

MATERIAL SAFETY DATA SHEET

TECO® Human Intact Proinsulin ELISA-Kit

Doc. No. TE1012

Date: 21-Feb-2018

Section 1 - Product and Company Identification

1.1 Manufacturer Information

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1.2 Product Information

Product Name: TECO® Human Intact Proinsulin ELISA-Kit (Catalog #: TE1012)

For in vitro diagnostic use only

For professional use only

Product form: Mixture (kit)

Intended Use: TECO® Human Intact Proinsulin ELISA-Kit is a 96 well, enzyme immunoassay for the quantitative determination of intact Proinsulin in human plasma and serum.

Components: Microtiter Plate, Dilution Buffer, Antibody HRP-Conjugate, TMB Substrate, Concentrated Wash Solution, Stop Solution, Standards A → F, Controls 1 and 2.

Section 2 – Hazards Identification

2.1 Classification according to (EC) No. 1272/2008 (CLP)

Not classified

2.2 Label elements according to (EC) No. 1272/2008

EUH phrases: EUH210 and EUH208 see section 6 for full text

2.3 Other Hazards

This kit contains substances of human origin and should be treated as a potential biohazard. These substances of human origin that enter into the reagent's compositions were checked and found negative for HBs antigen and anti-HIV1, anti-HIV2 and anti-HCV antibodies. No test method can offer an absolute guarantee of the absence of HIV, hepatitis B and C viruses, and other infectious agents. Consider these reagents as potentially infectious.

Section 3 – Composition / Information on Ingredients

3.1 Substance

Not applicable

3.2 Mixtures

The hazards identified with this product are those associated with the following component (s)


Ingredient Name	Pictogram	Kit Component	%	Product identifier	Classification according to (EC) 1272/2008	Specific concentration limits
TMB (S) 3,3',5,5'- Tetramethylbenzidine		Substrate (S)	100	CAS: 54827-17-7 EC: 264-769-6	H315 H319 H335 Skin Irrit. 2; Eye Irrit. 2; STOT	≤ 100%

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Ingredient Name	Pictogram	Kit Component	%	Product identifier	Classification according to (EC) 1272/2008	Specific concentration limits
Sulfuric acid	 Warning	Stop Solution (SL)	4,9 (w/w)	CAS: 7664-93-9 EC: 231-639-5	H314	
Albumins blood serum		Standards (A-F) Controls (1 + 2)	100	CAS: 9048-46-8 EC: 232-936-2	H302	

Substances of human origin that enter into the reagents compositions were checked and found negative for HBs Antigen and anti-HIV1, anti-HIV-2 and anti-HCV antibodies. No test method can offer an absolute guarantee of the absence of HIV, hepatitis and C viruses and other infectious agents. Consider these reagents as potentially infectious.

Section 4 – First Aid Measures

4.1 Description of first aid measures

General

If you feel unwell, ask for medical attention (show the labels where possible).

After skin contact

Remove affected clothing and wash all exposed skin area with mild soap and water, followed by a warm water rinse.

After eye contact

Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do and continue rinsing.

After Inhalation

If breathing becomes difficult, remove victim to fresh air and keep in a rest position comfortable for breathing.

After Ingestion

If patient is conscious, wash out mouth with water and give at least 3 – 5 glasses of water to drink. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Not expected to present a significant hazard under anticipated conditions or normal use.

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available.

Section 5 – Fire Fighting Measures

5.1 Suitable extinguishing media

Use carbon dioxide, dry chemical powder or appropriate foam. Do not use a heavy water stream.

5.2 Special hazards arising from the substance or mixture

None known

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5.3 Advice for fire fighters

Use water spray or fog for cooling exposed containers.

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6 – Accidental Release Measures**6.1 Personal precautions****General measures**

Wear appropriate personal protective equipment, including but not limited to protective clothing, safety glasses and protective gloves.

For non-emergency personnel

Evacuate unnecessary personnel

For emergency responders

Equip cleanup team with proper protection and ventilate area

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains and other release to the environment.

6.3 Methods and material for containment and cleaning up

Wipe up liquid spills with absorbent paper. For solid spills, sweep up without raising dust. Once pick up is complete wash site with detergent and water. Decontaminate with a suitable disinfectant solution and keep in suitable, closed containers for disposal.

6.4 Reference to other sections

See sections 8 and 13.

Section 7 – Handling and Storage**7.1 Precautions for safe handling**

Material of human origin has been tested and found non-reactive for HIV 1 and 2 and HCV antibodies and HBsAg. All animal sourced material has been obtained from animals certified as healthy and free from disease. However, all potentially biohazardous components should be considered as potentially infectious. Level II containment should be applied.

Do not eat, drink or smoke in the laboratory. Do not pipette by mouth. Avoid inhalation. Avoid skin and eye contact. Wear appropriate protective clothing as described in subsection 8.2. Avoid the use of needles or other sharp implements. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Avoid release into drains; in case of accidental spillage, refer to section 6.

7.2 Conditions for safe storage, including any incompatibilities

Store in original container and keep containers tightly closed when not in use. Store in a dry place in the box supplied at a temperature between +2 and +8°C.

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7.3 Specific end use(s)

The TECO® Human Intact Proinsulin ELISA-Kit is intended for professional use only and to be used solely for the purpose as specified in subsection 1.2. Refer to kit instructions for details.

Section 8 – Exposure Controls and Personal Protection

8.1 Control parameters

No occupational exposure limits exist for any kit components. However, the following limits apply to component ingredients: sulfuric acid (see subsection 3.2 for components containing these substances):

Sulphuric acid: CAS 7664-93-9		
EU	Local name	Sulphuric acid (mist)
EU	IOELV TWA (mg/m ³)	0,05 mg/m ³
Ireland	Local name	Sulphuric acid (mist)
Ireland	OEL (8 hours ref) (mg/m ³)	0,05 mg/m ³
United Kingdom	Local name	Sulphuric acid (mist)
United Kingdom	WEL TWA (mg/m ³)	0,05 mg/m ³
United Kingdom	Remark (WEL)	The mist is defined as the thoracic fraction

8.2 Exposure controls

The following controls should be followed as appropriate to the situation and the quantities handled.

Hand protection

Wear suitable gloves (nitrile rubber). The exact break through time has to be provided by the manufacturer of the gloves and has to be observed.

Hygiene measures

General laboratory practice (see section 7).

Respiratory protection

Not required

Eye protection

Not required

Skin and body protection

Not required

Other equipment

Eye bath and safety shower

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Section 9 – Physical and Chemical Properties
9.1 Information on the basic physical and chemical properties

Kit component	Appearance	Odor	pH	Solubility in Water
Microplate	Colorless polystyrene microtiter plate	None	N/A	Not soluble
Standards A	Blue solid	None	N/A	Soluble
Standards B-F	Blue solid	None	N/A	Soluble
Controls 1 + 2	Blue solid	None	N/A	Soluble
Antibody-HRP Conjugate	Red liquid	None	~5.0	Soluble
Blocking Buffer	Blue liquid	None	~7.0	Soluble
Wash Solution	Colorless liquid	None	~6.0	Soluble
TMB (S)	Colorless liquid	None	~4.0	Soluble
Stop Solution	Colorless liquid	May be slightly sulfurous	<1.0	Soluble

There is no information available for the following categories: odor threshold, melting/freezing point, initial boiling point/boiling range, flash point, evaporation rate, flammability (solid, gas), upper/lower flammability or explosive limits, vapor pressure, vapor density, relative density, partition coefficient, auto ignition temperature decomposition temperature, viscosity, explosive properties or oxidizing properties.

9.2 Other information

All liquid components are miscible with water in all proportions.

Section 10 – Stability and Reactivity
10.1 Reactivity

No dangerous reactions known under normal conditions or use

Sulfuric acid is a strong oxidizing agent and has a corrosive effect. There is no data available on the other substances.

10.2 Chemical stability

All components have been found stable for stated shelf life when stored under the conditions as recommended in section 7..

10.3 Possibility of hazardous reactions

No hazardous reactions known for kit components although, hazardous reactions occur for the following substances listed in subsection 3.2:

Ingredient	Hazardous Reaction
Sulfuric Acid	Violent reactions possible with acetonitrile, organic nitro compounds, potassium permanganate, metal halogenates, perchlorates and alkali metals. Contact with metals liberates toxic gas.

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10.4 Conditions to avoid

No conditions to avoid known

10.5 Incompatible materials

No incompatible materials known

10.6 Hazardous decomposition products

No decomposition products are formed if kit is stored and used under the specified storage and handling conditions

Section 11 – Toxicological Information**11.1 Information on toxicological effects****TMB (S)**

3,3',5,5'-Tetramethylbenzidine: CAS no 54827-17-7 toxicological information

- LD50 Intra peritoneal Mouse: 135 mg/kg
- LD50 Oral Quail: >316 mg/kg

Stop Solution (ST)

Sulfuric acid: CAS no 7664-93-9, toxicological information

- LD50 Oral Rat: 2140 mg/kg
- LC50 Inhalation Rat: 510 mg/ M3/2H
- Causes burn
- May be harmful if absorbed through the skin
- Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract
- Toxic if inhaled.
- May be harmful if swallowed
- Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes and skin
- Inhalation may result in spasm, inflammation and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema
- Symptoms of exposure may include burning sensation

11.2 Route of Exposure

Skin Contact: May cause skin irritation.

Skin Absorption: May be harmful if absorbed through skin.

Eye Contact: May cause eye irritation.

Ingestion: May be harmful if swallowed

Section 12 – Ecological Information**12.1 Toxicity**

No information available.

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12.2 Persistence and degradability

No additional information available.

12.3 Bioaccumulative potential

No additional information available.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

No additional information available.

12.6 Other adverse effects

No additional information available. It is, however, recommended that reagents do not enter drains in large quantities.

Section 13 – Disposal Considerations**13.1 Waste treatment methods**

Waste residues: human origin wastes must be disposed of in conformity with existing local regulations.

Soiled packaging: Dispose of in accordance with existing regulations. Contaminated containers must be treated the same way as the respective chemicals. Waste material packaging code (2001/118/EC): 15 01 10 (packaging containing of or contaminated by dangerous substances).

Section 14 – Transportation Information

This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

Transport of this product can be carried out at ambient temperature but in the event of delays store at 2 – 8°C with all reagents contained within the packaging provided.

14.1 UN number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

See sections 6 to 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable.

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Section 15 – Regulatory Information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.**

This MSDS complies with regulation (EC) No. 453/2010

15.2 Chemical safety assessment

No chemical safety assessment has been carried out for the substances of the mixture by the supplier.

Section 16 – Other Information**General**

This MSDS has been compiled in accordance with Commission Regulation (EU) No. 453/2010.

Full text of H and EUH statements

H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation
H410	Very toxic to aquatic life with long lasting effects
EUH208	May produce an allergic reaction
EUH210	Safety data sheet available on request

Abbreviations

STOT Special Target Organ Toxicity

Disclaimer

For research and in-vitro diagnostic use only!

Not for drug, household or other uses.

The above information is believed to be correct but does not purport to be all-inclusive and is provided for guidance only. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. TECOmedical AG shall not be held liable for any damage or injury resulting from handling or from contact with the above product and assumes no responsibility to the accuracy or completeness of the data contained herein. It is the responsibility of the purchaser to ensure that laboratory workers who use this product are aware of its hazards and take all necessary precautions to prevent contact, ingestion, inhalation or any other mode of exposure.