

SECTION 1: Identification**1.1. Identification**

Product form	: Mixture
Product name	: Sofia hCG FIA
Product code	: 20229, 20266

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, CA 92121 - 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: 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 labeling**

No labeling 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	: 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 (acute and delayed)

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	: 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.

6.1.2. For emergency responders

Protective equipment : Wear appropriate PPE as required.

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

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
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butyl acetate=1)	: 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
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
No data available Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosion limits	: Not applicable
Explosive properties	: No data available
Oxidizing 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
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
Viscosity, kinematic	: Not applicable

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.

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 (IMDG) Not regulated
Air transport (IATA) 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

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

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.