

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Mixture
Product name	: Sofia hCG FIA
Product code	: 20229, 20266
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@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**Labeling according to Regulation (EC) No. 1272/2008 [CLP]**

No labeling 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	: 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	: Specific treatment: Seek medical attention if ill effect develops.

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 : Wear appropriate PPE as required.

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:

Disposable nitrile gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing, as necessary

Personal protective equipment symbol(s):

Other information:

Do not eat, drink or smoke when using this product. Wash hands after handling the components of this kit.

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Plastic cassette containing test strip.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=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 (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: Not applicable
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
Oxidizing properties	: No data available
Explosion 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
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

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.
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 / IMDG / IATA

14.1. UN number

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

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

14.4. Packing group

Packing group (ADR) : Not regulated

Packing group (IMDG) : Not regulated

Packing group (IATA) : 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

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 candidate substance

15.1.2. National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Germany

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

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

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information
Indication of changes:

New EU SDS template.

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.

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.