not regulated

UN-No. (IATA): Not regulated

UN-No. (ADN): 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 REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances
15.1.2. National regulations

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

Germany

Regulatory reference: Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)

Employment restrictions: Observe restrictions according to Act on the Protection of Working Mothers (MuSchG)

Observe restrictions according to Act on the Protection of Young People in Employment (jarbSchG)


15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways</td>
</tr>
<tr>
<td>ADR</td>
<td>European Agreement concerning the International Carriage of Dangerous Goods by Road</td>
</tr>
<tr>
<td>ATE</td>
<td>Acute Toxicity Estimate</td>
</tr>
<tr>
<td>BLV</td>
<td>Biological limit value</td>
</tr>
<tr>
<td>CAS No</td>
<td>Chemical Abstract Service number</td>
</tr>
<tr>
<td>CLP</td>
<td>Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008</td>
</tr>
<tr>
<td>DMEL</td>
<td>Derived Minimal Effect level</td>
</tr>
<tr>
<td>DNEL</td>
<td>Derived-No Effect Level</td>
</tr>
<tr>
<td>EC50</td>
<td>Median effective concentration</td>
</tr>
<tr>
<td>EC-No.</td>
<td>European Community number</td>
</tr>
<tr>
<td>EN</td>
<td>European Standard</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>IMDG</td>
<td>International Maritime Dangerous Goods</td>
</tr>
<tr>
<td>LC50</td>
<td>Median lethal concentration</td>
</tr>
<tr>
<td>LDS0</td>
<td>Median lethal dose</td>
</tr>
<tr>
<td>LOAEL</td>
<td>Lowest Observed Adverse Effect Level</td>
</tr>
<tr>
<td>NOAEC</td>
<td>No-Observed Adverse Effect Concentration</td>
</tr>
<tr>
<td>NOAEL</td>
<td>No-Observed Adverse Effect Level</td>
</tr>
<tr>
<td>NOEC</td>
<td>No-Observed Effect Concentration</td>
</tr>
<tr>
<td>OEL</td>
<td>Occupational Exposure Limit</td>
</tr>
<tr>
<td>PBT</td>
<td>Persistent Bioaccumulative Toxic</td>
</tr>
<tr>
<td>PNEC</td>
<td>Predicted No-Effect Concentration</td>
</tr>
<tr>
<td>RID</td>
<td>Regulations concerning the International Carriage of Dangerous Goods by Rail</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>vPvB</td>
<td>Very Persistent and Very Bioaccumulative</td>
</tr>
<tr>
<td>WGK</td>
<td>Water Hazard Class</td>
</tr>
</tbody>
</table>

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

Full text of H- and EUH-statements:

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

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.