GOLD STANDARD DIAGNOSTICS

SAFETY DATA SHEET

Microgen Listeria ID
(Cat. nr. MID67)

SECTION 1: Identification of the substance/preparation and of the Company/Undertaking

1.1. Product identifier
Product name
Microgen Listeria ID

Cat. Nr.
MID67

1.2. Relevant identified uses of the substance or mixture and uses advised against
A bacterial identification system for Listeria species.

1.3. Details of the supplier of the safety data sheet
Gold Standard Diagnostics Budapest Kft.
Fóti út 56/A.
1047 BUDAPEST
HUNGARY
Contact information: www.goldstandarddiagnostics.com/contacts
Phone: + 36 20 457 1204

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:
Not classified.
For the full text of H-statements mentioned in this Section: see Section 16.

2.2. Label elements

Hazard Pictograms:
-

Signal word:
-

Hazard statements:
-

Precautionary statements:
-

Supplemental hazard information:
-

Substances contributing of hazard identification:
-

2.3. Other hazards:
See PBT and vPvB assesment results in section 12.5.
Endocrine disrupting properties : see sections 11.2. and 12.6.

SECTION 3: Composition/information on ingredients

3.1.Substances
Not applicable.

3.2. Mixtures

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..

10M sodium hydroxide and Hydrochloric acid is used for pH adjustment

Component	CAS No.	EC-No.	Index-No.	REACH-No.	Concentration	Classification according to Regulation (EC) No. 1272/2008 [CLP]	H-statements	Special conentration limits/M-factor/ATE
10M sodium hydroxide*	1310-73-2	215-185-5	011-002-00-6	-	<0,5	Met. Corr. 1 Skin Corr. 1A Eye Dam. 1	H290 H314 H318	Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %
Hydrochloric acid	-	231-595-7	017-002-01-X	-	<0,5	STOT SE 3 Skin Corr. 1B	H314 H335	Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 % STOT SE 3; H335: C ≥ 10 %

* **:** Manufacturer classification, which differs from the harmonized classification
For the full text of H-statements mentioned in this Section: see Section 16.
The product does not contain Substances of Very High Concern (SVHC)..

SECTION 4: First Aid Measures

4.1.Description of first aid measures:

GENERAL INFORMATION:

In case of accident or feeling sick immediately consult a physician. Show this safety data sheet or the product label to the doctor in attendance!

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

FOLLOWING INGESTION:

Not likely exposure route . Clean mouth with water and drink plenty of water. Do not induce vomiting. Consult a physician.

FOLLOWING INHALATION:

Not likely exposure route. Move to fresh air.

FOLLOWING SKIN CONTACT

Not likely exposure route . Wash off with soap and plenty of water. In case of irritation consult a physician.

FOLLOWING EYE CONTACT:

Not likely exposure route . Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

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

No information available.

4.3.Indication of any immediate medical attention and special treatment needed

Treat sympstoms.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Suitable extinguishing media : use agent most appropriate to extinguish surrounding fire.
Unsuitable extinguishing media : no information available.

5.2. Special hazards arising from the substance or mixture

Substance is non-flammable.
Thermal decomposition can lead to release of irritating gases and vapours.

5.3 . **Advice for firefighters**

Protective equipment: Wear self-contained breathing apparatus pressure-demand, and full protective gear.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid contact with skin, eyes and clothing.

For emergency personnel

Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid contact with skin, eyes and clothing.

See sections 7 and 8.

6.2. Environmental precautions

Should not be released into the environment. Do not let it enter into surface water or sanitary sewer system.

6.3. Methods and materials for containment and cleaning up

Soak up with inert absorbent material. Disposal: see section 13 Clean contaminated surface thoroughly.

6.4. Reference to other sections

See sections 7, 8 and 13

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

In vitro 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.

Advice on protection against fire and explosion: Normal measures for preventive fire protection

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Keep at temperatures between 2 -8˚C.Keep away from acids, strong oxidizing agents.

7.3. Specific end use(s)

No information available.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Exposure limits (Source GESTIS)

Substance Hydrogen chloride

CAS No. 7647-01-0

	Limit value - ppm	Eight hours mg/m³		Limit value - ppm	Short term mg/m³
Belgium	5	8		10 (1)	15 (1)
Denmark				5 (1)	8 (1)
European Union	5	8		10 (1)	15 (1)
Finland				5 (1)	7,6 (1)
Germany (AGS)	2	3		4 (1)	6 (1)
Germany (DFG)	2	3	4 (1)	6 (1)	
Hungary	5	8	10	16 (1)	
Ireland	5	8	10 (1)	15 (1)	
Italy	5	8	10 (1)	15 (1)	
Latvia	5	8	10 (1)	15 (1)	
Norway			5 (1)	7 (1)	
Romania	5	8	10 (1)	15 (1)	
Sweden	2	3	4 (1)	6 (1)	
The Netherlands	5	8	10 (1)	15 (1)	
Turkey	5	8	10 (1)	15 (1)	

Remarks

Belgium (1) 15 minutes average value

Denmark (1) 15 minutes average value

European Union (1) 15 minutes average value Bold-type: Indicative Occupational Exposure Limit Value (IOELV) ~ (for references see bibliography)

Finland (1) 15 minutes average value

Germany (AGS) (1) 15 minutes average value

Germany (DFG) (1) 15 minutes average value

Hungary (1) 15 minutes average value

Italy (1) 15 minutes average value

Latvia (1) 15 minutes average value

Norway (1) Ceiling limit value

Romania (1) 15 minutes average value

Sweden (1) 15 minutes average value

The Netherlands (1) 15 minutes average value

Turkey (1) 15 minutes average value

Substance Sodium hydroxide
CAS No. 1310-73-2

	Limit value -Eight hours		Limit value - Short term	
	ppm	mg/m³	ppm	mg/m³
Austria		2 inhalable aerosol		4 inhalable aerosol
Belgium		2 (1)		
Denmark		2		2 (1)
Finland				2 (1)
France		2		
Hungary		1		2 (1)
Ireland				2 (1)
Latvia		0,5		
New Zealand				2 (1)
Norway				2 (1)
Poland		0,5		1 (1)
Romania		1		3 (1)
Spain		2		
Sweden		1 (1)		2 (1)(2)
Switzerland		2 inhalable aerosol		2 inhalable aerosol
United Kingdom				2 (1)

Remarks
Belgium (1) Additional indication "M" means that irritation occurs when the exposure exceeds the limit value or there is a risk of acute poisoning. The work process must be designed in such a way that the exposure never exceeds the limit value. For evaluation, the sampled period should be as short as possible. However, the sampled period shall be long enough to perform a reliable measurement. The measured result shall be related to the considered period.
Denmark (1) Ceiling limit value
Finland (1) Ceiling limit value
Hungary (1) 15 minutes average value
Ireland (1) 15 minutes reference period
New Zealand (1) Ceiling limit value
Norway (1) Ceiling limit value
Poland (1) 15 minutes average value
Romania (1) 15 minutes average value
Sweden (1) Inhalable fraction (2) 15 minutes average value
United Kingdom (1) 15 minutes average value

Recommended monitoring procedures: Methods for measurement of the workplace atmosphere have to correspond to the requirements of norms DIN EN 482 and DIN EN 689

8.2.Exposure controls: Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Caution is necessary to prevent skin contact, eye contact, cloth contact and spilling into the floor.

5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers exposed to chemical pathogenic factors, pursuant to Section 11(2) in the case of hazardous substances not regulated by limit values, the employer is obliged to reduce the level of exposure to the lowest level expected according to scientific and technical standards , at which level, according to the current state of science, the dangerous substance has no health-damaging effect. When using in an open system, use local exhaust where possible. If local extraction is not possible or is insufficient, adequate ventilation of the work area must be ensured.

General protective and hygienic measures
Do not eat, drink or smoke when using this product.
Wash hands after using the product.

Appropriate engineering controls
Handle in a fume cupboard or under local exhaust ventilation.

Individual protection measures, such as personal protective equipment:

a) eye/face protection
Safety eyewear or face protection complying with an approved standard (European Standard EN 166) should be used. Safety glasses with shields.

b) skin protection

i. hand protection: Chemical-resistant, impervious gloves complying with an approved standard (European Standard EN374) should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

ii. other: body protection: Laboratory coat.

c) respiratory protection
Respiratory protection is not required under normal and intended conditions of use.

d) thermal hazards
None.

Environmental exposure controls
Do not let product enter drains.

Personal protective equipment selections vary based on potential exposure conditions such as applications, handling practices, concentration and ventilation. Information on the selection of protective equipment for use with this material, as provided above, is based upon intended, normal usage. If there is different than normal usage of the material it is advised to consult a safety specialist about the type of personal protective equipment and other actions that should be taken.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appaerance 1x dropper bottle of Haemolysin Reagent; 20x Bottles Suspending Media; 20x plastic strips coated with 25µL per well of dried substrates
Color Not available
Odor Not available
Odor threshold Not available
Melting point/freezing point Not available
Initial boiling point and boiling range Not available
Falmmability Not flammable.
Upper/lower flammability or explosive limits Not available
Flash point Not available
Auto-ignition temperature Not available
Decomposition temperature Not available
pH Not available
Kinematic viscosity Not available
Solubility Not available
Partition coefficient: n-octanol/water Not available
Vapor pressure Not available

Density and/or relative density Not available
Relative vapor density Not available
Particle characteristics Not available.

9.2. Other information

9.2.1. Information with regard to physical hazard classes
Not classified.

9.2.2. Other safety characteristics
No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity
No data available.

10.2 Chemical stability
Stable under recommended storage conditions. Do not use after stated expiry date. Store at 2-8°C.

10.3.Possibility of hazardous reactions
No data available.

10.4.Conditions to avoid
Excess heat.

10.5.Incompatible materials
Acids. Strong oxidizing agents.

10.6.Hazardous decomposition products
None under normal use conditions.

SECTION 11: Toxicological Information

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

Acute toxicity:
No information available.

Skin corrosion / irritation:
No information available.

Serious eye damage/irritation:
No information available.

Respiratory or skin sensitization:
No information available.

Germ cell mutagenicity:
No information available.

Carcinogenicity:
No information available.

Reproductive toxicity:
No information available.

STOT-single exposure:
No information available.

STOT-repeated exposure:
No information available.

Aspiration hazard:
No information available.

Relevant toxicological data:
No information available.

Information on likely routes of exposure:
No information available.

Symptoms related to the physical, chemical and toxicological characteristics:

- Skin contact: No specific information available.
- Eye contact: No specific information available.
- Inhalation: No specific information available.
- Ingestion: No specific information available.
- Other: No information available.

Delayed and immediate effects as well as chronic effects from short and long term exposure:
See section 4.2.

Interactive effects:
No information available.

Absence of specific data:
No information available.

Mixtures:
No information available.

Mixture versus substance information:
No information available.

11.2 Information on other hazards

Endocrine disrupting properties
None of the components are listed.

Other information
No information available.

SECTION 12: Ecological Information

Do not allow product to reach surface water, waterways or soil.

12.1 Toxicity
Contains no substances known to be hazardous to the environment.

12.2.Persistence and degradability
No information available.

12.3 Bioaccumulative potential
It is not expected to bioaccumulate.

12.4 Mobility in soil
Spillage unlikely to penetrate soil.

12.5.Results of PBT and vPvB assessment
No information available.

12.6.Endocrine disrupting properties
None of the components are listed.

12.7.Other adverse effects
No further relevant information available.

SECTION 13: Disposal Considerations

13.1.Waste treatment methods
Product disposal:
Dispose of contents in accordance with local/regional/national/international regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

Packaging disposal:
Dispose of container in accordance with local/regional/national/international regulations.

Physical, chemical properties, which could influence waste management:
No information available.

Sewage disposal-relevant information:
No information available.

SECTION 14: Transport Information

Product is not classified as a dangerous good for transport.

ADR/RID

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

ADN:

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

IMDG

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user:-

ICAO-TI/IATA-DGR

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

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

EU Regulations:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2020/878of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

15.2.Chemical safety assesment:
Chemical safety assessement has not been carried out for this product.

SECTION 16: Other information

Identification of changes
4.0 Revision and harmonization of the data sheet in accordance with applicable international legislation.

Abbreviations and acronyms:
ATE: Acute Toxicity Estimate. PBT: persistent, bioaccumulative and toxic. vPvB: very persistent, very bioaccumulative. LD50 lethal dose, LC50 Lethal concentration. EC50 Effective concentration. EWC: European Waste Catalog. IARC: International Agency for Research on Cancer. RTECS: Registry of Toxic Effects of Chemical Substances. VOC: Volatile Organic Carbon. PNEC: Predicted no effect concentration. LFL: Lower Inflammatory Limit. UFL: Upper Flammability Limit. LEL lower explosion limit. UEL: Upper explosion limit. STOT: Specific Target Organ Toxicity. LDLo Lethal dose, low. IC50: Inhibitory concentration. SVHC: Substances of very high concern. NOAEL: No-observed-adverse-effect level. LOAEL: Lowest-observed-adverse-effect level

Full text of H-statements from section 2 and 3:
H290 – May be corrosive to metals.
H315 – Causes skin irritation.
H318 – Causes serious eye damage.
H335 – May cause respiratory irritation
H314 – Causes severe skin burns and eye damage.
H319 – Causes serious eye irritation

Precautionary statements:
-

Further training advices:
No information available.

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.

This Safety Data Sheet was prepared on the basis of documentation provided by the manufacturer and complies with the requirements of Regulation (EC) No. 878/2020

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.

No representation, warranty or guarantee, expressed or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.