TUBERCULOCIDAL EFFICACY TESTS
EN 14348 – PHASE 1 STEP 2

DIFFICIL-S

Clinimax Ltd

HOSPITAL INFECTION RESEARCH LABORATORY
CITY HOSPITAL
DUDLEY ROAD
BIRMINGHAM B18 7QH

November 2007

MANUFACTURER

Clinimax Ltd
Shepards Grove West,
Stanton,
Bury St. Edmonds,
Suffolk.
IP31 2AR

TEST PRODUCTS

DIFFICIL-S Part A:

Ingredients – Sodium chlorite (>30%), Disodium hydrogenorthophosphate, Sodium dodecyl sulphate and Sodium carbonate.

DIFFICIL-S Part B:

Ingredients – Citric acid monohydrate and sodium dichlorocyanurate dehydrate.

The test product comprises the mixture of Part A and Part B (sachets of at least 12.5g each) into 10L water.

Lot number: Part A: 50221A **Expiry Date**: 09/2009
Part B: 50221B **Expiry Date**: 09/2009

STORAGE CONDITIONS

Room temperature, in a dry place out of direct sunlight.

TEST ORGANISMS

Mycobacterium terrae NCTC 10856

TEST METHOD AND VALIDATION

EN 14348 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the medical area including instrument disinfectants (Phase 2, step 1).

PRODUCT TEST CONCENTRATION

1.25x supplied

APPEARANCE PRODUCT

Clear green solution

CONTACT TIMES

5, 10, 15 and 60 minutes

TEST TEMPERATURE

20°C

INTERFERING SUBSTANCE

Bovine albumin:-

Clean conditions - 0.03 % albumin (final concentration)

Dirty conditions - 0.3 % albumin (final concentration) plus 3% washed sheep erythrocytes

INHIBITION METHOD

Dilution/neutralization

NEUTRALIZER

Double strength Nutrient Broth

Tests were performed to establish the suitability of this neutralizer in inhibiting the activity of the disinfectant without being toxic to the test organisms (method described in EN 14348).

SUMMARY OF TEST METHOD

The disinfectant was prepared in accordance with EN14348, in sterile hard water, immediately prior to testing.

The EN 14348 test method involves mixing 1 ml of the test bacteria with 1 ml of soil (0.3% or 3% albumin) and then adding 8 ml of test disinfectant. After the required contact time, 1 ml is removed to 9 ml of recovery broth (8ml neutralizer and 1ml diluent), which is then plated onto 7H11 selective media, to detect surviving test bacteria.

REQUIREMENT

The test product when tested in accordance with the test methodology described under simulated clean and dirty conditions shall demonstrate at least a 4 $\log_{10}$ reduction in 60 minutes.

RESULTS

TUBERCULOCIDAL ACTIVITY USING PHASE 2 STEP 1 SUSPENSION TEST EN 14348

(All tests carried out in duplicate)

$\log_{10}$ Initial Count (Challenge)	**Contact Time**	**$\log_{10}$ Reduction Achieved**					
		Clean Conditions (0.3 % Albumin)			**Dirty Conditions** (3 % Albumin)		
		Test 1	**Test 2**	**Mean**	**Test 1**	**Test 2**	**Mean**
8.31	5 mins	>7.31	>7.31	**>7.31**	>7.31	>7.31	**>7.31**
	10 mins	>7.31	>7.31	**>7.31**	>7.31	>7.31	**>7.31**
	15 mins	>7.31	>7.31	**>7.31**	>7.31	>7.31	**>7.31**
	60 mins	>7.31	>7.31	**>7.31**	>7.31	>7.31	**>7.31**

To meet the requirements of EN14348 a >4 $\log_{10}$ reduction of the test bacteria within 60 minutes is required.

CONCLUSION

'DIFFICIL-S' demonstrates tuberculocidal activity at 20°C under clean (0.03% albumin) and dirty (0.3% albumin/0.3% sheep erythrocytes) conditions. A >4 log_{10} (99.99%) reduction was achieved with the test organism, *Mycobacterium terrae*.

In accordance with EN14348 a >4 Log_{10} reduction of the test bacteria within 60 minutes is required. This was achieved after a contact time of 5 minutes; therefore 'DIFFICIL-S' meets the test criteria and passes the test.

Testing by the Hospital Infection Research Laboratory does not imply approval or endorsement of this product.

.....
CR Bradley
Laboratory Manager

.....
K Chana
Biomedical Scientist

.....
Dr AP Fraise
Director