

Effective date: 04/10/2026	Hy-Labs Cat. No: TT402	MSDS FORMAT	
Doc. No: MSDS- TT402		MATERIAL SAFETY DATA SHEET	Replace Doc: NA

1- Product and Company Identification

Product Name	LOWENSTEIN - JENSEN (LJ W. GLYC. PACT)
Reference number	TT402
Identified uses	Prepared microbiological culture medium in agar tube format for cultivation and isolation of Mycobacterium species, including members of the Mycobacterium tuberculosis complex, for laboratory in-vitro use only. Not for human or animal consumption.
Manufacturer	Hy-Laboratories Ltd. Park Tamar, Rehovot, 76326, Israel Tel: 972-8-9366475 Fax: 972-8-9366474

2- HAZARDS IDENTIFICATION

GHS Classification (Regulation (EC) No 1272/2008 / GHS): The finished, prepared agar tube (a solid, egg-based coagulated medium) is not classified as a hazardous mixture under GHS/CLP for most hazard classes; Contains malachite green and antimicrobial agents; **Malachite green** is classified Danger — including Aquatic Acute 1 and Aquatic Chronic 1 (very toxic to aquatic life, long-lasting effects). Sensitive individuals may experience irritation or sensitization. Avoid contact with eyes and prolonged or repeated skin contact.

Label elements: No signal word, hazard pictogram, or hazard statement is applied by default to the finished product;

Biological/allergen hazard: This medium contains whole eggs (a major food allergen) as a primary bulk ingredient, and should be handled with awareness of possible allergic sensitivity in personnel. The medium is specifically designed to isolate Mycobacterium tuberculosis and other mycobacteria; once inoculated with a clinical specimen or handling a culture, this must be treated as a significant biohazard requiring Biosafety Level 3 (BSL-3) practices and facilities (or per applicable local regulations for mycobacteria/TB handling) - standard BSL-2 precautions used elsewhere in this product line are NOT sufficient for Mycobacterium tuberculosis.

Antimicrobial supplements: The PACT selective supplement (polymyxin B, amphotericin B, carbenicillin, trimethoprim) raw materials are sensitizers, irritants, or acute-toxicity classified in concentrate; the finished tube contains only trace residues (see Section 3).

3- COMPOSITION/INFORMATION ON INGREDIENTS

This product is a solid, egg-based, coagulated selective culture medium in tubes, prepared from the following components. The formulation is given as supplied per 1600 mL of total medium (600 mL mineral/glycerol/starch/malachite green salt solution + 1000 mL whole eggs); per-liter concentrations are also given for consistency with this SDS series.

A) MINERAL SALT SOLUTION BASE (600 mL per 1600 mL batch)

- 1) L-Asparagine: 3.60 g/1.6L batch (approx. 2.25 g/L). Not classified as hazardous.
- 2) Monopotassium Phosphate (KH₂PO₄): 2.40 g/1.6L batch (approx. 1.50 g/L). Not classified as hazardous.
- 3) Magnesium Sulfate: 0.24 g/1.6L batch (approx. 0.15 g/L). Not classified as hazardous.
- 4) Magnesium Citrate: 0.60 g/1.6L batch (approx. 0.375 g/L). Not classified as hazardous.
- 5) Starch, from Potato: 30.00 g/1.6L batch (approx. 18.75 g/L). Not classified as hazardous.
- 6) Malachite Green (CAS No. 569-64-2): 0.40 g/1.6L batch (approx. 0.25 g/L, 250 mg/L, 0.025% w/v in the finished tube).
- 7) Glycerol: 12.00 g/1.6L batch (approx. 7.5 g/L). Not classified as hazardous, even in concentrated/undiluted form.
- 8) Water (purified/deionized): 600 mL/1.6L batch, solvent/diluent for the salt solution.

B) EGG COMPONENT (1000 mL per 1600 mL batch)

- 9) Whole Eggs (fresh, homogenized): 1000 mL/1.6L batch (approx. 625 mL/L, 62.5% v/v). Biological material; Not classified as a hazardous chemical. Eggs are a recognized major food allergen - personnel with known egg allergy

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should be aware of this content;

C) PACT SELECTIVE ANTIMICROBIAL SUPPLEMENT (added to the 1.6 L batch; standard PACT supplement composition)

10) Polymyxin B: 320,000 IU/1.6L batch (approx. 200,000 IU/L).

11) Amphotericin B: 16 mg/1.6L batch (approx. 10 mg/L).

12) Carbenicillin (as the disodium salt): 160 mg/1.6L batch (approx. 100 mg/L).

13) Trimethoprim: 16 mg/1.6L batch (approx. 10 mg/L).

Overall: With the exception of the malachite green aquatic-hazard question flagged in Section 2, all raw-material contributions in the finished tube are far below standard GHS generic concentration cut-offs for classification of the mixture.

4- First Aid Measures

Eye contact (finished product): Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Seek medical attention if irritation persists.

Skin contact: Wash thoroughly with soap and water. Remove contaminated clothing. Seek medical attention if irritation develops or persists.

Inhalation: Not an expected route of exposure for the finished solid medium. Move to fresh air. Seek medical attention if symptoms occur.

Ingestion: Rinse mouth with water. Do not induce vomiting. Seek medical advice if discomfort occurs or a significant amount of the finished product is swallowed.

Note to physician: Treat symptomatically. If a tube has been inoculated with or is suspected of containing Mycobacterium tuberculosis, any significant exposure (e.g., needlestick, splash to mucous membranes, or aerosol generation) should be managed per your institution's TB/mycobacterial exposure protocol and reported immediately to occupational health.

5- Fire Fighting Measures

The finished, prepared product is a solid, coagulated egg-based medium and is not flammable or readily combustible under normal conditions.

Suitable extinguishing media: Use extinguishing media appropriate to the surrounding fire (water spray/fog, CO2, dry chemical, foam).

Unsuitable extinguishing media: None known.

Specific hazards: None known for the finished product. Heating may produce irritating or hazardous decomposition products, including carbon oxides and nitrogen-containing compounds.

Special protective equipment for firefighters: Use self-contained breathing apparatus and full protective equipment for fires involving surrounding materials.

6- Accidental Release Measures

Personal precautions: Ensure adequate ventilation. Avoid contact with eyes, skin, and mucous membranes. Wear standard laboratory PPE (gloves, lab coat, eye protection). If a tube has been inoculated, treat as a significant biohazard (see Section 2) and follow your institution's mycobacterial spill procedure, which may require specialized containment beyond routine spill cleanup.

Environmental precautions: Prevent spilled material, and especially any malachite green-containing waste, from entering drains, waterways, or soil (malachite green is very toxic to aquatic life with long-lasting effects).

Methods for containment and cleanup: For the finished, uninoculated product, wearing appropriate PPE, collect broken tubes/spilled medium using a scoop or absorbent material and disinfect the area; avoid generating aerosols. For spills involving inoculated/mycobacterial material, follow your institution's specific TB/mycobacterial spill response procedure. Dispose of waste as described in Section 13.

7- Handling and Storage

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Handling: Handle the finished, uninoculated tubes using standard microbiological/good laboratory practice. Avoid contact with eyes, skin, and mucous membranes. Do not ingest. Wash hands after handling. All work with clinical specimens suspected of containing Mycobacterium tuberculosis, or with cultures/isolates from this medium, must be performed in a certified biological safety cabinet within a facility meeting Biosafety Level 3 (BSL-3) requirements (or per applicable local/national mycobacteriology biosafety regulations) - this is a stricter requirement than the BSL-2 precautions used elsewhere in this product line.

Storage: Store prepared tubes tightly closed, in their original packaging, in a slanted position as appropriate, protected from light, as indicated on the product label/certificate of analysis. Typically stored refrigerated (2-8°C) until the labeled expiry date; avoid freezing. Do not use if the medium shows signs of contamination, liquefaction, or discoloration inconsistent with expected appearance.

8- Exposure Controls, Personal Protection

Occupational exposure limits: No specific occupational exposure limits (OEL/TLV) have been established for this finished product or for malachite green specifically.

Engineering controls: Handle the finished, uninoculated product in a well-ventilated area. ALL work with inoculated tubes or mycobacterial cultures must be performed in a certified Class II (or higher) biological safety cabinet within a BSL-3 facility.

Personal protective equipment:

Eye protection: Safety glasses for finished, uninoculated product handling.

Skin protection: Laboratory coat and disposable gloves for finished product handling; Individuals with known antibiotic hypersensitivity (especially to penicillins, given carbenicillin content) should take particular care.

Respiratory protection: Not normally required for handling the finished, uninoculated solid tubes; a NIOSH-approved N95 (or higher) respirator or powered air-purifying respirator (PAPR) is required for work with Mycobacterium tuberculosis cultures/specimens per BSL-3 practice, in addition to engineering controls.

9- Physical and Chemical Properties

Appearance: Solid/slanted agar medium in prepared tubes; green to greenish medium (color from malachite green).

Odor: Faint characteristic odor

pH: Approx. 6.8-7.4

Flammability: Not flammable (solid, predominantly aqueous/proteinaceous matrix)

Solubility: Not applicable (solid, coagulated matrix)

Flash point: Not expected to be flammable as supplied.

Other properties: Not determined for the final prepared product.

10- Stability and Reactivity

Chemical stability: The finished product is stable under normal conditions of storage (refrigerated, protected from light) until the labeled expiry date. Antibiotic potency may decline with prolonged storage, heat, or light exposure.

Possibility of hazardous reactions: No hazardous polymerization is expected. None known for the finished product under normal use.

Conditions to avoid: Freezing, excessive heat (which may cause further coagulation/cracking), prolonged light exposure, and microbial contamination during storage of the finished product.

Incompatible materials: Strong oxidizing agents and conditions that compromise the container or product integrity.

Hazardous decomposition products: None expected under normal conditions of use and storage of the finished product.

11- Toxicological Information

Acute toxicity: The finished product is a low-hazard laboratory culture medium for most raw-material contributions; the malachite green content (approx. 0.025% w/v) is calculated to be below Acute Tox. 4 mixture cut-offs. Contact may cause mild irritation in susceptible individuals. Components such as malachite green and antimicrobial agents may present component-specific toxicological or sensitization hazards. See Section 2 for the

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important caveat regarding aquatic-hazard classification, which is handled separately from acute mammalian toxicity.

Skin/eye irritation, sensitization (finished product): Not expected to be significantly irritating or sensitizing at the concentrations present in the finished tube under normal end-user handling; individuals with known antibiotic allergies (especially penicillin-class) should exercise caution.

Allergen note: This product contains whole egg, a major food allergen; personnel with known egg allergy handling raw egg material during manufacturing should be aware of this.

Biological hazard: This medium is specifically designed to isolate Mycobacterium tuberculosis and other mycobacteria. Any inoculated tube, or handling of resulting cultures, presents a significant infection risk (including via aerosol/droplet transmission) and must be handled under BSL-3 containment per Section 7/8.

12- Ecological Information

Ecotoxicity: The finished product contains malachite green at approx. 0.025% w/v, a substance classified as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1/Chronic 1) in concentrate. Avoid releasing unused/expired medium, or waste tubes to drains, waterways, or soil without appropriate treatment.

Persistence and degradability: Malachite green is known to be environmentally persistent and is not readily biodegradable; the other organic components (egg protein, starch, amino acids) are expected to be biodegradable.

Bioaccumulative potential: Malachite green and its reduced metabolite (leucomalachite green) are known to bioaccumulate in aquatic organisms; this is a property of concern for the raw material and for any significant environmental release of the finished product or manufacturing waste.

Other adverse effects: Dispose of used/inoculated media and all malachite green-containing waste appropriately (see Section 13) to avoid environmental release.

13- Disposal Information

This product is intended to culture Mycobacterium tuberculosis and other mycobacteria; **once inoculated**, tubes must be treated as significant biohazardous waste and handled/decontaminated per your institution's BSL-3/mycobacterial waste procedures (typically autoclaving at validated cycles for mycobacterial inactivation) before further disposal.

Unused/unopened finished product may be disposed of as general laboratory waste in accordance with local regulations, unless local rules require malachite green-containing or antibiotic-containing waste to be handled separately.

Dispose of contents/container in accordance with applicable local, national, and international regulations.

14- Transport Information

Finished product: Not classified as a dangerous good for transport by road (ADR), rail (RID), sea (IMDG), or air (IATA/ICAO) when unused and unopened.

UN Number: Not applicable

UN Proper Shipping Name: Not applicable (finished product)

Transport Hazard Class(es): Not applicable (finished product). Transport in closed, secure containers/tubes, protected from physical damage and temperature extremes.

Packing Group: Not applicable (finished product)

Special precautions: Shipment of tubes inoculated with, or suspected of containing, Mycobacterium tuberculosis is subject to strict biological substance transport regulations (e.g., UN2814, Category A Infectious Substance, or UN3373 Category B depending on risk assessment) and specialized packaging requirements - this must be assessed by qualified personnel before any such shipment.

15- Regulatory Information

The finished product's classification under Regulation (EC) No 1272/2008 (CLP) / GHS is not fully resolved in this document - see the Section 2 note requiring confirmation of malachite green's aquatic-hazard (M-factor) contribution to the finished mixture.

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As this medium is intended for the isolation of Mycobacterium tuberculosis (a reportable/notifiable pathogen in essentially all jurisdictions and a well-recognized serious occupational and public health hazard), users must ensure strict compliance with applicable local biosafety (BSL-3), biosecurity, and public health/TB notification requirements - this is a higher regulatory bar than other products in this SDS series.

For In-Vitro Diagnostic (IVD)/laboratory use only - ensure compliance with applicable local IVD and biosafety regulatory requirements.

Users are responsible for determining any additional applicable regulations for their jurisdiction and intended use.

This MSDS is prepared for the final LOWENSTEIN - JENSEN (LJ W. GLYC. PACT) prepared agar tube product. Users are responsible for determining compliance with applicable GHS/CLP and other local, national and international requirements.

16- Other Information

For In-Vitro use only.

Disclaimer

The information contained in this Safety Data Sheet is believed to be accurate based on the current knowledge of the product and its components. It is intended solely as guidance for the safe handling, storage, use, transport, and disposal of the product and should not be considered a warranty or quality specification. Users are responsible for ensuring compliance with applicable local, national, and international regulations.