

# Product Specification Sheet

*Triple Wrap Sterile Tryptone Soya Agar  
with Lecithin, Polysorbate 80, Sodium Thiosulphate, L-Histidine*

Intended Usage: A general purpose medium, for the microbial control of aseptic processes within manufacturing clean-rooms or isolators, particularly in the pharma/biopharma industry.

For professional use only.

<b>PO5501B</b>	
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**Thermo Scientific™ Triple Wrap Sterile Tryptone Soya Agar  
with Lecithin, Polysorbate 80, Sodium Thiosulphate, L-Histidine**

Form of Product	Poured plate
Storage	2 – 25°C
Filling weight	25 g ± 0.5 g
Packaging	10 plates triple-wrapped in clear film Primary film with moisture control patch, secondary film VHP barrier with immobilised desiccant sachet, tertiary film dust cover, product label incorporates irradiation and VHP exposures indicators
Sterility Assurance Level	10 <sup>-5</sup>
pH	7.3 ± 0.2
Colour	Ivory, transparent
Shelf life	43 weeks
Intended Usage	A general purpose medium, for the microbial control of aseptic processes within manufacturing clean-rooms or isolators, particularly in the pharma/biopharma industry. For professional use only.
Technique	Depends on the different methods. For information see Specification Sheet for Thermo Scientific™ Oxoid™ CM0131.

Typical formulation*	g/l
Tryptone	15.0
Soya peptone	5.0
Sodium chloride	5.0
Polysorbate 80	5.0 ml
Lecithin	0.7
Sodium thiosulfate	0.5
L-Histidine	1.0
Agar	15.0

\*Adjusted as required to meet performance standards.

### Quality Control

1. Control for general characteristics, labeling and printing.
2. Contamination Check
  - ≥ 120 h @ 20 – 25 °C, aerobic
  - ≥ 120 h @ 30 – 35 °C, aerobic
3. Microbiological control

Positive Controls	Growth
<b>Inoculum 10 – 100 colony forming units (cfu), quantitative Incubation conditions: up to 3 days @ 30-35°C, aerobic</b>	
<i>Escherichia coli</i> ATCC® 8739™	2 – 10 mm, cream colonies.
<i>Staphylococcus aureus</i> ATCC® 6538™	1 – 2 mm, cream shiny colonies.
<i>Pseudomonas aeruginosa</i> ATCC® 9027™	3 – 8 mm, green-yellow colonies.
<i>Bacillus subtilis</i> ATCC® 6633™	4 – 8 mm, cream colonies.
<i>Staphylococcus epidermidis</i> ATCC® 12228™	1 mm, cream colonies.
<i>Kocuria rhizophila</i> ATCC® 9341™	0.5 – 0.75 mm, yellow colonies.
<b>Inoculum 10 – 100 colony forming units (cfu), quantitative Incubation conditions: up to 3 days @ 20-25°C, aerobic</b>	
<i>Bacillus subtilis</i> ATCC® 6633™	4 – 8 mm, cream colonies.
<b>Inoculum 10 – 100 colony forming units (cfu), quantitative Incubation conditions: up to 5 days @ 30-35°C, aerobic</b>	
<i>Aspergillus brasiliensis</i> ATCC® 16404™	10 – 30 mm, white mycelium, black spores.
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies.
<b>Inoculum 10 – 100 colony forming units (cfu), quantitative Incubation conditions: up to 5 days @ 20-25°C, aerobic</b>	
<i>Aspergillus brasiliensis</i> ATCC® 16404™	10 – 30 mm, white mycelium, black spores.
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies.

<b>Inoculum 10 – 100 colony forming units (cfu), quantitative</b> <b>Incubation conditions: up to 2 days @ 32°C, anaerobic</b>	
<i>Clostridium sporogenes</i> ATCC® 19404™	Good growth, cream colonies.
Colony counts shall be $\geq$ 50% of the control medium Tryptone Soya Agar or Sabouraud Dextrose Agar.	

Tested in accordance with the methods described in the current United States pharmacopoeia for the microbiological control and monitoring of aseptic processing environments.

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