

SAFETY DATA SHEET

(According to regulation (EC) 1907/2006.)

Product Name: **Rapi-D™** Quantitative Vitamin D Test,

botissCARE **Rapi-D™** Quantitative Vitamin D Test

BIOSYNEX **Rapi-D™** Quantitative Vitamin D Test

VHC Vitamin D test

Catalogue # 1155Q-10, 1155Q250, 1156Q-25, 1157Q-25, 1000J-25

Date SDS established: September 26, 2024

Revision number: 02

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1 IDENTIFICATION OF THE SUBSTANCE/ MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: **Rapi-D™** Quantitative Vitamin D Test
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Components: Test Device, Sample Buffer, UniSampler, RFID Card,
Package Insert

1.2 Relevant identified uses of the substance or mixture and uses advised against:
In vitro diagnostic use. For professional use only.

1.3 Details of the supplier of the safety data sheet:

Affimedix, Inc.
3556 Investment Blvd.
Hayward, CA 94545, USA
Tel: +1-510-398-8111
Fax: +1-510-398-8132
E-mail: info@affimedix.com

1.4 Emergency telephone number

Call your local emergency center.

2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Not a hazardous substance or mixture according to EU regulation 1272/2008 (CLP).

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

Classification according to OSHA Hazard Communication Standard 29 CFR 1910.1200: As an article, the device is exempt from OSHA's Hazard Communication Standard 29 CFR 1910.1200.

2.2 Label elements

Not a hazardous substance or mixture.

2.3 Other hazards

None

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3 COMPOSITION/INFORMATION ON INGREDIENTS

No dangerous ingredients present.

4 FIRST AID MEASURES

4.1 Description of first aid measures

In case of skin contact, wash off with soap and plenty of water.

In case of eye contact, flush eyes with water as a precaution.

If swallowed, never give anything by mouth to an unconscious person, and rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Unsuitable extinguishing media: unknown

5.2 Special hazards arising from the substance or mixture:

Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides

5.3 Advice for firefighters:

Wear self-contained breathing apparatus for firefighting if necessary.

6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Avoid dust formation. Avoid breathing vapours, mist or gas. For personal protection see section 8.

6.2 Environmental precautions:

Do not let product enter drains.

6.3 Methods and material for containment and cleaning up:

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

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7 HANDLING AND STORAGE

- 7.1 Precautions for safe handling:
Keep out of reach of children.
- 7.2 Conditions for safe storage, including any incompatibilities:
Store in the original container at 4 - 30°C.
- 7.3 Specific end use(s):
No other specific uses are stipulated

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters
Contains no substances with occupational exposure limit values.

- 8.2 Exposure Controls
Appropriate engineering controls
General industrial hygiene practice.

Personal protective Equipment:

General protective and hygienic measures:

Specimens should be handled as potentially infectious materials. Refer to EU directive 2000/54/EC or US Regulation 29 CFR 1910.1030 for information on handling biohazardous materials.

Wash hands before breaks and at the end of work. Clean work areas with hypochlorite or other disinfecting agent.

Respiratory protection:

Required, if there is a risk of splashing or aerosol generation during sample handling

Protection of hands: Disposable gloves Material of gloves: Latex/natural rubber.

Penetration time of glove material: Gloves resistance is not critical when the product is handled according to the instructions for use.

Eye protection: Safety glasses or face shield.

Body protection: Lab coat

9 PHYSICAL AND CHEMICAL PROPERTIES

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9.1 Information on basic physical and chemical properties

General Information Form: The device is an article containing solid components

Appearance: Laminated test strip, housed in a plastic holder.

Odor: Odorless

Flash point: Not applicable.

Self-igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

9.2 Other Information

None

10 STABILITY AND REACTIVITY

10.1 Reactivity:

No data available

10.2 Chemical stability:

The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions:

No data available

10.4 Conditions to avoid:

No data available

10.5 Incompatible Materials

No data available

10.6 Hazardous decomposition products

No data available

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Quantitative data on the toxic effects of this product is not available.

Primary effects:

After skin contact: No irritating effects anticipated.

After eye contact: No irritating effects anticipated.

Sensitization: No sensitizing effects known.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Quantitative data on the toxic effects of this product is not available.

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12.2 Persistence and degradability

The device contains plastic and other components that are not readily degradable.

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Used devices and other contaminated materials should be disposed of as potentially biohazardous waste.

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.

European waste catalogue: 18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.

Packaging: Disposal must be made in accordance with local waste management regulations. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information

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14 TRANSPORT INFORMATION

- 14.1 UN number: Not applicable
- 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: Not applicable
- 14.6 Special precautions for user: Not applicable
- 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable

15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals:
None of the ingredients is listed

Regulation (EU) No 1005/2009 on substances that deplete the ozone layer:
None of the ingredients is listed

Directive 2012/18/EU (SEVE SO III):
Named dangerous substances – ANNEX I: none of the ingredients is listed.

Information about limitation of use: Not required.

15.2 Chemical Safety Assessment
Data not available

16 OTHER INFORMATION

Hazard statements and Precautionary statements referred elsewhere in the safety data sheet:
None

Further information

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

Changes to previous version of the SDS: first version of the document.