



TECHNICAL DATA SHEET

DESCRIPTION TRYPTONE SOYA BROTH, BAGGED
SGL PRODUCT CODE BG3661

An enrichment medium also known as casein soya bean digest broth designed to recover a wide range of micro-organisms as described in the European Pharmacopoeia (EP) 2.6.12 and 2.6.13 and United States Pharmacopoeia (USP) <61> and <62>.

The infusion bags have two ports designed for accessing the tryptone soya broth contents. One port is luer-activated and is opened using the stem of a syringe (needlefree). The second port is opened using a hypodermic needle or similar spike device.

FORMULATION

Typical product composition*:

COMPONENT	WEIGHT / VOLUME
Enzymatic digest of casein	17.0 g
Enzymatic digest of soybean	3.0 g
Sodium chloride	5.0 g
Dipotassium hydrogen phosphate	2.5 g
Glucose monohydrate	2.5 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, amber to brown liquid
pH at 20-25°C	7.3 ± 0.2

STERILITY TESTS	SPECIFICATION CRITERIA
Incubation at 20-25°C for 14 days	No growth detected
Incubation at 30-35°C for 14 days	No growth detected

GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
<i>Staphylococcus aureus</i> ATCC 6538 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 days
<i>Pseudomonas aeruginosa</i> ATCC 9027 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 days
<i>Bacillus subtilis</i> ATCC 6633 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 days
<i>Candida albicans</i> ATCC 10231 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 days
<i>Aspergillus brasiliensis</i> ATCC 16404 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 days



GROWTH PROMOTION / INHIBITION TESTS	SPECIFICATION CRITERIA
<i>Escherichia coli</i> ATCC 8739 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 days
<i>Kocuria rhizophila (Micrococcus luteus)</i> ATCC 9341 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 days
<i>Pseudomonas aeruginosa</i> ATCC 27853 NMT 100 CFU inoculum	Growth detected at both 20-25°C and 30-35°C incubation after not more than 3 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) and tested by a UKAS (ISO 17025) accredited laboratory (Ref No. 4356).