

EFFICACY TESTS (EN 1650)
NEWGENN INSTRUMENT DISINFECTANT

NEWGENN RESEARCH LIMITED

SCIENTIFIC SERVICES
MILL FARM
MILL LANE
TUNSTEAD
NORWICH
NR12 8HP

Manufacturer: NewGenn Research Limited,
5 Shepherds Grove Industrial Estate - West,
Stanton,
Bury St. Edmunds,
Suffolk IP31 2AR

Test Products:

NewGenn Instrument Disinfectant

Ingredients - Didecyl dimethyl ammonium chloride
Alkyl dimethyl benzyl ammonium chloride
Cocopropylenediamine guanidinium acetate
Orthophthalaldehyde
pH stabilisers, defoamer

Lot No: 4065

Storage Conditions: Room temperature

Test Organisms *Aspergillus niger* ATCC 16404
(spores)

Candida albicans ATCC 10231
(vegetative)

Test Method and Validation EN1650 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 1).

| | |
|--------------------------------|--|
| Product test concentration | neat (i.e. 80% in the test) |
| Appearance of product dilution | Clear solution |
| Contact time | 1 minute and 15 minutes |
| Test Temperature | 20 C |
| Interfering substance | Bovine albumin 0.3% (dirty solutions) |
| Inhibition method | Dilution neutralisation |
| Neutraliser | Tween 80 10%, Lecithin 3 %, Sodium thiosulphate 0.5% Cystine 0.1 % Histidine 0.1 % |

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN1650)

Summary of test method

The test method is described in EN1650 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional area (Phase 2, step 1). Copies of EN 1650 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves mixing 1ml of the test fungi with 1ml of soil (albumin), and then adding 8ml of disinfectant solution. After the contact time, 1ml is removed and added to 9ml of recovery/neutraliser solution which is then plated out to detect surviving organisms.

Fungicidal activity of NewGenn Instrument Disinfectant

Using Phase 2 step 1 Suspension Test EN1650

Dirty conditions (0.3% albumin)

(Test carried out in duplicate)

| Test Organism | Contact time | Log 10 initial count (challenge) Mean | Log 10 reductions achieved Mean |
|--------------------------------|--------------|--|---------------------------------------|
| Candida albicans | 1 min | 6.51 | > 5.51 |
| | 15 min | 6.51 | > 5.51 |
| Aspergillus niger (spores) | 1 min | 6.23 | 3.24 |
| | 15 min | 6.23 | 4.53 |

To satisfy the requirements of this test a > 4log(10) reduction in test fungi is required within 15 minutes

Conclusion

NewGenn Instrument Disinfectant, when tested under dirty conditions as specified in EN1650 complies with the criteria for acceptance (> 4 log (10) reduction in 15 minutes) in 1 minute and 15 minutes against *Candida albicans*, and at 15 minutes against *Aspergillus niger* spores, but fails at 1 minute against *Aspergillus niger* spores.

A handwritten signature in black ink on a light green background. The signature is cursive and appears to read 'KM. Self'.

KM. Self, M.B.I.C.Sc.,M.R.S.H.
Proprietor

25th June 2004