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 : Myco*MEIA*® *Aspergillus* Assay Accessories – Myco*MEIA* 25X Concentrated Wash Solution; Myco*MEIA* Sample Processing Columns; Myco*MEIA* Uncoated Plates

Product Code : 25070; 25024; 25025

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.	EMERGO EUROPE
1812 Ashland Ave., Suite 100	Westervoorstsedijk 60
Baltimore, MD, 21205	6827 AT Arnhem
Telephone: +1-410-801-7947	The Netherlands
Email: techsupport@pearldx.com	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

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

Myco*MEIA* Concentrated 25X Wash Solution

Myco*MEIA* Sample Processing Columns

Myco*MEIA* Uncoated Plates

These substances are 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]

Myco*MEIA* Concentrated 25X Wash Solution

Myco*MEIA* Sample Processing Columns

Myco*MEIA* Uncoated Plates

According to Regulation (EC) No. 1272/2008 [CLP], these products do 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

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

Myco*MEIA* Concentrated 25X Wash Solution

Myco*MEIA* Sample Processing Columns

Myco*MEIA* Uncoated Plates

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

SECTION 4: First aid measures

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.

4.1 Most important symptoms and effects, both acute and delayed

No data available.

4.2 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 product itself does not burn. Coordinate fire-fighting measures to the fire surroundings.
Unsuitable Extinguishing Media	: No restrictions.

5.2 Special hazards arising from the substance or mixture

No specific hazards.

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

Emergency Procedures : Evacuate unnecessary personnel.

6.1.2 For emergency responders

Personal Protective Equipment : Refer to Section 8 of this SDS for appropriate personal protective equipment.

Emergency Procedures : No specific emergency procedures.

6.2 Environmental precautions

No specific environmental precautions

6.3 Methods and material for containment and cleaning up:

Clean spills with absorbent material. Rinse spill area with water.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective Measures	: Wear gloves when handling.
General Occupational Hygiene	: Do not eat, drink, or smoke when using this product. Wash hands thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities

Storage Conditions : Store between 2-8ºC or as indicated in the Package Insert/IFU.

7.3 Specific end use(s)

For *in vitro* diagnostic use only.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Does not contain substances above concentration limits requiring an occupational exposure limit.

8.2 Exposure controls

Personal Protective Equipment	: Avoid all unnecessary exposure. Wear safety glasses, gloves, 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

MycoMEIA Concentrated 25X Wash Solution

MycoMEIA Sample Processing Columns

MycoMEIA Uncoated Plates

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

Other components	: Stable under normal conditions.

10.2 Chemical Stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

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)

Serious Eye Damage / Irritation

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)

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

Single Exposure : Not classified (Based on available data, the classification criteria are not met)

Specific Target Organ Toxicity

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

Dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to daphnia and other aquatic invertebrates

No data No data available

Toxicity to algae

No data No data available

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

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

12.6 Other adverse effects

No data available

12.7 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.

12.8 Other adverse effects

No data available

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

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

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

16.1 Full Text of Hazard Statements and Precautionary Statements

None

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