TECOmedical
A EUROBIO SCIENTIFIC COMPANY

MATERIAL SAFETY DATA SHEET TECO® Fungus (1-3)-β-D Glucan Assay	Doc. TE1068 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
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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® Fungus (1-3)-β-D Glucan Assay(Catalog #: TE1068), UDI-DI 7640146270085

For in vitro diagnostic use only
For professional use only

Product form: Mixture (kit)

Intended Use: TECO® Fungus (1-3)-β-D Glucan Assay is based on spectrophotometry for the quantitative detection of (1-3)-β-D Glucan in human serum.

Components: Main Reagent, Treatment Solution, Standard, Control, Diluent, Reconstitution Solution, Microwell strip plate.

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

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
Boc-Val-Leu-Gly-Arg-pNA acetate		Main Reagent	0.002 w/v	CAS: 68223-95-0 EC: N/A	Not classified	N/A
0.01M KOH		Treatment Solution	0.056 w/v	CAS: 1310-58-3 EC: 215-181-3	H302 H314 H315 H319	Skin Corr. 1A H314 C ≥ 5 % Skin Corr. 1B H314 2 % ≤ C < 5 % Skin Irrit. 2 H315 0.5 % ≤ C <2 % Eye Irrit. 2 H319 0.5 % ≤ C < 2 %

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.

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 but should, nonetheless, be handled as potentially infectious.

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)

TECO® Fungus (1-3)-β-D Glucan 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.

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: Potassium hydroxide (see subsection 3.2 for components containing these substances):

Potassium hydroxide: CAS 1310-58-3		
EU	Local name	Potassium hydroxide
EU	WEL STEL (mg/m^3)	2 mg/m^3
Ireland	Local name	Potassium hydroxide
Ireland	OEL (8 hours ref) (mg/m^3)	2 mg/m^3
United Kingdom	Local name	Potassium hydroxide
United Kingdom	WEL STEL (mg/m^3)	2 mg/m^3

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

Section 9 – Physical and Chemical Properties

9.1 Information on the basic physical and chemical properties

Kit component	Appearance	Odor	pH	Solubility in Water
Microwell strip plate	Colorless polystyrene microplate	None	N/A	Not soluble
Main Reagent	Colorless liquid	None	N/A	Soluble
Treatment Solution	Colorless liquid	None	~13.0	Soluble
Standard	Colorless liquid	None	N/A	Soluble
Control	Colorless liquid	None	N/A	Soluble
Diluent	Colorless liquid	None	~7.0	Soluble
Reconstitution Solution	Colorless liquid	None	~7.0	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

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
Potassium hydroxide	Contact with water, acids, flammable liquids, and organic halogen compounds, especially trichloroethylene, may cause fire or explosion. Contact with nitromethane and other similar nitro compounds cause formation of shock sensitive salts. Contact with metals such as aluminum, tin and zinc could cause formation of flammable hydrogen gas.

10.4 Conditions to avoid

No conditions to avoid known

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

Reconstitution Solution

Tris Hydroxymethyl aminomethane HCl: CAS no 7647-01-0, 77-86-1 toxicological information

- LD50 oral rat > 5000 mg/kg, OECD 425
- LD50 dermal rat > 5000 mg/kg, OECD 402
- Irritating to eyes, respiratory system, and skin

Treatment Solution

KCL: CAS no 7447-40-7 toxicological information

- LD50 oral rat: 2600 mg/kg

KOH: CAS no 1310-58-3 toxicological information

- LD50 oral rat LD50: 273 mg/kg
- Investigated as a mutagen
- Skin Irritation Data (std Draize, 50 mg/24 H): Human, Severe; Rabbit, Severe
- Eye Irritation Data (Rabbit, non-std test,1 mg/24 H, rinse): Moderate

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

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.

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 – 8oC 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.

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
H319	Causes serious eye irritation
H361	Suspected of damaging fertility or the unborn child
EUH210	Safety data sheet available on request