Doc. No. TE1067

Date: 30-Sep-2024

Section 1 - Product and Company Identification

1.1 Manufacturer Information

TECO*medical* **AG**, Gewerbestrasse 10, CH-4450 Sissach, Switzerland; Tel. +41 (0)61 985 81 00; Fax +41 (0)61 985 81 09 e-mail: <u>info@tecomedical.com</u>; web: <u>www.tecomedical.com</u>; 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® Aspergillus Galactomannan Assay (Catalogue #: TE1067,
UDI-DI 7640146270078)**For in vitro diagnostic use only**
For professional use onlyProduct form:Mixture (kit)Intended Use:TECO® Aspergillus Galactomannan Assay is based on sandwich Enzyme-linked Immunosorbent Assay (ELISA). It is used
for the detection of Aspergillus galactomannan antigen in human serum and bronchoalveolar lavage fluid (BAL).Components:Microwell Strip Plate, Negative Control Serum, Cut-off Control Serum, Positive Control Serum, Conjugate, Sample
Treatment Solution, Concentrated Washing Solution, Substrate Solution, Stopping Solution, adhesive cover for

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

microtiter plate

EUH phrases: EUH210 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
ТМВ		Substrate	100	CAS: 54827-17-7	H315	<u><</u> 100%
3,3',5,5'-		Solution		EC: 264-769-6	H319	
Tetramethylbenzidine					H335	
					Skin Irrit. 2;	
					Eye Irrit. 2; STOT	
Sulphuric acid		Stop Solution	20 (v/v)	CAS: 7664-93-9	H314	10 % ≤ C < 15 %
2M H ₂ SO ₄	Warning			EC: 231-639-5	H318	

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Ingredient Name	Pictogram	Kit Component	%	Product identifier	Classification according to (EC) 1272/2008	Specific concentration limits
Proclin 300		 Control Pos. 	0.05	CAS: 55965-84-9	H302	≤ 0.1%
5-chloro-2-		 Control Neg. 	(v/v)	EC: 932-593-5	H314	
methyl-4-iso- thiazolin-3-one		 Concentrate 			H317	
[EC no. 247-500-7] and 2-		d Wash			H318	
methyl-2H -isothiazol-3-one		Buffer			H334	
[EC no. 220-239-6] (3:1)		 Conjugate 				
EDTA		 Sample 	3.5	CAS: 6381-92-6	Not classified	
0.12M		Treatment	(w/v)	EC: 205-358-3		
		Solution				

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.

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.

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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 clean-up 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, used in the preparation of this kit has been tested and found non-reactive for HIV-1 and HIV-2 as well as for HCV antibodies and HbsAg but should, nonetheless, be handled as potentially infectious.

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)

TECO[®] Aspergillus Galactomannan Assay is intended for professional used only and to be used solely for the purpose as specified in subsection 1.2. Refer to kit instructions for details.

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Section 8 – Exposure Controls and Personal Protection

8.1 Control parameters

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No occupational exposure limits exist for any kit components. However, the following limits apply to component ingredients: Sulphuric 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/m³)	0,05 mg/m ³
Ireland	Local name	Sulphuric acid (mist)
Ireland	OEL (8 hours ref) (mg/m³)	0,05 mg/m ³
United Kingdom	Local name	Sulphuric acid (mist)
United Kingdom	WEL TWA (mg/m³)	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	рН	Solubility in Water
Microtiter Plate	Colourless polystyrene microplate	None	N/A	Not soluble
Conjugate	Amber orange liquid	None	~7.0	Soluble
Concentrated Wash Solution	Colourless liquid	None	~7.4	Soluble
Sample Treatment Solution	Colourless liquid	None	~5.0	Soluble
Substrate solution	Colourless to slight blue liquid	None	~7.0	Soluble
Stop Solution (2M H ₂ SO ₄)	Colourless liquid	None	<2.0	Soluble
Negative and positive Control	Colourless liquid	None	~7.4	Soluble
Cut-off Control Serum	Colourless liquid	None	~7.4	Soluble

There is no information available for the following categories: odour 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

Sulphuric 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
Sulphuric Acid	Violent reactions possible with acetonitrile, organic nitro compounds, potassium permanganate, metal halogenates, perchlorates and alkali metals. Contact with metals liberates toxic gas.
	halogenates, perchiorates and alkan metals. Contact with metals liberates toke gas.

10.4 Conditions to avoid

No conditions to avoid known

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10.5 Incompatible materials

Different metals

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

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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

Sulphuric Acid: CAS no 7664-93-9 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 oedema of the larynx and bronchi, chemical pneumonitis, and pulmonary oedema
- 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: Causes eye burns.

Ingestion: May be harmful if swallowed

Inhalation: May be harmful if inhaled. Causes respiratory tract irritation.

Section 12 – Ecological Information

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No additional information available.

12.3 Bio accumulative potential

No additional information available.



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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 should be carried out at $2 - 8^{\circ}$ C. In the event of delays store at $2 - 8^{\circ}$ 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.

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. 2020/878

15.2 Chemical safety assessment

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



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Section 16 – Other Information

General

This MSDS has been compiled in accordance with Commission Regulation (EU) No. 2020/878.

Full text of H and EUH statements

H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation

EUH210 Safety data sheet available on request

Disclaimer

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.