MATERIAL SAFETY DATA SHEET

(According to regulation (EC) 1907/2006 and amendments)
Product name: Interleukin-8 human ELISA
Catalog #: DE4700

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1	Product name	Interleukin-8 human ELISA
	Catalog #	DE4700
	Kit components	Microtiter plate Calibrators 0 to 5 Specimen diluent Incubation Buffer Anti-IL-8-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. +49 (0) 431 / 71922 0 info@demeditec.de
1.4	In emergencies	Call your local emergency center

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

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

Anti-IL-8-HRP Conjugate
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)

Anti-IL-8-HRP Conjugate

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-IL-8-HRP Conjugate & Incubation Buffer
Contains material of bovine origin.

Calibrators 0 to 5, Controls 1 and 2, Specimen Diluent
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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous ingredients:

Component		Classification	concentration
Anti-IL-8-HRP Conjugate containing:			
Maleic acid			
CAS-No. EC-No. Index-No.	110-16-7 203-742-5 607-095-00-3	Acute toxicity 4, H302 Eye Irritation 2, H319 STOT SE, H335 Skin irritation 2, H315	< 1.5%
Stop Solution containing:			
Hydrochloric acid			
CAS-No. EC-No. Index-No.	7647-01-0 231-595-7 017-002-01-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
- 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

4.2 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/m3	Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
	STEL	10 ppm 15 mg/m3	
	TWA	1 ppm 2 mg/m3	UK. EH40 WEL - Workplace Exposure Limits
	STEL	5 ppm 8 mg/m3	

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, Specimen Diluent, Calibrators 0 to 5: Lyophilized, soluble in water
Incubation Buffer, Washing Solution, Chromogen, Stop Solution, Anti-IL-8-HRP Conjugate, Substrate Buffer: Liquid

9.2 Other Information

No data available

10. Stability and reactivity

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

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity

HCl: 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-IL-8-HRP conjugate, Specimen diluent, 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
H314 Causes severe skin burns and eye damage
H315 Causes skin irritation
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
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
P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

16.6 Training advice

This product is designed for use by professionals.

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.
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MSDS established : 2018-11-28
Revision number : 4