

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 06/28/2017 Revision date: 12/13/2022 Supersedes: 01/30/2020 Version: 1.2

SECTION 1: Identification

Identification

Product form : Article

Product name : QuickVue hCG Urine Test

Product code : 20109, 20109IN

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

<u>qehs@quidel.com</u> - <u>quidel.com</u>

: 1.866.519.4752 Emergency number

SECTION 2: Hazard(s) identification

Classification of the substance or mixture

Emergency telephone number

GHS US classification

Not classified

1.4.

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

First-aid measures after skin contact

Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Remove victim to fresh air and keep at

rest in a position comfortable for breathing.

: Wash skin with plenty of water. First-aid measures after eye contact : Rinse eyes with water as a precaution.

: Call a poison center/doctor/physician if you feel unwell. First-aid measures after ingestion

4.2. Most important symptoms and effects (acute and delayed)

Immediate medical attention and special treatment, : Treat symptomatically.

if necessary

SECTION 5: Fire-fighting measures

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

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

Personal precautions, protective equipment and emergency procedures 6.1.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

12/13/2022 EN (English US) SDS ID: SD2010902EN00 (12/22) Page 1



Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 06/28/2017 Revision date: 12/13/2022 Supersedes: 01/30/2020 Version: 1.2

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

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:

Protective gloves

Eye protection:

Safety glasses

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):









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.

Color : No data available
Odor : No data available
Odor threshold : No data available

12/13/2022 EN (English US) SDS ID: SD2010902EN00 (12/22) 2/4



Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 06/28/2017 Revision date: 12/13/2022 Supersedes: 01/30/2020 Version: 1.2

: No data available рΗ 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 : Non flammable. Flammability Vapor pressure No data available Relative vapor density at 20°C No data available No data available Relative density : No data available Solubility : No data available Partition coefficient n-octanol/water (Log Pow) 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

: Not classified Acute toxicity (oral) Acute toxicity (dermal) : Not classified : Not classified Acute toxicity (inhalation) : Not classified Skin corrosion/irritation Serious eye damage/irritation : Not classified Respiratory or skin sensitization : Not classified : Not classified Germ cell mutagenicity Carcinogenicity : Not classified : Not classified Reproductive toxicity STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified Viscosity, kinematic : Not applicable

12/13/2022 EN (English US) SDS ID: SD2010902EN00 (12/22) 3/4



Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Issue date: 06/28/2017 Revision date: 12/13/2022 Supersedes: 01/30/2020 Version: 1.2

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.

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

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

Not regulated

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

QuickVue One-Step hCG Urine Test

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

QuickVue One-Step hCG Urine Test CAS No 100%

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372

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

Indication of changes:

Regulatory Review.

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.

12/13/2022 EN (English US) SDS ID: SD2010902EN00 (12/22) 4/4