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TECHNICAL DATA SHEET

DESCRIPTION TSA AIRCHECK® + N 4W - IRR 4 X WRAP VHP + NEUTS,

DEEP FILL, 90MM PLATES

SGL PRODUCT CODE 5509

Tryptone Soya Agar (TSA), also known as casein soya bean digest agar, is a medium primarily designed to recover a wide range of micro-organisms as described in the European Pharmacopoeia (EP) 2.6.12 and United States Pharmacopeia (USP) <61>. The medium contains a variety of neutralising agents to reduce the growth inhibiting effects of a range of potentially interfering or antimicrobial substances. The 90mm diameter plates are quadruple wrapped and irradiated to ensure sterility and intended for use in cleanroom environments. The deeper fill volume allows for greater exposure times in high air flow areas.

FORMULATION

Typical product composition*:

COMPONENT	WEIGHT / VOLUME
Pancreatic digest of casein	15.0 g
Papaic digest of soya bean	5.0 g
Sodium chloride	5.0 g
Agar	15.0 g
Polysorbate 80	5.0 ml
Lecithin	0.7 g
Histidine	1.0 g
Sodium thiosulphate	0.5 g
Purified water	1000 ml

^{*}Product may be adjusted and/or supplemented to meet performance criteria

QUALITY CONTROL SPECIFICATION

PHYSICAL TESTS	SPECIFICATION CRITERIA
Appearance	Clear, pale straw coloured gel
pH at 20-25°C	7.3 ± 0.2

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 30-35°C for a minimum of 14 days	No growth detected

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GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
Staphylococcus aureus ATCC 6538	50-200% CFU recovery compared to control at
NMT 100 CFU inoculum	30-35°C incubation after not more than 3 days
Pseudomonas aeruginosa ATCC 9027	50-200% CFU recovery compared to control at
NMT 100 CFU inoculum	30-35°C incubation after not more than 3 days
Bacillus subtilis ATCC 6633	50-200% CFU recovery compared to control at
NMT 100 CFU inoculum	30-35°C incubation after not more than 3 days
Candida albicans ATCC 10231	50-200% CFU recovery compared to control at
NMT 100 CFU inoculum	30-35°C incubation after not more than 5 days
Aspergillus brasiliensis ATCC 16404	50-200% CFU recovery compared to control at
NMT 100 CFU inoculum	30-35°C incubation after not more than 5 days

NMT = Not more than

NLT = Not less than

CFU = Colony forming units

Additional specification testing may be performed as requested by the customer.

Manufactured in compliance with ISO 9001 (Ref No FM37824).