

# MATERIAL SAFETY DATA SHEET

## TECO® Human Intact Proinsulin ELISA

Doc. No. TE1012

Date: 10-Feb-2023

### Section 1 - Product and Company Identification

#### 1.1 Manufacturer Information

TECOmedical AG, Gewerbestrasse 10, CH-4450 Sissach, Switzerland; Tel. +41 (0)61 985 81 00; Fax +41 (0)61 985 81 09  
e-mail: [info@tecomedical.com](mailto:info@tecomedical.com); web: [www.tecomedical.com](http://www.tecomedical.com); Tel. SOS 112

#### 1.2 EU representative

Eurobio Scientific SA, 7 Avenue de Scandinavie, ZA de Courtaboeuf, 91940 Les Ulis, France

#### 1.3 Product Information

Product Name: TECO® Human Intact Proinsulin ELISA (Catalog #: TE1012) *\*\*For in vitro diagnostic use only\*\**  
UDI-DI 7640146270016 *\*\*For professional use only\*\**

Product form: Mixture (kit)

Intended Use: TECO® Human Intact Proinsulin ELISA 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 16 for full text

#### 2.3 Other Hazards

Not classified

### 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)	<1%	CAS: 54827-17-7 EC: 264-769-6	H315 H319 H335	≤ 100% Skin Irrit. 2; Eye Irrit. 2; STOT

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Ingredient Name	Pictogram	Kit Component	%	Product identifier	Classification according to (EC) 1272/2008	Specific concentration limits
Sulfuric acid		Stop Solution	4.9 (w/w)	CAS: 7664-93-9 EC: 231-639-5	H314	Skin Corr. 1A; H314 C ≥ 15 %  Skin Irrit. 2; H315 5 % ≤ C < 15 %  Eye Irrit. 2; H319: 5 % ≤ C < 15 %
Thiomersal		Standards (A-F) Controls (1 + 2) Dilution buffer	0.02 (w/w)	CAS: 54-64-8 EC: 200-210-4	H300 H330 H310 H373 H400 H410	≤ 0.1%
Streptomycin sulfate		Wash solution	<30%	CAS: 3810-74-0 EC: 223-286-0	H361fd H302	≤ 100%
Sodium Salicylate		Anti-Proinsulin HRP conjugate			H302 H319 H361d	
Amphotericin B		Wash solution	<30%	CAS: 302-95-4 EC: 206-132-7	H302 H412	30 % ≤ C < 50 %
Proclin 300 5 Chloro 2 methyl 4 isothiazolin 3 one and 2 Methyl 2H isothiazol 3 one (3:1)		Anti-Proinsulin HRP conjugate	0.05 (w/w)	CAS: 55965-84-9 EC: 932-593-5	H331 H311 H301 H314 H317 H410	Skin Corr. 1B; H314 C ≥ 0.6 %  Skin Irrit. 2; H315 0.06 % ≤ C < 0.6 %  Eye Irrit. 2; H319 0.06 % ≤ C < 0.6 %  Skin Sens. 1; H317 C ≥ 0.0015 %

The full text of the H phrases can be found in section 16

## 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.

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**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

**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.

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### 6.4 Reference to other sections

See sections 8 and 13.

## Section 7 – Handling and Storage

### 7.1 Precautions for safe handling

Material of animal origin used in the preparation of this kit has been obtained from animals certified as healthy, but these materials should be handled as potentially infectious.

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.

### 7.3 Specific end use(s)

The TECO<sup>®</sup> Human Intact Proinsulin ELISA 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 <sup>3</sup> )	0,05 mg/m <sup>3</sup>
Ireland	Local name	Sulphuric acid (mist)
Ireland	OEL (8 hours ref) (mg/m <sup>3</sup> )	0,05 mg/m <sup>3</sup>
United Kingdom	Local name	Sulphuric acid (mist)
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	0,05 mg/m <sup>3</sup>
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.

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**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

## 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

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### 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.

### 10.4 Conditions to avoid

No conditions to avoid known

### 10.5 Incompatible materials

No data known for the kit components

### 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

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
- 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

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- 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.

**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.

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**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.

**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**

H300	Fatal if swallowed
H301	Toxic if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
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
H330	Fatal if inhaled
H331	Toxic if inhaled
H335	May cause respiratory irritation
H361fd	May damage fertility or the unborn child
H373	May cause damage to organs through prologued or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects



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- H412 Harmful to aquatic life with long lasting effects
- EUH208 May produce an allergic reaction
- EUH210 Safety datasheet available on request

**Disclaimer**

For in-vitro diagnostic use only!

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.