

Safety Data Sheet

Dynamiker *Aspergillus* Galactomannan Assay

Basic UDI-DI: 69303178MLM03MW

Catalogue No.: DNK-1402-1

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SECTION 1: Identification of the substance/mixture and of the company/under-taking
1.1. Product identifier

Product Name: Dynamiker *Aspergillus* Galactomannan Assay
 Catalogue number: DNK-1402-1, 96 tests
 Components: R1- Microtiter Strips, R2- Negative control serum, R3- Cut-off control serum, R4- Positive control serum, R5- Conjugate, R6- Sample Treatment Solution, R7- Concentrated Washing Solution (20×), R8- Substrate Solution, R9- Stopping Solution, M1- Plate Sealer

1.2. Relevant identified uses of the substance or mixture and uses advised against

For professional users only
 For in vitro diagnostic only

1.3. Details of the supplier of the safety data sheet

Company: Dynamiker Biotechnology (Tianjin) Co., Ltd.
 Address: No. 2 Building, Rongzhi Industry Park, No. 3667, Zhongbin Avenue, Sino-Singapore Eco-city, TEDA, Tianjin300467, China.
 Tel: +86-22-25264212
 Fax: +86-22-25264212

1.4. Emergency telephone number

+86-22-25264212

SECTION 2: Hazards identification
2.1. Classification of the substance or mixture

Not classified

2.2. Label elements

Not applicable

2.3. Other hazards

For professional use only. Training must be provided to ensure that all operating personnel are qualified to perform the test and familiar with potential hazards.

SECTION 3: Composition/information on ingredients
3.1. Substances

Not applicable

3.2. Mixtures

Hazardous ingredients	Concentration used	Classification according to (EC) 1272/2008 and Hazard Statement Code (s)	Specific concentration limits, M-factors and ATEs
R7- Concentrated Washing Solution (20×)			
Proclin300	0.05%	Acute toxicity, Oral (Category 4), H302; Skin corrosion (Sub-category	-

CAS-No.: - EC-No.: - Index-No.: -		1B), H314; Serious eye damage (Category 1), H318; Skin sensitization (Category 1), H317; Short-term (acute) aquatic hazard (Category 1), H400; Long-term (chronic) aquatic hazard (Category 1), H410	
R8- Substrate Solution			
TMB CAS-No.: 54827-17-7; EC-No.: 259-364-6 Index-No.: -	-	Acute toxicity, Oral (Category 4), H302; Carcinogenicity (Category 2), H351; Long-term (chronic) aquatic hazard (Category 4), H413	-
R9- Stopping Solution			
H ₂ SO ₄ CAS-No.: 7664-93-9; EC-No.: 231-639-5; Index-No.: 016-020-00-8	2 M	Corrosive to Metals (Category 1), H290; Acute toxicity, Oral (Category 5), H303; Skin corrosion/irritation (Category 1A), H314; Serious eye damage/eye irritation (Category 1), H318	Eye Irrit. 2: 5%≤C<15% Skin Corr. 1A: C≥15% Skin Irrit. 2: 5%≤C<15% Met. Corr. 1: ≥ 0.3 %:

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice

First aiders need to protect themselves. Show this material safety data sheet to the doctor in attendance.

If Inhalation

Move person into fresh air. If breathing difficult, call for emergency assistance and consult a physician.

If Ingestion

Seek medical attention immediately. If the person is conscious, rinse out mouth with water thoroughly. DO NOT induce vomiting. Never give anything by mouth to an unconscious person

If Skin Contact

Remove contaminated clothing. Flush affected area with large amounts of water and wash with soap. If severe symptoms develop, seek medical attention

If Eye Contact

Flush eyes thoroughly with large amounts of water for at least 15 minutes. Seek medical attention immediately.

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 data available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media

Use dry chemical or carbon dioxide, water spray, alcohol resistant foam.

Unsuitable extinguishing

No limitations of extinguishing agents are given.

5.2. Special hazards arising from the substance or mixture

No data available

5.3. Advice for firefighters

Full protective equipment with approved self-contained breathing apparatus, and appropriate procedures should be sufficient. Use caution in approaching fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel, wear appropriate lab personal protective equipment (PPE). Minimize exposure to contaminate area. Avoid direct contact to skin, eyes and mucous membranes. For emergency responders, equip cleanup team with proper protection and ventilate area.

6.2. Environmental precautions

Avoid spreading and drain-off of hazardous materials as well as generating vapours, mist or gas.

6.3. Methods and material for containment and cleaning up

Ensure that appropriate spill clean-up materials are used. Clean-up spill area with water and wipe dry. Dispose hazardous waste and transfer into a labelled container for disposal. Clean-up of infectious waste must be handled and discarded according to national regulations.

6.4. Reference to other sections

See sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Wear protective clothing, including lab coat, eye/face protection and disposable gloves (synthetic, non-latex gloves are recommended) and handle the kit reagents and patient samples with the requisite Good Laboratory Practices. Wash hands thoroughly after performing the test. Do not eat, drink, or smoke in the laboratory. Do not pipette by mouth. Avoid inhalation. Avoid skin and eye contact. Avoid the use of needles or other sharp implements. Avoid prolonged or repeated exposure. Avoid release into drains; in case of accidental spillage, refer to section 6.

7.2. Conditions for safe storage, including any incompatibilities

The kit can be stored at 2-8 °C for up to 12 months after production. It should be stored in moisture-proof, heat-proof, well-ventilated conditions, and avoid freezing. After opening or dilution, please refer to the storage condition and time as below.

Component	Storage	Stability
Microtiter Strips coated with anti-galactomannan antibodies	After opening, stored in the sealed bag with desiccant at 2~8°C	8 weeks

Controls (Negative/Cut-off/Positive)	After opening, stored at 2~8°C	8 weeks
Conjugate	After opening, stored at 2~8°C	8 weeks
Sample Treatment Solution	After opening, stored at 2~8°C	8 weeks
Concentrated Washing Solution	After opening, concentrated solution (20×) stored at 2~8°C	8 weeks
	After dilution, washing solution stored at 2~30°C	2 weeks
Substrate Solution	After opening, stored at 2~8°C in dark	8 weeks
Stopping Solution	After opening, stored at 2~30°C	8 weeks

7.3. Specific end use(s)

Mentioned in Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No substances for which occupational exposure limits exist.

8.2. Exposure controls

Ventilation	Adequate ventilation is required to limit the exposure towards potentially infectious human source material.
Hygiene Measures	Wash hands thoroughly after removing gloves. Wash contaminated clothes before re-use. Eye wash stations and safety showers are required in work environment.
Respiratory Protection	Not required for normal use of this product.
Hand Protection	Wear chemical resistant impenetrable gloves to protect from splash and intermittent contact. Disposal gloves should be changed often and never reused.
Eye Protection	Safety glasses, goggles are required to protect eyes.
Clothing Protective	Wear a lab coat protecting against chemicals.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	generally liquids, except solid microplate.
Colour	R2-R5 reagents are yellowy, R6-R9 reagents are colorless and transparent.
Odour	No data available
Melting point/freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability	No data available
Lower and upper explosion limit	No data available

Flash Point	Not applicable.
Auto-Ignition Temperature	Not applicable.
Decomposition temperature	No data available
pH:	All liquid reagents are between pH5-8, except acidic stopping solution (pH < 2.0).
Kinematic viscosity	No data available
Solubility	Liquid chemical components are soluble in water.
Partition coefficient n-octanol/water (log value)	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available
Particle characteristic	No data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

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 data available.

10.4. Conditions to avoid

Avoid freezing

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 hazard classes as defined in Regulation (EC) No 1272/2008

Not classified.

11.2. Information on other hazards

Endocrine disrupting properties

No data available

Other information

No data available

SECTION 12: Ecological information**12.1. Toxicity**

Acidic solution provides hazardous effect on drinking water and water organisms due to pH modification.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Dispose of all specimens and materials used to perform the test as though they contain an infectious agent. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.

SECTION 14: Transport information

This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number or ID 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

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of REGULATION (EC) No 1907/2006 and COMMISSION REGULATION (EU) 2020/878.

15.2. Chemical safety assessment

No data available

SECTION 16: Other information

Full text of H-Statements referred to under sections 3.

- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- H351 Suspected of causing cancer.
- H413 May cause long lasting harmful effects to aquatic life.
- H290 May be corrosive to metals.
- H303 May be harmful if swallowed.

Further information

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. Dynamiker Biotechnology (Tianjin) 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.

Revised Records

Revised version	Revised information	Revised reason	Revised data