

1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

- | | | |
|-----|---|---|
| 1.1 | Product name Catalog # Kit components | IFN-gamma human ELISA DE4434 Microtiter plate Calibrators 0 to 5 Anti-IFN- γ -HRP Conjugate Controls 1 and 2 Washing Solution Concentrated Chromogen Substrate Buffer 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)

Stop Solution
Skin corrosive 1B

2.1.2 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-IFN- γ -HRP Conjugate

Contains material from bovine origin.

Calibrators 0 to 5, Controls 1 and 2

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 |
|----------------------------------|------------------------------|---------------|
| Stop Solution containing: | | |
| Hydrochloric acid | | |
| CAS-No. 7647-01-0 | Skin Corrosive Cat. 1B, H314 | < 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

4.2 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE FIGHTING MEASURES
Concentrated 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 concentrated 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 | |

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

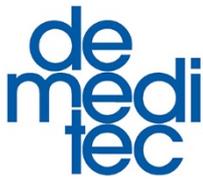
Respiratory Protection - Use respirators

Hand Protection - Chemical resistant Gloves

Eye Protection - Chemical Safety goggles

- Face shields

Skin Protection - Protective Clothing



MATERIAL SAFETY DATA SHEET

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

Product name: IFN-gamma human ELISA

Catalog #: DE4434

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 Chromogen, Stop Solution, Anti-IFN- γ -HRP Conjugate, Substrate

Buffer: Liquid

9.2 Other Information

No data available

10. STABILITY AND REACTIVITY

Concentrated 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

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 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. |

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

No data available

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- IFN- γ -HRP conjugate, calibrators 0 to 5, 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

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+310 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.

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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