Doc. No. TE1112

Date: 27-May-2022

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; web: 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 Wash solution

(Catalog #: TE1112, UDI-DI 7640146270207

For in vitro diagnostic use only

For professional use only

Product form: Mixture

Intended Use: Concentrated wash solution to be used in the TECO® Human Intact Proinsulin ELISA-Kit TE1012

Components: Concentrated Wash Solution

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, see section 16 for full text

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
Streptomycin sulfate	(!) (♣)	Wash solution	<0.02 (w/v)	CAS: 3810-74-0 EC: 223-286-0	H361fd H302	≤ 100%
Amphotericin		Wash solution	<30%	CAS: 302-95-4 EC: 206-132-7	H302 H412	30 % ≤ C < 50 %

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

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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

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

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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

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.

7.3 Specific end use(s)

The TECO® Human Intact Proinsulin ELISA Wash solution is intended for professional used only and to be used solely for the purpose as specified in subsection 1.2. Refer to TE1012 kit instructions for further details.

Section 8 – Exposure Controls and Personal Protection

8.1 Control parameters

No occupational exposure limits exist for any kit components.

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.

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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

Component	Appearance	Odor	рН	Solubility in Water
Wash Solution	Colorless liquid	None	~6.0	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

TECO® Human Intact Proinsulin ELISA Wash solution is miscible with water in all proportions.

Section 10 - Stability and Reactivity

10.1 Reactivity

No dangerous reactions known under normal conditions or use

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 TECO® Human Intact Proinsulin ELISA Wash solution

10.4 Conditions to avoid

No conditions to avoid known

10.5 Incompatible materials

No incompatible materials known

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10.6 Hazardous decomposition products

No decomposition products are formed if the TECO® Human Intact Proinsulin ELISA Wash solution is stored and used under the specified storage and handling conditions

Section 11 – Toxicological Information

11.1 Information on toxicological effects

No known chronic effects

11.2 Route of Exposure

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 $2-8^{\circ}$ C with all reagents contained within the packaging provided.

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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.

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

H302 Harmful if swallowed

H361fd Suspected of damaging fertility or the unborn child

H412 Harmful to aquatic life with long lasting effects

EUH210 Safety data sheet 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 is 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.