

Safety Data Sheet

GENERIC EU SDS - ACCORDING TO REGULATION (EC) NO. 1272/2008

Version: 1.1

Revision date: 03.01.2022

Print date: 03.01.2022

NO COUNTRY SPECIFIC DATA

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

1.1 Product identifier *Preventis SmarTest®* Vitamin D Home

Product number: **PST80100EP04**

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

Relevant identified uses:

Preventis SmarTest® Vitamin D Home is a rapid test for the quantitative immunological determination of 25(OH)-vitamin D in capillary blood. This value allows monitoring of the vitamin D status and detection of a possible insufficiency or excess. The manual test system consists of an antibody-based strip test, a so-called lateral flow test, including a smartphone app developed for test evaluation. The test is an in vitro diagnostic and suitable for self-testing by laypersons 18 years of age and older. The package contains materials to perform one, single-use test.

1.3 Details of the supplier of the safety data sheet

Address: Immundiagnostik AG
Stubenwald Allee 8a
64625 Bensheim
Germany

Phone: +49-6251-701-900

Email: info@immundiagnostik.com

1.4 Emergency telephone number

Emergency number: +49 (0)6251 -701-900 (8:00 a.m. - 6:15 p.m.)

SECTION 2 Hazard identification

2.1 Classification of the substance or mixture

Classification according to the European Regulation 1272/2008/EC

Product is **not classified as hazardous** according to the European Regulation 1272/2008/EC.

2.2 Label elements

No labeling required.

2.3 Other hazards

None

SECTION 3 Composition/information on ingredients

3.1 Substances / 3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

No dangerous ingredients present.

SECTION 4 First aid measures

4.1 Description of first aid measures

General advice:

Consult a doctor if you feel unwell. Show this safety data sheet to the attending physician.

In case of skin contact:

Wash affected areas with plenty of water. Remove all contaminated clothing. Seek medical attention if necessary.

In case of eye contact:

Keep eyes open, flush thoroughly with clean water for several minutes. Seek medical attention if necessary.

If swallowed:

Do not drink the contents of the buffer tube, avoid direct contact with the liquid. Immediately wash contaminated areas thoroughly after skin contact! Rinse mouth thoroughly with plenty of water. Never give anything by mouth to an unconscious person. Consult a doctor/physician.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media: Water spray, alcohol-resistant foam, dry chemical or carbon dioxide
Adjust firefighting actions to the requirements of the adjacent fire.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), Sulphur oxides.

5.3 Advice for firefighters

In case of fire, wear appropriate respirator if necessary.

SECTION 6 Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Avoid contact with eyes, skin, mucous membranes and clothing. Avoid dust formation. Avoid breathing vapours, mist or gas.

6.2 Environmental precautions

Avoid release to the environment.

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.

SECTION 7 Handling and Storage**7.1 Precautions for safe handling**

The test is sensitive to humidity, direct sunlight and high temperatures. Therefore, protect the test from heat.

7.2 Conditions for safe storage, including any incompatibilities

No special requirements for storage.
Storage temperature: See product label. Do not freeze.

7.3 Specific end use(s)

See section 1.2.

SECTION 8 Exposure controls/personal protections**8.1 Control parameters****Components with workplace control parameters**

Contains no substances with occupational exposure limit values

8.2 Exposure controls**Appropriate engineering controls**

Observe the general safety and hygiene measures when handling chemicals: Keep food and beverages away. Do not eat or drink while handling the product. Wash hands well after handling the product.

Personal protective equipment**Eye and face protection**

Avoid contact with eyes.

Skin protection/Protection of hands

Avoid contact with skin.

Respiratory protection

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

SECTION 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|---|---|
| Appearance: - The physical state (solid, liquid, gas) - color | No data available |
| Odor | Odorless |
| Odor threshold | no data available |
| pH | no data available |
| Melting point/ freezing point | no data available |
| Initial boiling point and boiling range | no data available |
| Flash point | no data available |
| Evaporation rate | no data available |
| Flammability (solid, gas) | no data available |
| Upper/lower flammability or explosive limits | no data available |
| Vapour pressure | no data available |
| Relative density | no data available |
| Solubilities | no data available |
| Partition coefficient: n-octanol/water | no data available |
| Auto-ignition temperature | Product is not self-igniting. |
| Decomposition temperature | no data available |
| Viscosity | no data available |
| Explosive properties | Product does not present an explosion hazard. |
| Oxidising properties | no data available |

9.2 Other information

No data available.

SECTION 10 Stability and reactivity

10.1 Reactivity: Not specified

10.2 Chemical stability: The product is stable in accordance with the recommended storage conditions.

10.3 Possibility of hazardous reactions: Not specified

10.4 Conditions to avoid: Not specified

10.5 Incompatible materials: Not specified

10.6 Hazardous decomposition products: Not specified

SECTION 11 Toxicological information

11.1 Information on toxicological effects (mixture)

| | |
|------------------------|---|
| Acute toxicity: | Quantitative data on the toxic effects of this product is not available. |
| Irritation: | After skin contact: No irritating effects anticipated. After eye contact: No irritating effects anticipated. |
| Sensitization: | No sensitizing effects known. |

SECTION 12 Ecological information

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

12.2 Persistence and degradability: The device contains plastic and other components that are not readily degradable.

12.3 Bioaccumulative potential: No information available.

12.4 Mobility in soil: No information available.

12.5 Results of PBT and vPvB assessment: No information available.

12.6 Other adverse effects: No information available.

SECTION 13 Disposal considerations

13.1 Waste treatment methods

Product and contaminated packaging

After use, dispose of all test components, including the camera test card and test instructions, in the household waste.

SECTION 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 Packaging 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 MARPOL and the IBC Code

Not applicable.

SECTION 15 Regulatory information

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1272/2008

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

This product is not subject to labeling requirements according to Regulation (EC) No. 1272/2008.

15.2 Chemical safety assessment

No data available.

SECTION 16 Other information

H-code(s) used in this data sheet

Hazard statement(s)

None

This Safety data sheet has been adjusted according to COMMISSION REGULATION (EU) 2015/830 of 28 May 2015.

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