

MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)

Product name: 25-OH Vitamin D total ELISA

Catalog #: DE1971

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name Catalog # Kit components	25-OH Vitamin D Total ELISA DE1971 Microtiter plate Incubation Buffer Concentrated conjugate Concentrated HRP Conjugate Buffer Calibrators 0 to 5 Controls 1 and 2 Wash Solution Chromogen: TMB Stop Solution
1.2	Intended Use	In vitro diagnostic use
1.3	Company	Demeditec Diagnostics GmbH Lise-Meitner-Str. 2 24145 Kiel Germany Tel. +49 (0) 431 / 71922 0 info@demeditec.de
1.4	In emergencies	Call your local emergency centre

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

2.1.1 Classification according to Regulation (EC) no 1272/2008 (CLP)

Incubation Buffer

Skin sensitisation CAT 1
Repr. Cat 1B; Lact.

Conjugate Buffer, Calibrators 0-5 and Controls

Skin sensitisation CAT 1

Stop Solution

Skin corrosive 1B

2.1.2 Classification according to Directive 1999/45/EC

Incubation Buffer, Conjugate Buffer, Calibrators 0-5 and Controls

Irritation

2.1.3 Additional Information

none

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2.2 Label elements:

Labeling according to Regulation (EC) no 1272/2008 (CLP)

Incubation Buffer



H317–H360D–H362

P201–P280–P281–P302+352–P308+313–P333+313–P363

Danger

Conjugate Buffer, Calibrators 0-5 and Controls



H317

P280–P302+352–P333+313–P363

Danger

Stop Solution



H314

P280–P301+330+331–P305+351+338–P309+310

Danger

2.3 Other hazards:

Incubation Buffer

Contains proteins from bovine, ovine and murine origin.

Conjugate Buffer

Contains proteins from bovine origin.

Calibrators 0 to 5 and Controls 1 and 2.

Contain material from equine origin .

Contain material from human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

Component	Classification	concentration
Incubation Buffer containing:		
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)		
CAS-No. 55965-84-9	Skin Sensitization CAT 1, H317	< 0,06%
Index-No. 613-167-00-5	T, N, R43	
Penta deca fluoro octanoic acid - PFOA		
CAS-No. 335-67-1	Acute toxicity, Oral CAT 4, H302	< 1%
EC-No. 206-397-9	Candidate to SVHC C, R22-34-52/53	
Calibrators 0-5, Controls and Conjugate Buffer containing:		
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)		
CAS-No. 55965-84-9	Skin Sensitization CAT 1, H317	< 0,06%
Index-No. 613-167-00-5	T, N, R43	
Stop Solution containing:		
Hydrochloric acid		
CAS-No. 7647-01-0	Skin Corrosive CAT 1B, H314	< 5%
EC-No. 231-595-7	Xi	
Index-No. 017-002-01-X		

4. FIRST AID MEASURES

4.1 Description of first aid measures

Stop Solution, Incubation Buffer, Conjugate Buffer, Calibrators 0-5 and Conjugate

After skin contact: - Wash immediately with soap and plenty of water for at least 10 minutes.

- Consult a physician.

- Remove and wash contaminated clothing before re-use.

After eye contact: - Wash immediately with plenty of water for at least 15 minutes.

- Consult immediately a physician

After ingestion:

- Do NOT induce vomiting.

- Never give anything by mouth to an unconscious person.

- Rinse mouth with water.

- Consult a physician.

After inhalation:

- Transfer the person to an open place.

- If he does not breathe, proceed to artificial respiration or provide oxygen.

- Consult a physician.

4.2 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE FIGHTING MEASURES

All Kit Components

Suitable extinguishing media:

- All non combustible extinguishing media allowed

Unsuitable extinguishing media:

- No data available

Special exposure hazards:

- No generation of hazardous or toxic gases in dangerous quantities

Instructions:

- Due to small quantities: no special instructions apply

Special protective equipment for firefighters:

- Wear a breathing apparatus and protective clothing to avoid all contact with the skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

All Kit Components

Personal protection: see 8

Environmental precautions:

- Prevent soil and water pollution
- Discharge according to local regulations

Clean-up:

- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

7. HANDLING AND STORAGE

All Kit Components

Handling:

- Observe normal hygiene standards
- Discharge according to local regulations
- Remove and clean contaminated clothing
- Handle and open the container with care

Storage:

- Keep container tightly closed
- Meet the legal requirements
- Keep away from: heat sources, combustible materials, acids, metals
- Storage temperature: see component label

Specific purposes:

- NA

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Component	No. Value	Control parameters	Basis
Hydrochloric acid CAS 7647-01-0	TWA	5 ppm 8 mg/m ³	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
	STEL	10 ppm 15 mg/m ³	
	TWA	1 ppm 2 mg/m ³	UK. EH40 WEL - Workplace Exposure Limits
	STEL	5 ppm 8 mg/m ³	

8.2 Exposure Controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

8.2.2 Personal protection equipment

All Kit Components

Respiratory Protection - Insufficient ventilation: wear respiratory protection

Hand Protection - Gloves

Eye Protection - Safety goggles

- Face shields

Skin Protection

- Protective Clothing

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Microtiter Plate: plate

Controls 1 and 2, Calibrators 0 to 5: Lyophilized, soluble in water

Washing Solution, concentrated conjugate, concentrated HRP, Incubation Buffer, Conjugate buffer, Stop solution, Chromogen (TMB): Liquid

9.2 Other Information

No data available

10. STABILITY AND REACTIVITY

All Kit Components

Stability: All components are stable until expiry date if stored in specified conditions (see label)

Reactivity/Hazardous decomposition products: No hazardous decomposition products are formed in high quantities

Conditions/Materials to avoid: None known

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

ProClin 300 (contains mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)):

Acute toxicity	No data available
Skin corrosion/irritation	Skin - rabbit - Corrosive
Serious eye damage/irritation	Eyes - rabbit - Corrosive to eyes
Respiratory or skin sensitization	May cause allergic skin reaction.
Germ cell mutagenicity	No data available
Carcinogenicity	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	No data available
STOT-single exposure	No data available
STOT-repeated exposure	No data available
Aspiration hazard	No data available
Potential Health effects	Inhalation: Harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract. Ingestion: Harmful if swallowed. Causes burns. Skin: May be harmful if absorbed through skin. Causes skin burns. Eyes: Causes eye burns. Aggravated Medical Condition May provoke asthmatic response in persons with asthma who are sensitive to airway irritants,
Additional information	Not available.

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HCI:

Acute toxicity
 Skin corrosion/irritation
 Serious eye damage/irritation
 Respiratory or skin sensitization
 Germ cell mutagenicity
 Carcinogenicity

No data available
 Skin - rabbit - Causes burns
 Eyes - rabbit - Corrosive to eyes
 No data available.
 No data available
 IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
 STOT-single exposure

No data available
 The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

STOT-repeated exposure
 Aspiration hazard
 Potential Health effects

No data available
 No data available
 Inhalation: May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract. Causes respiratory tract irritation.
 Ingestion: May be harmful if swallowed. Causes burns
 Skin: May be harmful if absorbed through skin. Causes skin burns.
 Eyes: Causes eye burns.

Signs and Symptoms of Exposure

burning sensation, Cough, wheezing, laryngitis, Shortness of breath, spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonitis, pulmonary edema, Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes, and skin.

Additional information

RTECS: MW4025000.

PFOA:

Acute toxicity
 Skin corrosion/irritation
 Serious eye damage/irritation
 Respiratory or skin sensitization
 Germ cell mutagenicity

LD50 Intraperitoneal - rat - 189 mg/kg

Carcinogenicity

No data available
 No data available
 No data available.
 Genotoxicity in vivo - rat – Oral: DNA damage
 Genotoxicity in vivo - rat – Intraperitoneal: DNA damage
 IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
 STOT-single exposure
 STOT-repeated exposure
 Aspiration hazard
 Potential Health effects

No data available
 No data available.
 No data available
 No data available
 Inhalation: May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract.
 Ingestion: Harmful if swallowed. Causes burns.
 Skin: May be harmful if absorbed through skin. Causes skin burns.
 Eyes: Causes eye burns.

Signs and Symptoms of Exposure

Cough, Shortness of breath, Headache, Nausea, Vomiting

Additional information

RTECS: RH0781000.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity

HCI: Toxicity to fish LC50 - *Gambusia affinis* (Mosquito fish) - 282 mg/l - 96 h

12.2 Persistence and degradability

No data available

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

ProClin 300: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

PFOA: Harmful to aquatic life.

13. DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste (91/689/EEC).

Packaging/container: Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- Patient samples, Calibrators 0 to 5 ,Controls 1 and 2 , incubation buffer and conjugate buffer are potentially infectious. They should be disposed of following established safety procedures and local regulations.
- All the kit components must be considered as hazardous waste. They should be disposed of following local regulations.

14. TRANSPORT INFORMATION

Not applicable

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

no data available

15.2 Chemical Safety assessment

no data available

16. OTHER INFORMATION

16.1 Indication of changes

v1: SDS changes as required by current REACH regulation (as amended by 453/2010).
Classification and labeling according to CLP added.

16.2 Abbreviations and acronyms

N Dangerous for the environment
T Toxic
C Corrosive
Xi Irritation

16.3 Key literature references and sources for data

SDS sheets provided by suppliers of raw materials.

16.4 Classification and procedure used to derive the classification for mixtures according to regulation EC 1272/2008 – CLP

Classification of mixtures is based on the calculation method.

16.5 Relevant R-phrases and/or H-P statements

R22 Harmful if swallowed
R43 May cause sensitization by skin contact
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

H314 Causes severe skin burns and eye damage
H317 May cause an allergic skin reaction
H360 May damage fertility or the unborn child
H362 May cause harm to breast-fed children

P201 Obtain special instructions before use
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection
P281 Use personal protective equipment as required.
P301+330+331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P302+352 IF ON SKIN: Wash with plenty of soap and water
P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+313 IF exposed or concerned: Get medical advice/attention
P309+310 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician
P333+313 If skin irritation or rash occurs: Get medical advice/attention
P363 Wash contaminated clothing before reuse

16.7 Training advice

This product is designed for use by professionals.

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16.8 Further information

NOTE: The safety analysis of the lyophilized components in this kit has been performed on the reconstituted components. Therefore, the information in this MSDS and product labeling relates to the components as they will be used, i.e. after reconstitution.

The human blood components included in this kit have been tested by European approved and/or FDA approved methods and found negative for HBsAg, anti-HCV and anti-HIV-1 and 2. No known method can offer complete assurance that human blood derivatives will not transmit hepatitis, AIDS or other infections. Therefore, handling of reagents, serum or plasma specimens should be in accordance with local safety procedures.

All animal products and derivatives have been collected from healthy animals. Bovine components originate from countries where BSE has not been reported.

The information provided on this MSDS 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.

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