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## 1. Identification of the product and manufacturer

### 1.1. Product identifier

Name: FungaDia-Aspergillus Antigen ELISA  
 FungaDia-Aspergillus Antigen ELISA is an enzyme sandwich microplate immunoassay Kit for the qualitative detection of Aspergillus galactomannan antigen in adult and pediatric serum samples and bronchoalveolar lavage (BAL) fluid samples.

Description:

Article Number: ASPE-096  
 CAS-Number: Not applicable

### Relevant identified uses of the substance or mixture

Medical device / Laboratory reagents / Immunoassay.

The product is intended for professional use.

These mixtures do not contain nanoparticles in their formulation.

### 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

### 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:



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Signal word:	Warning
Hazard statements:	None Reduce labeling (< 125 ml)
Precautionary statements:	None Reduce labeling (< 125 ml)
PBT:	Not applicable
vPvB:	Not applicable

### 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
1	ASPE-001 (R1)	FungaDia-Aspergillus ELISA microplate in aluminum pouch with desiccant	Coated 96-wells Microplate Aluminum pouch Desiccant	Label
1 x 25 ml	ASPE-002 (R2)	Concentrated washing solution (20x) in bottle	Concentrated washing solution (20x) Bottle	Label
1 x 2 ml	ASPE-003 (R3)	Negative control in bottle	Negative control Bottle	Label
1 x 2 ml	ASPE-004 (R4)	Cut-off control in bottle	Cut-off control Bottle	Label
1 x 2 ml	ASPE-005 (R5)	Positive control in bottle	Positive control Bottle	Label
1 x 7 ml	ASPE-006 (R6)	Anti-Aspergillus Galactomannan antibody conjugated with HRP in bottle	Anti-Aspergillus Galactomannan antibody conjugated with HRP Bottle	Label
1 x 12 ml	ASPE-007 (R7)	Sample Treatment Solution	EDTA solution Bottle	Label
1 x 25 ml	ASPE-008 (R8)	Chromogen TMB solution in bottle	Chromogen TMB solution Bottle	Label
1 x 12 ml	ASPE-009 (R9)	Stopping Solution in bottle	Stopping Solution H2SO4 Bottle	Label

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5	ASPE-020 (M1)	Plate Sealer	n/a	n/a
1	ASPE-010	Instruction for Use leaflet	n/a	n/a
1	R-104	GaDia Printed box	Label	n/a

#### Description:

ASPE-002: Concentrated washing solution contains thiomersal

ASPE-003: Negative control contains thiomersal

ASPE-004/005: Positive and cut-off Controls contain thiomersal and galactomannan from microbial origin (*Aspergillus fumigatus*). There is no intact microorganism present in these products, however, generally accepted good laboratory practices appropriate to biological reagents should still be employed when handling these products.

ASPE-006: Anti-galactomannan antibody conjugated to HRP contains thiomersal

ASPE-007: Sample treatment solution contains thiomersal and EDTA

ASPE-008: Chromogen TBM solution contains thiomersal

ASPE-009: Stop solution contains Sulfuric acid (H<sub>2</sub>SO<sub>4</sub>)

CAS-Nr.	Component	Classification EC No 1272/2008	Concentration
54-64-8	Thiomersal	Specific target organ toxicity - repeated exposure (Category 2), H373 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Acute toxicity, Oral (Category 2), H300 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410	<0.02%
60-00-4	EDTA	Acute toxicity, Inhalation (Category 4), H332 Specific target organ toxicity - repeated exposure, Inhalation (Category 2), Respiratory Tract, H373 Long-term (chronic) aquatic hazard (Category 3), H412	<5%
7664-93-9	Sulfuric Acid	Corrosive to Metals (Category 1), H290 Skin corrosion (Sub-category 1A), H314 Serious eye damage (Category 1), H318	<10%

## 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.

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## 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
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.
General safety and hygiene-measures:	Keep away from food and drinks. Take off dirty and soaked clothes immediately.

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Respiratory protection:	Wash hands before breaks and after work is completed.
Hand protection:	Not required.
Material of gloves:	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.
Eye protection:	It is recommended to wear protective glasses when handling the stop solution or clinical samples.
Body protection:	Lab coat.

## 9. Physical and chemical properties

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

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Dangerous decomposition products: No dangerous decomposition products known.

## 11. Toxicological information

Primary irritant effect: on the skin: Component ASPE-009 is irritant  
on the eyes: Component ASPE-009 is irritant

Sensitization: No sensitizing effect known

Additional toxicological information: 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.

## 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.  
Water hazard class 1 (German regulation): slightly hazardous for water. Do not allow undiluted products and large amounts to reach ground water, water course or sewage system.

General notes: No further relevant information available.

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.

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## 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:	<p>Not dangerous according to the above specifications.</p> <p>This product is part of a kit. Information in this section refers to the kit as a whole.</p>
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:	R36 R38
Hazard-determining components for labelling:	
R-phrases:	Irritating to eyes. Irritating to skin.
S-phrases:	None
Water hazard class:	Water hazard class 1 (German regulation): slightly hazardous for water.

*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.*