Microgen Listeria ID
(Cat. nr. MID-67)

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

1.1. Product identifier
Product name:
Microgen® Listeria ID
Cat. N.
MID-67

1.2. Product use
A bacterial identification system for Listeria species.

1.3. Company/Undertaki ng identification
Gold Standard Diagnostics Budapest Kft.
Fóti út 56 A. ép.
1047 BUDAPEST
HUNGARY
customerservice.bud@eu.goldstandarddiagnostics.com
www.goldstandarddiagnostics.com

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:
Not hazardous.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC:
Not hazardous.

Information concerning particular hazards for human and environment:
No additional information available**.**

Other hazards that do not result in classification:
Not applicable

2.2. Labelling according to Regulation (EC) No 1272/2008:
No labelling is required

SECTION 3: Composition/information on ingredients

Components	CAS number / EC Number	Concentration
Plastic Strips with 11 wells each coated with a dried biochemical substrate. Wells 1-11 coated respectively with: Esculin; Mannitol; Xylose; Arabitol; Ribose; Rhamnose; Trehalose; Tagatose; Glucose-1-Phosphate; Methyl-D-Glucose; Methyl-D-Mannose Well number 12 is empty and is used for an in-well haemolysis reaction when haemolysin reagent is added to a bacterial suspension.	-	-

SECTION 4: First aid measures

Eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician

Skin contact
Wash off with soap and plenty of water. Consult a physician

Ingestion
Clean mouth with water and drink plenty of water. Do not induce vomiting.

Inhalation
Move fresh air

Equipment to be available at the workplace for specific and immediate treatment
Eye –washing and skin-washing facilities

SECTION 5: Firefighting measures

5.1. Extinguishing media
Substance is non-flammable; use agent most appropriate to extinguish surrounding fire.

5.2. Special hazards arising from the substance or mixture
Thermal decomposition can lead to release of irritating gases and vapours.

5.3. Advice for firefighters
Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions
Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up
Soak up with inert absorbent material. Clean contaminated surface thoroughly.

SECTION 7: Handling and storage

7.1. Handling
Invitro diagnostic reagent. Handle with the appropriate precautions. Read the Instructions for Use. Always follow Good Laboratory Practice when using this product. Avoid contact with eyes, skin and clothing.

7.2. Storage
Keep container tightly closed in a dry and well-ventilated place. Keep at temperatures between 2 -8˚C.

SECTION 8: Exposure controls/personal protection

8.1. Exposure Limit Values
The product does not contain any hazardous materials with occupational
Exposure limits established.

8.2. Exposure controls

8.2.1. Occupational

Respiratory	Respiratory protection is not required under normal and intended conditions of use.
Hands	Protective gloves
Eyes	Safety glasses with shields recommended to EN 166
Body	Laboratory coat

SECTION 9: Physical and chemical properties

MID-67A	1x dropper bottle of Haemolysin Reagent
MID-67B	20x Bottles Suspending Media
MID-67C	20x plastic strips coated with 25µL per well of dried substrates.

SECTION 10: Stability and reactivity

10.1. Stability
Stable under recommended storage conditions. Do not use after stated expiry date. Store at 2-8 ˚C

10.2. Materials/Conditions to avoid
Excess heat

10.3. Hazardous decomposition products
Acids**,** Strong oxidizing agents

10.4. Hazardous decomposition products
None under normal use conditions.

SETION 11: Toxicological information

11.1. Acute toxicity
No data available

11.2. Sensitisation - skin
May cause skin and eye irritation.

11.3. Serious Eye damage/Irritation
No data available

SECTION 12: Ecological information

- Toxicity: Contains no substances known to be hazardous to the environment.
- Persistence and degradability: No data available.
- Bioaccumulative potential: Does not bio accumulate
- Mobility in soil: Spillage unlikely to penetrate soil.
- Results of PBT and vPvB assessment: PBT: Not applicable, vPvB: Not applicable.
- Other adverse effects: None Known

SECTION 13: Disposal considerations

Dispose of according to any local, national or regional regulations.

SECTION 14: Transport information

14.1. UN Number
Not regulated

14.2. Proper shipping name
Not regulated

14.3. Class
Not regulated

14.4. Packing Group
Not regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Health, safety or environmental information is not required on the label (according to Regulation (EC) No 1272/2008).

SECTION 16: Other information

16.1. Recommended restrictions on use:
This product is intended to be used for laboratory use only by technical staff trained in microbiological techniques. Classification and labelling have been performed according to CLP Regulations.

Read the Instructions for Use for further information on limitations of use.

16.2. Sources of information used to compile this sheet
Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH): Article 31: Requirements for safety data sheets, and Annex II: Guide to the compilation of safety data sheets, OJL, 136, 29.5.2007, pp 35-36 and pp 84-89.

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 (in short CLP).

Commission Decision 2000/532/EC establishing a list of wastes pursuant to Article 1 (a) of Directive 75/442/EEC on Waste and Article 1 (4) of Directive 91/689/EEC on Hazardous Waste. CONSLEG: 2000D0532-01/01/2002, Office for Official Publications of the European Communities.

Approved Supply List (8th edition), Information provided for the classification and labelling of substances and preparations for supply, United Kingdom Health and Safety Commission, 2005 (based on Annex I of 67/548/EEC).

Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices, Annex I, Essential Requirements, OJ L, 331, 7.12.98, p 20.

List of approved workplace exposure limits, Table 1 of EH40/2005, United Kingdom Health and Safety Commission, 2ND edition published 2011, implementing the European Commission's Indicative Occupational Exposure Limit Values Directive 2009/161/EU.

16.3. Changes from previous version

The Ownership of the documents has been changed. The legal Manufacturer is Gold Standard Diagnostics Budapest Kft. (Chapter 1.3).

All sections: updated format and details according to REACH GUIDELINES Annex-II and CLP.

The above information is based on data available and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determinations of the effects, properties and protections which pertain to their particular conditions.

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