



## TECHNICAL DATA SHEET

**DESCRIPTION** TSA SURFACECHECK® P – PENASE IRR 3 X WRAP VHP CONTACT PLATES

**SGL PRODUCT CODE** 5341

Tryptone Soya Agar (TSA) Surfacecheck® P, 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 Penase, a  $\beta$  lactamase designed to inactivate penicillin and allow microbial growth. The contact plates are triple wrapped and irradiated to ensure sterility and intended for use in cleanroom environments predominantly for monitoring the bioburden of flat surfaces where penicillin or other susceptible  $\beta$  lactam antibiotics may be present.

### 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
Penase	250 IU
Purified water	1000 ml

\*Product may be adjusted and/or supplemented to meet performance criteria

### QUALITY CONTROL SPECIFICATION

PHYSICAL TESTS	SPECIFICATION CRITERIA
Appearance	Translucent, pale straw coloured gel
pH at 20-25°C	7.3 $\pm$ 0.3

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 20-25°C for at least 5 days	No growth detected
Incubation at 30-35°C for at least 5 days	No growth detected

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

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NMT = Not more than

NLT = Not less than

CFU = Colony forming units

PENASE ACTIVITY TEST	SPECIFICATION CRITERIA
Neutralisation of Penicillin 250µmol/L	Neutralisation of Penicillin detected

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

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