

INFORMATION DATA SHEET OF HAZARDOUS MIXTURE (IVD CULTURE MEDIA, SUPPLEMENT)

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY

1.1 Product identifiers

Product name (dehydrated media): Lowenstein-Jensen Medium Base

Product name (ready to use media):

Lowenstein-Jensen medium w/o MG w/o G w/o P:	110 x 16 mm: LJM40006-01-AO (6 ml, slant)
Lowenstein-Jensen medium + MG w/o G w/o P:	110 x 16 mm: LJM40006-02-AO (6 ml, slant)
Lowenstein-Jensen medium + MG + G w/o P:	110 x 16 mm: LJM40006-03-AO (6 ml, slant)
Lowenstein-Jensen medium + MG w/o G + P:	110 x 16 mm: LJM40006-04-AO (6 ml, slant)
Lowenstein-Jensen medium + MG + G + P:	110 x 16 mm: LJM40006-05-AO (6 ml, slant)

Code: LJM

Supplement (in ready to use media): Glycerol Supplement (GLC)
Sterile mixed whole egg
Sodium pyruvate
Malachite green

1.2 Relevant identified uses of the mixture

Recommended use: Microbiological diagnostics
(IVD, a medical device under Directive 97/79 / EC)

Uses advised against: No information available

1.3 Details of the supplier of the safety data sheet

Manufacturer/distributor: BIOLAB Inc.
H-1141 Budapest, Öv u. 43. Hungary

Phone: +36-1-221-9614

Fax: +36-1-364-2006

E-mail: export@biolab.hu

1.4 Emergency telephone number

Emergency telephone: Please contact the regional Authority in your country.

2. HAZARDS IDENTIFICATION

Warning!

The hazards data below concern to the dehydrated form of the products only. In case of ready to use media the concentration of the hazardous components (in g/litre) do not exceed the hazard limits of the relevant regulation, therefore they cannot be classified as hazardous substance or mixture according to Regulation (EU) 1272/2008 EK (CLP).

2.1 Classification of substance or mixture

Classification according to Regulation (EU) No 1272/2008 (CLP):

Eye Irrit. 2 H319
Aquatic Chronic 3 H412

2.2 Label elements

Labelling in accordance with Regulation (EU) No 1272/2008 (CLP):

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Signal word: Warning
Hazard Statements: H319, H412
Precautionary Statements: P273, P280, P305+351+338
Full text of H- and P-phrases mentioned above: see in section 16.

Pictograms:



2.3 Other hazards

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

It is not necessary to publish the components.

Harmful components according to Regulation (EU) No. 1272/2008

Components	Classification	Concentration
Malachit green		
CAS-No. 2437-29-8 EU-No. 219-441-7	Acute Tox. Oral 4, Eye Dam. 1, Repr. 2, Aquatic Chronic 1, Aquatic Acute 1; H302, H318, H361D, H410, H400; P273, P280, P301+P310, P305+P351+P338, P308+P313	1,05 %

Full text of the H and P phrases: see in section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice: Consult a physician. Show the label and this safety data sheet to the doctor in attendance. Never administer anything orally to persons who are unconscious.

After inhalation: Remove the victim from exposure and move into open air. Consult a physician.

After skin contact: Remove contaminated clothing. Flush the skin with water, then wash thoroughly with soap and water.

After eyes contact: Rinse out eyes with plenty of clean and cold water while pulling eyelids up, and seek medical assistance.

After ingestion: Rinse the mouth with water and seek immediate medical attention. Never administer anything orally to persons who are unconscious. Never induce vomiting.

4.2 Most important symptoms and effect, both acute and delayed

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

No information available

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing media

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Use water spray, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

In case of fire: Carbon-oxides, nitrogen oxides.

Thermal decomposition can lead to release of irritating gases and vapore.

5.3 Advice for fire-fighters

Wear self contained breathing equipment for firefighting.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid generation of dusts; do not inhale dusts. Provide appropriate exhaust ventilation. Use personal protective clothing.

For personal protection see section 8.

6.2 Environmental precautions

Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and material for containment and cleaning up

Take up dry. Keep in suitable, closed containers for disposal. Clean up affected area.

6.4 Reference to other sections

Refer to protective measures listed in Section 8 and 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid direct contact with the material, spillage, ingestion, eye and skin contact, inhalation. No eating and smoking during working. In the application area, smoking, eating and drinking must be prohibited. Bathing facilities with hot water, emergency douche and eye irrigator have to be ensured. Wash hands after working with the product. Remove contaminated clothing.

7.2 Conditions for safe storage, including any incompatibilities

Store the dehydrated media tightly closed in a dry place at room temperature. Store the bottled media protected from light at room temperature. Store the tubed media protected from light at 2-8 °C.

7.3 Specific end use(s)

Use in laboratories.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

The product does not contain substances with Professional Exposure Environmental Limit Values.

Exposure limits

Allowable workplace concentration (AK) (mg/m³): No information available

Workplace peak concentration: (CK) mg/m³: No information available

Biological exposure: No information available

8.2 Exposure controls

General instructions

Avoid direct contact with the material, spillage, ingestion, eye and skin contact, inhalation. No eating and smoking during working. Bathing facilities with hot water, emergency douche and eye irrigator have to be ensured. Wash hands after working with the product. Remove contaminated clothing.

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Personal protection:	Wear protection clothing, remove the contaminated clothing. Wash hands after working with the substance.
Personal protection equipment:	respirator required (type P1) when dusts are generated
Eye protection:	Wearing protective goggles is recommended against dust and splash. Use eye protection equipment approved by the related standards eg. NIOSH (USA) or EN 166 (EU).
Hand protection:	use disposable gloves (nitrile caoutchouc 0,11 mm, breakthrough time 0,11 mm, breakthrough time > 480 min.), and wash hands after working with this substance

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance (dehydrated medium):	Homogeneous hygroscopic powder
Colour (dehydrated medium):	Greenish
Odor (dehydrated medium):	No information available
pH before autoclaving (25 °C):	7,1 approx.
Appearance (ready to use medium):	Gel
Colour (ready to use medium):	Light green
Odor (ready to use medium):	No information available
pH (ready to use medium, 25 °C):	7,0 – 7,2
Water solubility:	> 38 g/1600 ml
Odor threshold:	No information available
Melting point/range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Flammability range:	No information available
Vapor pressure:	No information available
Vapor density:	No information available
Relative density:	No information available
Partition coefficient (n-octanol/water):	No information available
Autoignition temperature:	No information available
Decomposition temperature:	No information available
Viscosity:	No information available
Explosive properties:	No information available
Oxidizing properties:	No information available

9.2 Other information

No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity

No information available

10.2 Chemical stability

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

No information available

10.4 Conditions to avoid

No information available

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10.5 Incompatible materials

No information available

10.6 Hazardous decomposition products

See details in section 5.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	No information available
Skin irritation/corrosion:	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 component of this product present at levels greater than or equal to 0,1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity:	No information available
STOT – single exposure:	No information available
STOT – repeated exposure:	No information available
Aspiration hazard:	No information available

12. ECOLOGICAL INFORMATIONS

12.1 Toxicity

No information available

12.2 Persistence and degradability

No information available

12.3 Bioaccumulative potential

No information available

12.4 Mobility in soil

No information available

12.5 Results of PBT and vPvB assessment

No information available

12.6. Other adverse effects

Do not dispose of the residue into water, sewage or soil.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Residue is classified as hazardous.

Contaminated packaging: Handle contaminated empty packaging in the same way as the substance itself.

Waste treatment regulations: Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

14.1 UN-number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID:

Not dangerous goods

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IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: no IMDG: no IATA: no

14.4 Packaging

ADR/RID: no IMDG: no IATA: no

14.5 Environmental Hazards

ADR/RID: no IMDG: no IATA: no

14.6 Special precautions for user

No special precautions required

14.7 Transport in bulk according to Annex II of MARPOL and the IBC code

Not applicable, packaged goods

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 1907/2006 (REACH) and 1272/2008 EK (CLP-GHS)

15.2 Chemical safety assessment

There has been no evaluation a chemical safety assessment of the product.

16. OTHER INFORMATION

The last revision of the Safety Data Sheet due to the compliance with 2015/830 EC regulation affected the entire document.

Full text of abbreviations applied in the Safety Data Sheet:

LC₅₀ The concentration of poison in mg / m³ in inhaled air, which kills 50% of the experimental animals during a fixed period of inhalation treatment.

LD (lethal dose) It means fatal dose in case of swallowing and skin absorption.

STOT SE: Specific target organ toxicity - single exposure

PBT: persistent, bioaccumulative and toxic

vPvB: very persistent, very bioaccumulative

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

RID: European Agreement concerning the International Carriage of Dangerous Goods by Road

IMDG: International Maritime Dangerous Goods

IATA: International Air Transport Association

According to 1272/2008 EC (CLP) regulation, Article 1., paragraph 5., point d:

„This regulation do not have to be applied to the following forms of substances and mixtures that are intended for end-users and classified as ready-made articles: (...) **medical devices as defined in Directive 98/79 / EC**”.

The classification of the mixture indicated in 2.1 according to the components and concentrations indicated in section 3.2 of Regulation (EC) No 1272/2008 is based on using a calculation method.

Full text of H and P phrases:

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H302	Harmful if swallowed.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H361D	Suspected of damaging fertility or the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.

Information on further training: no data available.

The datasheet is not a specification, the provided data are not the subject of contract and not the quality specification of the delivered batches.

Please do not hesitate to contact us if you find any errors in our data sheets despite our efforts.

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