

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- | | | |
|-----|---|---|
| 1.1 | Product name
Catalog #
Kit components | TNF-alpha human ELISA
DE4641
Microtiter plate
Calibrators 0 to 5
Conjugate Buffer
Incubation Buffer
Anti-TNF- α -HRP Conjugate
Controls 1 and 2
Washing 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. Nr. +49 (0)431/71922-0
e-mail: 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 and Conjugate Buffer**

Acute toxicity 4

Eye Irritation 2

STOT SE

Skin irritation 2

Stop Solution

Skin corrosive 1B

2.1.3 Additional Information

none

2.2 Label elements:

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

Incubation Buffer and Conjugate Buffer

 H312-H319-H335-H315
 P261-P273-P280-P305+351+338

Warning

Stop Solution

 H314
 P280-P301+330+331-P305+351+338-P309+311

Danger

2.3 Other hazards:

- Anti-TNF- α -HRP Conjugate** Contains material from bovine origin
- Calibrators 0 to 5** Contains 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.
- Controls 1 and 2** Contains 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.
- Conjugate Buffer** Contains material from bovine origin
- Incubation Buffer** Contains material from bovine origin

3. COMPOSITION/INFORMATION ON INGREDIENTS
Hazardous ingredients:

Component	Classification	concentration
Conjugate Buffer and Incubation Buffer containing:		
Maleic acid		
CAS-No. 110-16-7 EC-No. 203-742-5 Index-No. 607-095-00-3	Acute toxicity 4, H302 Eye Irritation 2, H319 STOT SE, H335 Skin irritation 2, H315	< 2%
Stop Solution containing:		
Hydrochloric acid		
CAS-No. 7647-01-0 EC-No. 231-595-7 Index-No. 017-002-01-X	Skin Corrosive Cat. 1B, H314	< 5%

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
- After inhalation:*
- Do not induce vomiting (only applies to Stop Solution)
 - 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

4.2 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.

5. FIRE FIGHTING MEASURES

Chromogen, Stop Solution

- Suitable extinguishing media:*
- Carbon dioxide, dry chemical powder or appropriate foam
 - Do not use water
- Unsuitable extinguishing media:*
- No data available
- Special exposure hazards:*
- Strong dehydrating agent which may cause ignition of finely divided materials on contact. (only applies to stop solution)
 - Emits toxic fumes under fire conditions
 - Water reactive material (only applies to stop solution)
- Instructions:*
- Prevent contact with skin and eyes
- Special protective equipment for firefighters:*
- Wear self-contained breathing apparatus and protective clothing

Other 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

7. HANDLING AND STORAGE

All Kit Components

Handling:

- Use only in a chemical fume hood (only applies to chromogen, stop solution)
- 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	



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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 - Use respirators

Hand Protection - Chemical resistant Gloves

Eye Protection - Chemical Safety goggles

- Face shields

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, Calibrators 0 to 5: Lyophilized, soluble in water

Conjugate Buffer, Incubation Buffer, Washing Solution, Chromogen, Stop Solution, Anti-TNF- α -HRP

Conjugate, Substrate Buffer: Liquid

9.2 Other Information

No data available

10. STABILITY AND REACTIVITY

Chromogen

Stability: Stable until expiry date if stored in specified conditions (see label)

Reactivity/Hazardous decomposition products: Thermal decomposition may produce carbon monoxide, carbon dioxide and nitrogen oxides.

Conditions/Materials to avoid: Strong oxidizing agents

Other 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

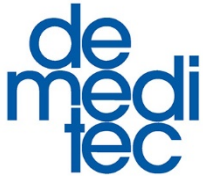
11.1 Information on toxicological effects

HCl:

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 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.

Maleic acid:

Acute toxicity	LD50 Oral - rat - 708 mg/kg Remarks: Behavioral:Convulsions or effect on seizure threshold. Behavioral:Muscle weakness. Gastrointestinal:Ulceration or bleeding from stomach. LC50 Inhalation - rat - 1 h - > 720 mg/m3 LD50 Dermal - rabbit - 1.560 mg/kg Remarks: Behavioral:Tremor.
Skin corrosion/irritation	Skin - rabbit Result: Mild skin irritation - 24 h
Serious eye damage/eye irritation	Eyes - rabbit Result: Severe eye irritation
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
Specific target organ toxicity - single exposure	



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Specific target organ toxicity - repeated exposure May cause respiratory irritation.
no data available
Aspiration hazard no data available
Additional Information RTECS: Not available
Gastrointestinal disturbance

Specific target organ toxicity - repeated exposure no data available
Aspiration hazard no data available

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

Maleic acid: Forms corrosive mixtures with water even if diluted. Harmful effect due to pH shift.

Endangers drinking-water supplies if allowed to enter soil or water. Discharge into the environment must be avoided.

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-TNF- α -HRP conjugate, Conjugate Buffer, calibrators 0 to 5, Incubation Buffer, Controls 1 and 2, 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**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 H-P statements

H312 Harmful in contact with skin
H315 Causes skin irritation
H314 Causes severe skin burns and eye damage
H319 Causes serious eye irritation
H335 May cause respiratory irritation

P261 Avoid breathing dust/fume/gas/mist/vapours/spray

P273 Avoid release to the environment

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

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

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

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

16.6 Training advice

This product is designed for use by professionals.



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16.7 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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