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TECHNICAL DATA SHEET

DESCRIPTION SDA AIRCHECK® + N, NEUTRALISERS, IRR 3 X WRAP VHP

DEEP FILL, 90MM PLATES

SGL PRODUCT CODE 5382

Sabouraud Dextrose Agar (SDA) is a medium primarily designed to recover yeasts and moulds. The formulation is 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 triple 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
Dextrose	40.0 g
Peptic digest of animal tissue	5.0 g
Pancreatic digest of casein	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	Translucent, pale yellow gel
pH at 20-25°C	5.6 ± 0.4

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 20-25°C for 14 days	No growth detected

GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
Candida albicans ATCC 10231	50-200% CFU recovery compared to control at
NMT 100 CFU inoculum	20-25°C incubation after not more than 5 days
Aspergillus brasiliensis ATCC 16404	50-200% CFU recovery compared to control at
NMT 100 CFU inoculum	20-25°C incubation after not more than 5 days

NMT = Not more than

NLT = Not less than

CFU = Colony forming units

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

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