

OXOID PRO-TECT TRIPLE WRAPPED IRRADIATED CONTACT PLATE**PO0678D****Typical Formula***

	grams per litre
Pancreatic digest of casein	15.0
Enzymatic digest of soya bean	5.0
Sodium chloride	5.0
Agar	15.0

Additions

Sodium thiosulphate	0.5
Lecithin	0.7
L-histidine	1.0
Agar	5.0
Polysorbate 80	5.0 ml

*adjusted as required to meet performance standards

Preparation

Suspend Tryptone Soya Agar (40 grams / litre) in de-ionised water add sodium thiosulphate (0.5 grams / litre), lecithin (0.7 gram / litre), L-histidine (1.0 gram / litre), Agar (5.0 grams / litre) and Tween 80 (5.0 ml / litre) in de-ionised water. Sterilise at 121°C for 15 minutes. Cool and aseptically dispense into 55mm contact plates. Label dishes, wrap and label pack.

Format

Ten 55 mm plates triple wrapped in a nylon film wrap. Each plate is ink-jet printed with (abbreviated) product name, product code, lot number and expiry date.

Labels

Label gives details of product name, product code, recommended storage temperature, lot number and expiry date.

Physical Characteristics

pH	7.3 ± 0.2
Colour	Straw
Clarity	Transparent
Fill weight	13.5 ± 0.675
Irradiation Dose	11.5 – 22.0 kGy

Packaging and presentation

General appearance of packaging and label should be satisfactory. Label data should be correct.

Contamination Check

Macroscopic examination should show no evidence of microbial growth after incubation at 20 - 25°C and 30 - 35°C for 5 days.

Microbiological Tests Using Optimum Inoculum Dilution

Positive controls

Inoculum 10 - 100 colony forming units

Results after incubation at 30-35°C for up to 3 days

<i>Staphylococcus aureus</i>	ATCC®6538	1-3 mm, straw colonies
<i>Escherichia coli</i>	ATCC®8739	3-5 mm, cream colonies
<i>Bacillus subtilis</i>	ATCC®6633	3-9 mm, irregular, straw colonies
<i>Pseudomonas aeruginosa</i>	ATCC®9027	2-5 mm, straw colonies

Results after incubation at 20-25°C for up to 3 days

<i>Bacillus subtilis</i>	ATCC®6633	3-9 mm, irregular, straw colonies
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Results after incubation at 20-25°C for up to 5 days

<i>Candida albicans</i>	ATCC®10231	2-3 mm, cream colonies
<i>Aspergillus brasiliensis</i>	ATCC®16404	10-30 mm, white mycelia, black spores

Results after anaerobic incubation 32°C for up to 2 days

<i>Clostridium sporogenes</i>	ATCC®19404	1-2 mm, grey to cream colonies
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Colony counts shall be equal to or greater than 50% of the control media (Tryptone Soya Agar or Sabouraud Dextrose Agar)

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

Storage conditions

Store away from the light between 2-10°C.

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