

Doc. TE1088

Date: 30-Sep-2024

1.1 Manufacturer Information

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1.2 EU representative

Lotus NL BV, Koninging Julianaplein 10, 1e verd. 2595 AA The Hague, The Netherlands

1.3 Product Information

Product Name:TECO® Fast Fungus (1-3)-β-D-Glucan Lateral Flow Assay
(Catalogue #: TE1088, UDI-DI 6930317801462)**For in vitro diagnostic use only**
For professional use onlyProduct form:Mixture (kit)Intended Use:TECO® Fast Fungus (1-3)-β-D-Glucan Lateral Flow Assay is intended for quantitative determination of fungal
(1-3)-β-D-glucan in human serum or plasma samples.

Components: Test Cassette, Sample treatment solution A, Sample treatment solution B, Control 1, Control 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 see section 16 for full text

2.3 Other Hazards

None 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)

according to (EC) 1272/2008	Specific concentration limits
lo. 1310-58-3 H302 b. 215-181-3 H314 H315 H319	Skin Corr. 1A; H314: $C \ge 5 \%$ Skin Corr. 1B; H314: $2 \% \le C < 5 \%$ Skin Irrit. 2; H315: $0,5 \% \le C < 2 \%$ Eye Irrit. 2;
	(EC) 1272/2008 0. 1310-58-3 H302 . 215-181-3 H314 H315 H315



MATERIAL SAFETY DATA SHEET

TECO[®] Fast Fungus (1-3)-β-D-Glucan Lateral Flow Assay

Doc. TE1088

Date: 30-Sep-2024

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 firefighters

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.



Doc. TE1088

Date: 30-Sep-2024

6.3 Methods and materials 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)

TECO[®] Fast Fungus (1-3)- β -D-Glucan Lateral Flow 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/m³)	2 mg/m ³		



Doc. TE1088

Date: 30-Sep-2024

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 basic physical and chemical properties

Kit component	Appearance	Odor	рН	Solubility in Water
Test Cassette	White cassette	None	N/A	Not soluble
Sample Treatment Solution A	Colourless liquid	None	~13.0	Soluble
Sample Treatment Solution B	Colourless liquid	None	~7.0	Soluble
Controls	Colourless liquids	None	~7.2	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 safety 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:



Doc. TE1088

Date: 30-Sep-2024

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.

10.3 Conditions to avoid

No conditions to avoid known

10.4 Incompatible materials

Different metals

10.5 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

Treatment Solution

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

Ingestion:	Harmful if swallowed
Skin contact	Causes severe skin burns
	Causes skin irritation
Eye contact	Causes serious eye irritation
	Causes eye damage

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.



Doc. TE1088

Date: 30-Sep-2024

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.

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.



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Doc. TE1088

Date: 30-Sep-2024

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.
- 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. Dynamiker Biotechnology Co. Ltd. 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.