Quidel Medical Test Device/Test Device Kit

Safety Data Sheet SDS-4620-EN

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations and Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Revision:5

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

1.1. Product identifier

Product form : Article

Product name : Quidel Medical Test Device/Test Device Kit

Product code :

Article	SKU	SKU	SKU	SKU	SKU	SKU
Quidel Triage® BNP Test	98000XR	98000XREU	98000XRCH	98833EU	-	-
Quidel Triage® Cardiac Panel	97000HS	97000HSEU	97021HS	97022HS	97000HSCH	97000HSEUJP
Quidel Triage® Cardio2 Panel	97500EU	97500CH	-	-	-	-
Quidel Triage® Cardio3 Panel	97400EU	-	-	-	-	-
Quidel Triage® D-Dimer Test	98100	98100EU	98100CH	98100EUJP	98831EU	-
Quidel Triage® NT-proBNP Test	98700EU	98834EU	-	-	-	-
Quidel Triage® PLGF Test	98800EU	98800CH	-	-	-	-
Quidel Triage® Profiler SOB™ Panel	97300EU	97300CH	-	-	-	-
Quidel Triage® TOX Drug Screen	94400EU	-	-	-	-	-
Quidel Triage® TOX Drug Screen, 94600	94600	-	-	-	-	-
Quidel Triage® Troponin I Test	98600EU	98600CH	98832EU	-	-	-
Quidel TriageTrue™ High Sensitivity Troponin I Test	97600EU	-	-	-	-	-

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

1.2.1. Relevant identified uses

Main use category : A medical diagnosis test device or test device kit composed of hard plastic parts.

The Quidel Medical Test Device is composed of dried reagents encased within the plastic cassette or strip.

Industrial/Professional use spec : Varies depending on product, please see specific product insert.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Quidel Cardiovascular Inc.
9975 Summers Ridge Road
San Diego, California 92121 - United States
T 1.800.874.1517 - F 1.858.453.4338
qehs@quidel.com - quidel.com

1.4. Emergency telephone number

Emergency number : For Quidel Medical Test Device information and technical assistance, please contact the Quidel Technical Support at 1-800-874-1517

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

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

No labeling applicable

2.3. Other hazards

No additional information avaliable

SECTION 3: Composition/information on ingredients

No additional information available

3.1. Substance

Not applicable

3.2. Mixture

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 general : Under normal conditions of use, no adverse effects to health have been observed.

First-aid measures after skin contact : Contact with reagents within the Quidel Medical Test Device may cause irritation. Wash affected skin with soap and water. Rinse immediately with plenty of water. Under normal use, no contact with internal reagents is expected.

First-aid measures after eye contact : Contact with reagents within the Quidel Medical Test Device may cause irritation. Flush eyes with fresh water for at least 15 minutes. Seek medical attention as needed. Under normal use, no contact with internal reagents is expected.

First-aid measures after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/injuries after inhalation : None under normal use.

Symptoms/injuries after skin contact : None under normal use.

Symptoms/injuries after eye contact : None under normal use.

Symptoms/injuries after ingestion : None under normal use.

Chronic symptoms : None under normal use.

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 chemical, chemical foam, or other standard means to extinguish the fire.

Unsuitable extinguishing media : No unsuitable extinguishing media known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No direct or indirect fire hazard identified.

Explosion hazard : No direct explosion hazard.

Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

5.3. Advice for firefighters

Precautionary measures fire : Evacuate area. Stop leak if safe to do so.

Firefighting instructions : No specific fire-fighting instructions required

Protection during firefighting : Do not attempt to take action without suitable protective equipment

Other information : This product is made up of hard plastic parts that will give off carbon monoxide and other toxic gases when burned. Use self contained breathing apparatus (SCBA) when fighting fires with this product involved.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Absorb spillage to prevent material-damage

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment

Emergency procedures : Evacuate unnecessary personnel.

Measures in case of dust release : None known.

6.1.2. For emergency responders

Protective equipment : Dried reagents are encased within the plastic Quidel Medical Test Device.

Emergency procedures : A used Quidel Medical Test Device should be discarded in accordance with the facility's solid waste procedures and biological safety program disposal procedures.

6.2. Environmental precautions

Unused Test Devices are not hazardous.

6.3. Methods and material for containment and cleaning up

For containment	:	A used Quidel Medical Test Device should be discarded in accordance with the facility's solid waste procedures and biological safety program disposal procedures.
Methods for cleaning up	:	A used Quidel Medical Test Device should be discarded in accordance with the facility's solid waste procedures and biological safety program disposal procedures.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	:	Observe normal hygiene standards. Do not get in eyes, on skin, or on clothing. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Additional hazards when processed	:	Not expected to present a significant hazard under anticipated conditions of normal use.
Hygiene measures	:	After application of whole blood or derivative sample to Quidel Medical Test Device, handle in accordance with your facilities' biological safety program. Treat blood and blood products with universal precaution.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	:	Comply with applicable regulations. Proper handling and disposal methods should be established by the laboratory in accordance with local, state, federal and national regulations.
Storage conditions	:	See product insert sheet for special temperature requirements and handling instructions for the Test Device before application of human source sample.
Incompatible products	:	None known.
Incompatible materials	:	Away from heat sources.
Heat-ignition	:	Away from heat sources.
Information on mixed storage	:	None known.
Storage area	:	See product insert sheet for storage conditions.
Special rules on packaging	:	Keep only in original package.

7.3. Specific end use(s)

For in vitro diagnostic use by healthcare professionals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Use standard Good Laboratory Practices when handling a Quidel Medical Test Device.

8.2. Exposure controls

Appropriate engineering controls	:	Not applicable
Personal protective equipment	:	Use standard Good Laboratory Practices when handling or using a Quidel Medical Test Device.

Thermal hazard protection	:	Not applicable.
Environmental exposure controls	:	Avoid release to the environment
Consumer exposure controls	:	Not applicable.
Other information	:	Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	The Quidel Medical Test Device consists of dried reagents encased within the plastic Test Device. Refer to package insert for further description.
Colour	:	No data available
Odour	:	No data available
Odour threshold	:	No data available
pH	:	Not established
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available

Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	No data available
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The Quidel Medical Test Device is stable under conditions of use until the expiration date indicated on the corresponding label or per product insert sheet. No hazardous decomposition products expected.

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

High temperatures may render the Quidel Medical Test Device unusable due to deformation of the hard plastic parts and degradation of the internal reagents, although no extra hazards are expected.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products are not expected.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	:	Not classified
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
Specific target organ toxicity (single exposure)	:	Not classified
Specific target organ toxicity (repeated exposure)	:	Not classified
Aspiration hazard	:	Not classified
Potential Adverse human health effects and symptoms	:	No data available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	No known effects

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 the Quidel Medical Test Device in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	:	Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	:	Used Quidel Medical Test Device / Test Device Kits should be decontaminated and disposed of using an autoclave or by incineration as "other waste" - containing biological material. Biological waste material must be disposed of in accordance with your facility's biological safety program that is consistent with National, federal, state, and local regulations. To ensure compliance with anti-pollution and other laws of the country concerned, we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Additional information	:	Unused Quidel Medical Test Device / Test Device Kits should be disposed of in accordance with your facility's solid waste disposal policies.
Ecology - waste materials	:	Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport.

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Other information : No supplementary information available

14.6. Special precautions for user

14.6.1. Overland transport

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

No additional information available14.6.2. Transport by sea

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

No additional information available

14.6.3. Air transport

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

No additional information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 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

No additional information available

15.2. Chemical safety assessment

Not listed under California Proposition 65

SECTION 16: Other information

Other information : Store and handle according to packaged instructions.

Indication of changes:
Revision - See : *. Not applicable

SDS EU (REACH Annex II) Quidel 7/2020

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