AuSaMicS™ Life Science

Technical Data Sheet
AS-1271 | Rev. 2 | May 2026
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Broth, Modified

Catalogue No. AS-1271 **Letheen** · Neutralising Enrichment Broth · Cosmetics & Pharmaceutical QC

Section 1 — Product Identification

Product Name	Letheen Broth, Modified
Synonyms	Modified Letheen Broth; Letheen Broth Base Modified + Tween 80; CASO-Lecithin-Tween Broth
Catalogue Number	AS-1271
Product Format	Dehydrated powder
Dissolution	38 g/L in distilled water
Intended Use	Neutralising enrichment broth for microbiological examination of cosmetics, non-sterile pharmaceuticals, and preserved personal care products. Validated for recovery of organisms in the presence of QAC and phenolic preservatives.
Manufacturer	AuSaMicS Pty Ltd
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Section 2 — Mode of Action & Neutralisation Chemistry

The name "Letheen" is derived from Lecithin and Tween® — the two active neutralising agents that form the basis of this medium. The dual neutralisation system works by different but complementary mechanisms:

Lecithin (Soya Phospholipid, 0.7 g/L):

Lecithin is a phospholipid that inactivates quaternary ammonium compounds (QACs) such as benzalkonium chloride, benzethonium chloride, and cetylpyridinium chloride. QACs are cationic biocides that exert their antimicrobial activity by binding to negatively charged bacterial cell membrane phospholipids. Lecithin competitively binds QACs via its negatively charged phosphate head groups, forming stable non-toxic lecithin-QAC complexes. This prevents the QAC from interacting with test organisms, eliminating false-negative carryover inhibition.

Polysorbate 80 (Tween® 80, 5.0 g/L):

Polysorbate 80 is a non-ionic surfactant that neutralises phenolic disinfectants (phenol, cresols, chlorocresol), hexachlorophene, and parabens. Its polyoxyethylene chains form micelles that encapsulate the hydrophobic phenolic compounds, sequestering them in the micelle interior and preventing them from accessing test organisms. Tween 80 also aids in solubilising lipophilic components from cosmetic formulations that might otherwise inhibit growth.

Sodium Bisulfite (0.1 g/L):

A mild reducing agent that scavenges dissolved oxygen, lowering the oxidation-reduction potential of the broth. This aids recovery of oxidative-stressed organisms and aerotolerant anaerobes that may be present in cosmetic or pharmaceutical samples. Sodium bisulfite also partially neutralises aldehydes (e.g., formaldehyde, glutaraldehyde) if present.

Nutritional Components:

The peptone blend (meat peptone + casein peptone + beef extract + yeast extract) provides a rich nutrient base supporting recovery of both fastidious and non-fastidious organisms including bacteria, yeasts, and moulds that are common cosmetic contaminants (Staphylococcus, Pseudomonas, Candida, Aspergillus, Burkholderia). Dextrose supplements peptone catabolism during initial recovery of stressed organisms.

Section 3 — Composition

Ingredient	g / L	Function	Mechanism
Meat Peptone	20.0	Nitrogen & amino acid source	Enzymatic digest; peptides, amino acids, growth factors
Casein Peptone	5.0	Supplementary nitrogen source	Pancreatic casein digest; rich in tryptophan
Beef Extract	5.0	Carbon, vitamins, minerals	B-vitamins, organic acids, trace elements
Yeast Extract	2.0	Vitamins & co-factors	B-complex vitamins; essential for yeast & mould recovery
Lecithin (Soya)	0.7	QAC neutraliser	Phospholipid; binds & inactivates cationic QACs (e.g. benzalkonium chloride)
Polysorbate 80 (Tween® 80)	5.0	Phenolic neutraliser	Non-ionic surfactant; micellar sequestration of phenolics & hexachlorophene
Dextrose (D-Glucose)	1.0	Fermentable carbon source	Rapid energy source; aids recovery of stressed organisms
Sodium Chloride	5.0	Osmotic balance	Physiological ionic strength maintenance
Sodium Bisulfite	0.1	Reducing agent / antioxidant	Scavenges O_2; partial aldehyde neutralisation
Total	**43.8 g/L**	**Final pH 7.2 ± 0.2 at 25°C**	**Autoclave 121°C / 15 min**

⚠ *Note on lecithin concentration: The original FDA BAM formula specifies lecithin at 0.7 g/L. Some commercial sources list 0.5 g/L. AuSaMicS AS-1271 uses 0.7 g/L in accordance with the FDA BAM Appendix 2 reference formula and ISO 21149:2017 Annex D.*

Section 4 — Preparation

1. Suspend 38 g of dehydrated powder in 1 litre of distilled or deionised water.
2. Mix with gentle warming (45°C) until fully dissolved. A slight opalescence and precipitate is normal due to lecithin.

3. Adjust pH to 7.2 ± 0.2 if required.
4. Dispense into final containers (tubes, bottles, or flasks).
5. Autoclave at 121°C for 15 minutes. Do not over-autoclave — excess heat degrades Polysorbate 80 and reduces neutralisation capacity.
6. Allow to cool before use. Prepared broth should appear slightly opalescent, light to medium amber, with slight precipitate — this is normal and does not affect performance.
7. Inoculation: Add sample at 1:10 dilution. For cosmetics, transfer 1 mL or 1 g sample into 9 mL broth. Incubate at 30–35°C for 48–72 hours (bacteria) or 20–25°C for 5–7 days (yeast and mould).

Section 5 — Quality Control

Organism (ATCC)	Inoculum (CFU)	Incubation	Recovery
Staphylococcus aureus (6538)	*≤100*	*30–35°C / 48–72h*	*Good*
Escherichia coli (8739)	*≤100*	*30–35°C / 48–72h*	*Good*
Pseudomonas aeruginosa (9027)	*≤100*	*30–35°C / 48–72h*	*Good*
Candida albicans (10231)	*≤100*	*20–25°C / 5–7 days*	*Good*
Aspergillus brasiliensis (16404)	*≤100*	*20–25°C / 5–7 days*	*Good*

Dehydrated Appearance: Cream to light beige homogeneous powder.

Prepared Appearance: Slightly opalescent, light to medium amber; slight lecithin precipitate is normal and does not affect performance.

QC also includes: Neutralisation efficacy test against 0.1% benzalkonium chloride (QAC) and 0.5% phenol.

Section 6 — Storage

Dehydrated Powder	15–25°C in tightly sealed container, away from moisture, heat, and direct sunlight
Prepared Broth	2–8°C; use within 4 weeks of preparation. Discard if turbid prior to inoculation.
Shelf Life	Refer to expiry date on label

Section 7 — Regulatory Standards

Letheen Broth, Modified is referenced in and validated against:

· FDA BAM (Bacteriological Analytical Manual) — Appendix 2: Most Probable Number procedures; Cosmetics Chapter for neutralising enrichment

· ISO 21149:2017 — Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria

· ISO 21150:2015 — Cosmetics — Microbiology — Detection of Escherichia coli

· ISO 18415:2017 — Cosmetics — Microbiology — Detection of specified and non-specified microorganisms

· ISO 21148:2017 — Cosmetics — Microbiology — General instructions for microbiological examination

· AOAC Official Methods of Analysis — Methods for quaternary ammonium compound efficacy testing

Section 8 — Literature & References

#	Reference	Relevance
1	FDA. Bacteriological Analytical Manual (BAM). Appendix 2: Most Probable Number from Serial Dilutions. US FDA; updated 2023. [cosmetics.fda.gov/bam]	Primary US regulatory reference for Letheen Broth Modified in cosmetics testing

#	Reference	Relevance
2	International Organization for Standardization. ISO 21149:2017. Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria. Geneva: ISO; 2017.	Primary ISO standard mandating neutralising enrichment for cosmetics
3	International Organization for Standardization. ISO 21150:2015. Cosmetics — Microbiology — Detection of Escherichia coli. Geneva: ISO; 2015.	E. coli detection in cosmetics — specifies Letheen Broth Modified for enrichment
4	Dima S, et al. Evaluation of neutralising agents in microbiological testing of cosmetics. J Appl Microbiol. 2007;102(5):1434–1443.	Validation of lecithin-Tween neutralisation efficacy vs. QACs and phenolics
5	Becton Dickinson. Difco & BBL Manual, 2nd ed. 2009. Letheen Broth, Modified, Cat. 219395.	Reference commercial standard composition and QC criteria

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