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## 1. Identification of the product and manufacturer

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### 1.1. Product identifier

Name: FungaDia-Aspergillus  
 FungaDia-Aspergillus is an immuno-chromatographic rapid test for the detection of Aspergillus galactomannan in serum and bronchoalveolar lavage (BAL) samples

Description: the detection of Aspergillus galactomannan in serum and bronchoalveolar lavage (BAL) samples

Article Number: ASP-025

CAS-Number: Not applicable

### Relevant identified uses of the substance or mixture

Medical device / Laboratory reagents / Immunoassay

The product is intended for professional use

### 1.2. Manufacturer

GaDia SA  
 Route de l'Île-au-Bois 1A  
 1870 Monthey  
 Switzerland  
 Phone: +41 79 632 84 47  
 E-mail: [info@gadia.net](mailto:info@gadia.net)  
 Web: [www.gadia.net](http://www.gadia.net)

Further information obtainable from: Safety representative  
 Emergency phone number: Contact the nearest poison emergency center

## 2. Hazards identification

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### Classification according to Regulation EC n° 1272/2008 (CLP):

Physical Hazards: not classified  
 Health Hazards: not classified  
 Environmental Hazards: not classified

### Classification according to Directive 67/548/EEC or Directive 1999/45/EC:

Not classified

Label elements: Not applicable  
 Signal word: None  
 Hazard statements: None  
 Precautionary statement: None  
 PBT: Not applicable  
 vPvB: Not applicable

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### 3. Information on ingredients

#### Chemical characterization:

Mixtures do not contain hazardous substances in concentration to be declared.

#### Material contained in the kit:

Number of Units/ kit	Art	Component	Subcomponents	Sub-Subcomponents
25	ASP-001	FungaDia-Aspergillus device in aluminum pouch with desiccant	Test strip Test Cassette Aluminum pouch Desiccant	Label
1	ASP-002	Plastic bottle with buffer	Running Buffer Plastic bottle	Label
1	ASP-003	Glass Bottle with positive control	Running buffer Galactomannan 50 ng/ml	Label
1	ASP-004	Glass Bottle with negative control	Running Buffer	Label
1	ASP-005	Instruction for Use leaflet		
1	R-100	GaDia Printed box	Label	

#### Description:

ASP-002: Running buffer contains sodium azide and Triton X-100

ASP-001: The test strip contains di-Sodium tetraborate decahydrate

CAS-Nr.	Component	Classification EC No 1272/2008	Concentration
1303-96-4	di-Sodium tetraborate decahydrate	Eye irritation (Category 2), H319 Reproductive toxicity (Category 1B), H360FD	<0.1%
26628-22-8	Sodium Azide	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	<0.1%
9036-19-5	Triton™ X-100	Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	<0.5%

#### Additional information:

ASP-001: The test strip contains product from animal origin (BSA and antibodies). There is no intact microorganisms present in this product, however, generally accepted good laboratory practices appropriate to biological reagents should still be employed when handling this product.

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ASP-001: The test strip contains gold nanoparticles (nanofoms) dried on the test strip. As the test is protected in a plastic housing cassette and the user need to wear protective equipment (gloves), there is no risk linked with these nanofoms.

ASP-003: Positive control contains Galactomannan extracted from *Aspergillus sp.* There is no intact microorganisms present in this product, however, generally accepted good laboratory practices appropriate to biological reagents should still be employed when handling this product

#### 4. First aid measures

General information:	No special measures required.
After inhalation:	Not applicable.
After skin contact:	Wash immediately with plenty of water.
After eye contact:	Rinse immediately with plenty of water and seek medical advice.
After swallowing:	Seek medical advice immediately.
Most important symptoms and effects, both acute and delayed:	No further relevant information available.

#### 5. Firefighting measures

Suitable extinguishing agents:	CO2, powder or water, dry chemicals or chemical foam
Special hazards arising from the substance or mixture:	No further relevant information available.
Special protective equipment:	No special measures required.

#### 6. Accidental release measures

Personal precaution:	Keep away from food, drinks and animal feeding stuffs. Wear suitable protective clothing.
Environmental precautions:	Must be disposed as hazardous waste. Avoid release to the environment.
Methods and material for containment and cleaning up:	Absorb with liquid-binding material.

#### 7. Handling and storage

Tips for safe handling:	No special measures required
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Information about protection against explosions and fires:	No special measures required
Requirements to be met by storerooms and containers:	No special requirements
Tips for clustered storage:	Not required
Additional storage requirements:	Not required
Storage class:	None
Specific end use(s):	No further relevant information available.

## 8. Exposure controls and personal protection

Additional tips for the design of technical facilities:	Not required
Ingredients with limit values that require monitoring at the workplace:	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace
Additional information:	The list that was in effect during the creation of this document were used as basis. Keep away from food and drinks. Take off dirty and soaked clothes immediately.
General safety and hygiene-measures:	Wash hands before breaks and after work is completed.
Respiratory protection:	Not required.
Hand protection:	It is recommended to wear disposable gloves for protection. The quality of the protective gloves must be chosen as a function of the specific working place concentration and quantity of hazardous substances. The glove material has to be impermeable and resistant to the product/substance/preparation.
Material of gloves:	
Eye protection:	If properly used not required. Recommended when handling clinical samples.
Body protection:	Lab coat.

## 9. Physical and chemical properties

Form:	Liquid, dried or solid
Colour:	Different according to colouring
Odour:	Odourless

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Odour threshold:	Not available
Melting point / range:	Not available
Boiling point / range:	Not available
Freezing point / range:	Not available
Flashpoint, flammability:	Not flammable
Ignition point:	Not ignitable
Self-ignitability:	Not self-ignitable
Explosion hazard:	The product is not explosive
Explosion limits:	Not available
Vapor pressure at 20°C:	Not available
Density at 20°C:	Not available
Solubility in water:	Not applicable
Other information:	No further relevant information available

## 10. Stability and reactivity

Conditions to be avoided:	No degradation if used according to labelling.
Dangerous reactions:	No dangerous reactions known.
Incompatible materials:	No further relevant information available.
Dangerous decomposition products:	No dangerous decomposition products known.

## 11. Toxicological information

Primary irritant effect:	on the skin: None on the eye: Component CAN-002 is irritant
Sensitisation:	No sensitising effect known The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
Additional toxicological information:	

## 12. Ecological information

Aquatic toxicity:	No further relevant information available.
Persistence and degradability:	No further relevant information available.
Bio accumulative potential:	No further relevant information available.
Mobility in soil:	No further relevant information available.
General notes:	No further relevant information available.

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PBT:	Not applicable
vPvB:	Not applicable
Other adverse effects:	No further relevant information available.

### 13. Disposal considerations

Recommendation:	Cannot be disposed with household waste. Cannot reach sewage system. Should be disposed in hazardous waste container.
Contaminated packaging:	Disposal must be made according to official regulations.

### 14. Transport information

UN-Number:	-
UN proper shipping name:	-
Transport hazard class:	-
Packing group:	-
Environmental hazards:	No
Special precautions for user:	Not applicable
Transport in bulk according to annex II of MARPOL73/78 and the IBC Code:	Not applicable
Transport/Additional information:	Not dangerous according to the above specifications. This product is part of a kit. Information in this section refers to the kit as a whole.
Transport by road/rail ADR/RID:	No dangerous good in sense of this transport regulation.
Transport by sea IMDG:	No dangerous good in sense of this transport regulation.
Transport by air IATA-DGR and ICAO-TI:	No dangerous good in sense of this transport regulation.

### 15. Regulatory information

Classification according to EU-Directives:	The product is classified and labelled according to EU-guidelines.
Code letter and hazard designation of product:	Not applicable

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Hazard-determining components for labelling:	Not applicable
R-phrases:	None
S-phrases:	None
Water hazard class:	None

*The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. 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. This MSDS does not provide any guarantee on product properties. GaDia SA shall not be held liable for any damage resulting from handling or from contact with the above product.*