

## MATERIAL SAFETY DATA SHEET

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

Product name: Calcitonin ultra sensitive ELISA

Catalog #: DEKAP0421

### 1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- |     |                |  |
|-----|----------------|--|
| 1.1 | Product name   | Calcitonin ultra sensitive ELISA   |
|     | Catalog #      | DEKAP0421  |
|     | Kit components | Microtiter plate<br>Standards 0 to 5<br>Anti-hCT-HRP Conjugate<br>Conjugate buffer<br>Free Serum<br>Controls 1 and 2<br>Washing Solution<br>Chromogen: TMB<br>Free Serum Buffer<br>Stop Solution |
| 1.2 | Intended Use   | In vitro diagnostic use  |
| 1.3 | Company        | Demeditec Diagnostics GmbH<br>Lise-Meitner-Str. 2<br>24145 Kiel<br>Germany<br>Tel. +49 (0) 431 / 71922 0<br>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)**

##### **Stop Solution**

Skin corrosive 1B

##### **2.1.2 Classification according to Directive 1999/45/EC**

##### **Stop Solution**

Irritation

##### **2.1.3 Additional Information**

none

#### **2.2 Label elements:**

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

##### **Stop Solution**



H314

P280-P301+330+331-P305+351+338-P309+311

Danger

#### **2.3 Other hazards:**

##### **Anti-hCT-HRP Conjugate, Conjugate Buffer**

Contains material from bovine origin

##### **Controls 1 and 2, Free Serum, Standards 0 to 5**

Contains 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.

## MATERIAL SAFETY DATA SHEET

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

Product name: Calcitonin ultra sensitive ELISA

Catalog #: DEKAP0421

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous ingredients:

Component	Classification	concentration
<b>Stop Solution containing:</b>		
<b>Hydrochloric acid</b>		
CAS-No. 7647-01-0	Skin Corrosive CAT 1B, H314 Xi	< 5%
EC-No. 231-595-7		
Index-No. 017-002-01-X		

### 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

##### All Kit Components

- After ingestion:*
- Wash out mouth with water provided person is conscious
  - Consult a physician immediately
  - Do not induce vomiting (only applies to Stop Solution)
- After inhalation:*
- Transfer the person to an open place
  - If he does not breathe, proceed to artificial respiration
  - If breathing is difficult, give oxygen
- After skin contact:*
- Wash immediately with plenty of water for at least 15 minutes
  - Remove contaminated clothing and shoes
  - Consult a physician
- After eye contact:*
- Wash immediately with plenty of water for at least 15 minutes
  - 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:*
- Due to small quantities: no special instructions apply

### 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

## MATERIAL SAFETY DATA SHEET

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

Product name: Calcitonin ultra sensitive ELISA

Catalog #: DEKAP0421

### 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

### 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 <sup>3</sup>	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
	STEL	10 ppm 15 mg/m <sup>3</sup>	
	TWA	1 ppm 2 mg/m <sup>3</sup>	UK. EH40 WEL - Workplace Exposure Limits
	STEL	5 ppm 8 mg/m <sup>3</sup>	

#### 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

- Eye protection:* - Face shield  
*Hand protection:* - Gloves  
*Suitable materials:* - No data available  
*Skin protection:* - Protective clothing

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

**Microtiter Plate:** plate

**Controls 1 and 2, Standards 0 to 5, Free Serum:** Lyophilized, soluble in water

**Washing Solution, Anti-hCT-HRP Conjugate, Stop Solution, Chromogen (TMB), Conjugate Buffer,**

**Free Serum Buffer:** Liquid

#### 9.2 Other Information

No data available

## MATERIAL SAFETY DATA SHEET

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

Product name: Calcitonin ultra sensitive ELISA

Catalog #: DEKAP0421

### 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

##### HCI:

Acute toxicity	No data available
Skin corrosion/irritation	Skin - rabbit - Causes burns
Serious eye damage/irritation	Eyes - rabbit - Corrosive to eyes
Respiratory or skin sensitization	No data available.
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	The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.
STOT-repeated exposure	No data available
Aspiration hazard	No data available
Potential Health effects	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 burns.	Skin                May be harmful if absorbed through skin. Causes
Signs and Symptoms of Exposure	Eyes                Causes eye burns. 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.

### 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

No data available

## MATERIAL SAFETY DATA SHEET

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

Product name: Calcitonin ultra sensitive ELISA

Catalog #: DEKAP0421

### 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:*

- Tested specimens, anti-hCT-HRP conjugate, controls 1 and 2, free serum, conjugate buffer and standards 0 to 5 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

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

H314 Causes severe skin burns and eye damage

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection

P301+330+331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P309+311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician

#### 16.7 Training advice

This product is designed for use by professionals.

## **MATERIAL SAFETY DATA SHEET**

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

Product name: Calcitonin ultra sensitive ELISA

Catalog #: DEKAP0421

### **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.

**MSDS established** : 2014-07-07

**Revision number** : 2