

# Safety Data Sheet

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

Version: 1.1

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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](mailto: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<sub>x</sub>), 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)**

<b>Acute toxicity:</b>	Quantitative data on the toxic effects of this product is not available.
<b>Irritation:</b>	After skin contact: No irritating effects anticipated. After eye contact: No irritating effects anticipated.
<b>Sensitization:</b>	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)**

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None

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

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