

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulations (EU) 2015/830 and (EU) 2020/878.

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product Form : Mixture  
Product Name : MycoMEIA® *Aspergillus* Assay  
Product Code : 25001

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

Industrial/Professional Use: For Professional Use Only  
Use of the Substance/Mixture: In Vitro Diagnostic Medical Device

### 1.3. Details of the supplier of the safety data sheet

Manufacturer	European Authorized Representative
PEARL DIAGNOSTICS, Inc. 1812 Ashland Ave., Suite G17 Baltimore, MD, 21205 Telephone: +1-410-801-7947 Email: techsupport@pearldx.com	EMERGO EUROPE Westervoortsedijk 60 6827 AT Arnhem The Netherlands T +31 70 345 8570

### 1.4. Emergency telephone number

Telephone: +1-919-314-5535

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>:

#### Classification according to Regulation (EC) No 1272/2008

Corrosive to Metals (Category 1), H290

Skin irritation (Category 2), H315

Eye irritation (Category 2), H319

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

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Microwell plate

Concentrated 25X wash

Conjugate Diluent

Chromogen Solution

Plate Sealers

Negative Control (NC)

Threshold Control (TC)

Positive Control (PC)

30X Column Rinse

This substance is classified as not hazardous according to Regulation (EC) No. 1272/2008 [CLP]:

### 2.2 Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>:

Pictogram



Signal Word

Warning

Hazard statement(s)	
H290	May be corrosive to metals.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
Precautionary statement(s)	
P234	Keep only in original packaging.
P264	Wash skin thoroughly after handling.
P280	Wear protective gloves/ eye protection/ face protection.
P302 + P352 IF ON SKIN:	Wash with plenty of water.
P305 + P351 + P338:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313:	If skin irritation occurs: Get medical advice/ attention.
Reduced Labeling (<= 125 ml)	
Pictogram	none
Signal Word	Warning
Hazard statement(s)	none
Precautionary statement(s)	none
Supplemental Hazard Statements	none

Microwell plate  
 Concentrated 25X wash  
 Conjugate Diluent  
 Chromogen Solution  
 Plate Sealers  
 Negative Control (NC)  
 Threshold Control (TC)  
 Positive Control (PC)  
 30X Column Rinse

According to Regulation (EC) No. 1272/2008 [CLP], this product does not require labeling.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.1 Substance

Not applicable

### 3.2 Mixture

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No. 1272/2008 [CLP]:

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>:

Component	Classification	Concentration
CAS-No. 7664-93-9 EC-No. 231-639-5 Index-No. 016-020-00-8 Registration Number 01-2119458838-20-XXXX	Met. Corr. 1; Skin Corr. 1A; Eye Dam. 1; H290, H314, H318 Concentration limits: >= 15 %: Skin Corr. 1A, H314; 5 - < 15 %: Skin Irrit. 2, H315; 5 - < 15 %: Eye Irrit. 2, H319; >= 0,3 %: Met. Corr. 1, H290	>= 5 - < 10 %

Microwell plate  
 Concentrated 25X wash  
 Conjugate Diluent  
 Chromogen Solution  
 Plate Sealers

Negative Control (NC)  
Threshold Control (TC)  
Positive Control (PC)

30X Column Rinse

According to Regulation (EC) No. 1272/2008 [CLP], this product does not require labeling.

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

Stop Solution 2N sulfuric acid (H<sub>2</sub>SO<sub>4</sub>):

#### If inhaled

After inhalation: fresh air.

#### In case of skin contact

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

#### In case of eye contact

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

#### If swallowed

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

General	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if breathing is irregular or stopped.
Skin Contact	: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse.
Eye Contact	: IF IN EYES: Rinse skin cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion	: IF SWALLOWED: Rinse mouth. DO NOT induce vomiting.

### 4.2 Most important symptoms and effects, both acute and delayed

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>: The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.

### 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: The components in this kit do not burn. Use extinguishing measures that are appropriate to local circumstances and the

Unsuitable extinguishing media: For this substance/mixture no limitations of extinguishing agents are given.

### 5.2 Special hazards arising from the substance or mixture

Sulfur oxides

Not combustible.

Ambient fire may liberate hazardous vapours.

Fire may cause evolution of: Sulfur oxides

### 5.3 Advice for firefighters

No specific advice for firefighters.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

General Measures : Clean spills immediately with absorbent material and rinse the area with water.

#### 6.1.1 For non-emergency personnel

Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency

#### 6.1.2 For emergency responders

Protective equipment see section 8.

## 6.2 Environmental precautions

Do not let product enter drains.

## 6.3 Methods and material for containment and cleaning up:

Immediately clean up any spillage. Dispose of the cleaning material by an acceptable method. Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent and neutralizing material (e.g. Chemizorb® H<sup>+</sup>, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Protective Measures : Avoid contact with skin and eyes. Avoid ingestion and inhalation. Observe label precautions.  
 Hygiene measures : Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance. For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage Conditions : Store between 2-8°C as indicated in the Package Insert/IFU.  
 Storage class : Storage class (TRGS 510): 8B: Non-combustible, corrosive hazardous materials

### 7.3 Specific end use(s)

For *in vitro* diagnostic use only.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Ingredients with workplace control parameter

### 8.2 Exposure controls

Personal Protective Equipment : Avoid all unnecessary exposure. Wear safety glasses, gloves, and protective clothing.  
 Hand Protection : Wear protective gloves.  
 Eye Protection : Wear chemical goggles or safety glasses.  
 Respiratory Protection : No respiratory protection necessary.  
 Other Information : Do not eat, drink, or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>:

Physical state : Liquid  
 Color : Colorless  
 Odor : Odorless  
 Melting point/freezing point : No data available  
 Initial boiling point and boiling range : No data available  
 Flammability (solid, gas) : No data available  
 Upper/lower flammability or explosive limits : No data available  
 Flash point : Not applicable  
 Autoignition temperature : No data available  
 Decomposition temperature : No data available  
 pH : ca.1 at 20 °C  
 Viscosity, kinematic: : No data available  
 Viscosity, dynamic: : No data available  
 Water solubility: : Soluble (development of heat)  
 Partition coefficient: n-octanol/water : No data available  
 Vapor pressure No data available  
 Density : 1,1 g/cm<sup>3</sup> at 20 °C  
 Relative density : No data available  
 Relative vapor Density : No data available

Particle characteristics : No data available  
 Explosive properties : Not classified as explosive.  
 Oxidizing properties : Oxidizing potential

**Kit components:**

Physical State : Multiple kit components.  
 Color : Various  
 Odor : None reported  
 Odor Threshold : No data available.  
 pH : No data available.  
 Relative Evaporation Rate : No data available  
 Melting Point : No data available.  
 Boiling Point : No data available.  
 Flash Point : No data available.  
 Auto-ignition Temperature : Not applicable  
 Decomposition Temperature : No data available  
 Flammability (solid, gas) : Not applicable  
 Vapor Pressure : No data available.  
 Relative Vapor Density at 20 °C : No data available.  
 Relative Density : No data available.  
 Solubility : No data available.  
 Viscosity, Kinematic : No data available  
 Viscosity, Dynamic : No data available  
 Explosive Properties : Not applicable  
 Oxidizing Properties : Not applicable  
 Explosive Limits : Not applicable

**9.2 Other information**

No data available.

**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub> : Oxidizing agents  
 Other components : Stable under normal conditions.

**10.2 Chemical Stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>  
 Violent reactions possible with : Water, alkali metals, alkali compounds, ammonia, alkalines, metals, alkaline earth metals, alkaline earth compounds, metal alloys, acids  
 Other components : Stable under normal conditions.

**10.4 Conditions to avoid**

No data available.

**10.5 Incompatible materials**

Animal/vegetable tissues; gives off hydrogen by reaction with metals.

**10.6 Hazardous decomposition products**

In the event of fire: see section 5.

**SECTION 11: Toxicological information**

**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute Toxicity  
 Stop Solution 2N H<sub>2</sub>SO<sub>4</sub> : LD50 Oral - Rat - male and female - 2.140 mg/kg

Other components: : Not classified (Based on available data, the classification criteria are not met)  
 Skin Corrosion / Irritation : Not classified (Based on available data, the classification criteria are not met)  
 Stop Solution 2N H<sub>2</sub>SO<sub>4</sub> : Skin - Rabbit  
 Result: Extremely corrosive and destructive to tissue.  
 Remarks: (IUCLID)

Serious Eye Damage / Irritation : Causes serious eye damage.  
 Stop Solution 2N H<sub>2</sub>SO<sub>4</sub> : Not classified (Based on available data, the classification criteria are not met)  
 Other components: : Not classified (Based on available data, the classification criteria are not met)  
 Respiratory or Skin Sensitization : Not classified (Based on available data, the classification criteria are not met)  
 Germ Cell Mutagenicity : Not classified (Based on available data, the classification criteria are not met)  
 Stop Solution 2N H<sub>2</sub>SO<sub>4</sub> : Test Type: Ames test  
 Test system: Salmonella typhimurium  
 Result: negative  
 Remarks: (HSDB)

Other components: : Not classified (Based on available data, the classification criteria are not met)  
 Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)  
 Reproductive Toxicity : Not classified (Based on available data, the classification criteria are not met)  
 Specific Target Organ Toxicity : Not classified (Based on available data, the classification criteria are not met)  
 Single Exposure : Not classified (Based on available data, the classification criteria are not met)  
 Specific Target Organ Toxicity : Not classified (Based on available data, the classification criteria are not met)  
 Repeated Exposure : Not classified (Based on available data, the classification criteria are not met)  
 Aspiration Hazard : Not classified (Based on available data, the classification criteria are not met)

## 11.2 Information on other hazards

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>  
 Endocrine disrupting properties : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.  
 After inhalation of vapours : Irritative symptoms in the respiratory tract.  
 After skin contact : Severe irritations.  
 After eye contact : Corneal destruction.  
 After swallowing : Damage of the oral, oesophageal, and gastric mucous membranes; perforation of the esophagus frequently occurs; circulatory collapse may occur after 1-2 hours.  
 Other dangerous properties can not be excluded.  
 Handle in accordance with good industrial hygiene and safety practice

## SECTION 12: Ecological information

### 12.1 Persistence and degradability

No data available

### 12.2 Bioaccumulative potential

No data available

### 12.3 Mobility in soil

No data available

### 12.4 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

### 12.5 Other adverse effects

No data available

### 12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

#### 12.7 Other adverse effects

Stop Solution 2N H<sub>2</sub>SO<sub>4</sub>

Harmful effect due to pH shift. Neutralisation possible in waste water treatment plants. Discharge into the environment must be avoided.

Toxicity to daphnia and other aquatic invertebrates

Static test EC50 - Daphnia magna (Water flea) - > 100 mg/l - 48 h (OECD Test Guideline 202)

Toxicity to algae static test ErC50 - Desmodesmus subspicatus (green algae) - > 100 mg/l - 72 h (OECD Test Guideline 201)

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container to an approved waste disposal plant.

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / AND

#### 14.1 UN number

ADR/RID: 2796                      IMDG: 2796                      IATA: 2796

#### 14.2 UN proper shipping name

ADR/RID: SULPHURIC ACID

IMDG: SULPHURIC ACID

IATA: Sulphuric acid

#### 14.3 Transport hazard class(es)

ADR/RID: 8                      IMDG: 8                      IATA: 8

#### 14.4 Packing group

ADR/RID: II                      IMDG:                      II IATA: II

#### 14.5 Environmental hazards

ADR/RID: no                      IMDG Marine pollutant: no                      IATA: no

#### 14.6 Special precautions for user

No data available

#### 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 material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

#### 15.2 EU-Regulations

Contains no REACH substances with Annex XVII restrictions.

Contains no substance on the REACH candidate list.

Contains no REACH Annex XIV substances.

#### 15.3 National regulations

No additional information available.

#### 15.4 Chemical safety assessment

No chemical safety assessment has been carried out.

### SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

H290 May be corrosive to metals.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H319 Causes serious eye irritation

## SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product