MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)
Product name: 25-OH Vitamin D Total RIA
Catalog #: DER1971

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	25-OH Vitamin D Total RIA
	Catalog #	DER1971
	Kit components	Anti-25OH Vitamin D total Coated tubes 125I labelled 25OH Vitamin D Calibrators 0 to 5 Controls 1 and 2 Diluent Specimen Tracer Buffer Incubation Buffer Washing 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)

Specimen Diluent, Calibrators, Incubation Buffer, Controls and Tracer Buffer
Skin sensitisation CAT 1.

2.1.2 Classification according to Directive 1999/45/EC

Specimen Diluent, Calibrators, Incubation Buffer, Controls and Tracer Buffer
May cause sensitisation by skin contact.

2.1.3 Additional Information

Classification according to radioprotection regulations.

^{125}I labelled 25OH Vitamin D
Contains radioactive material.

2.2 Label elements:

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

Specimen Diluent, Calibrators, Incubation Buffer, Controls and Tracer Buffer

H317
P280–P302+352–P333+313-P363

Danger

2.2.2 Labeling according to radioprotection regulations

^{125}I labelled 25OH Vitamin D

2.3 Other hazards:

^{125}I labelled 25OH Vitamin D
Contains material from bovine origin. Tracer: 160 kBq.

Controls
Contain material of 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.

Calibrators
Contains material from equine origin.

Diluent Specimen
Contains material from equine origin.

Tracer buffer
Contains material from bovine origin.

Incubation buffer
Contains material from bovine, ovine and murine origin.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

Component	Classification	concentration
Specimen Diluent, Calibrators, Incubation Buffer, Controls and Tracer 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 Index-No. 613-167-00-5	Skin Sensitization CAT 1, H317 T, N, R43	< 0,06%

4. FIRST AID MEASURES

4.1 Description of first aid measures

All Kit Components

After skin contact:
- Wash immediately with soap and plenty of water for at least 10 minutes.
- Consult a physician in case of inflammation.
- In the case of a wound or cut rinse with plenty of water, then dress the wound.
- Remove contaminated clothing

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

After ingestion:
- Let drink a lot of water.
- Consult immediately a physician if ingested in large quantities or if any complaints

After inhalation:
- Transfer the person to an open place.
- If he does not breathe, proceed to artificial respiration or provide oxygen.
- Consult a physician.

4.3 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:
- The radioactive material should be wiped up immediately.
- Take up liquid spill into absorbent material
- Discharge of absorbed material according to local regulations
- Clean contaminated surfaces with water
- Wash clothing according to radioprotection rules

7. HANDLING AND STORAGE

All Kit Components
Handling:
- Handle radioactive material according to radioprotection rules
- 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.
- Storage temperature: see component label

Specific purposes:
- NA

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters
Components with workplace control parameters
Data not available

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
All Kit Components

Hand Protection	- Gloves
Eye Protection	- Safety goggles (^{125}I labelled 25OH Vitamin D)
	- Face shields
Skin Protection	- Protective Clothing

Operators handling radioactive material should be monitored according to local regulations regarding occupational medicine.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

I^{125}

Half-life: 59.9 days
Specific activity: 6.4 x 10^{14} $Bq.g^{-1}$

Coated Tubes: Tubes
Controls 1 and 2, Calibrators 0 to 5, Specimen Diluent and ^{125}I labelled 25OH Vitamin D: Lyophilized, soluble in water
All other components: 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

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

I^{125} labeled component(s):

Chronic and acute effects	Radioactivity related adverse effects are only observed at exposure levels that are very much higher than those experienced with the reagents in this kit.

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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
Aquatic toxicity
No data available

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.

13. DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste (91/689/EEC). Follow local regulations for radioactive waste.

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:

- Radioactive material should be disposed of following local regulations regarding radioactive waste.
- Patient samples, ^{125}I labelled 25OH Vitamin D, Calibrators 0 to 5, Controls 1 and 2, Diluent Specimen ,Tracer buffer and Incubation 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

Radioactive material, N.O.S., UN 2910 - except package

Land transport	AIEA/ADR/RID regulation (Class 7, fiche 1 - ADR)
Sea transport	IMDG regulation
Air transport	OACI/IATA regulation

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

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

R43 May cause sensitization by skin contact.

H317 May cause an allergic skin reaction.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P302+352 IF ON SKIN: Wash with plenty of soap and water.
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.

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.
This MSDS assumes that radioprotection principles and applicable regulations are known by the user.
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.

MSDS established : 2015-07-14
Revision number : 3