

**ASSESSMENT OF THE ACTIVITY OF
DUO MAX +
AGAINST
*CLOSTRIDIUM DIFFICILE***

DUO TECH LTD

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MANUFACTURER

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TEST PRODUCTS

Duo Max +

Lot number:

Not Stated

Expiry Date:

Not Stated

STORAGE CONDITIONS

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

TEST ORGANISM

Clostridium difficile NCTC 11209

TEST METHOD AND VALIDATION

No European Phase 2/ Step 1 test has as yet been described to establish sporicidal activity of chemical disinfectants against *Clostridium difficile* in the medical area. The only Phase 2/ Step 1 test published to date is EN 13704 which is designated for food, domestic and industrial areas. This test looks for a 3 log₁₀ reduction in 60 minutes under clean conditions only. The test product Duo Max + was tested against *C. difficile* spores using the test conditions i.e. temperature, organic load, described in other Phase 2/ Step 1 tests for the medical area.

PRODUCT TEST CONCENTRATION

As supplied by the manufacturer

CONTACT TIMES

5 and 60 minutes

TEST TEMPERATURE

20°C

INTERFERING SUBSTANCE

Clean conditions - 0.03% w/v bovine albumin (final concentration)

Dirty conditions - 0.3% w/v bovine albumin (final concentration) plus 0.3% v/v washed sheep erythrocytes (final concentration).

INHIBITION METHOD

Dilution/neutralization

NEUTRALIZER

Tween 80, 30g/l; saponin, 30g/l; lecithin, 3g/l; sodium thiosulphate, 5g/l; sodium lauryl sulphate, 5g/l; L-histidine, 1g/l; L-cysteine, 1g/l; sodium chloride, 8.5g/l; tryptone, 1g/l.

Tests were performed to establish the suitability of the neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms (method described in EN 1276). The above neutralizer was found to be suitable, with an additional dilution step, when

Tryptone Soya Agar supplemented with 7% v/v sheep blood, 0.1% w/v lecithin and 0.5% v/v Tween 80 was used.

SUMMARY OF TEST METHOD

A suspension of *Clostridium difficile* was prepared, containing at least 10^7 viable spores/ml. The EN 13704 test method involves mixing 1ml of the test bacteria with 1ml of soil (0.3% w/v albumin or 3% w/v albumin plus 3% v/v sheep erythrocytes) and then adding 8 ml of test disinfectant. After the required contact time, 0.1 ml is removed to 9.9 ml of recovery broth (8.9ml neutralizer and 1ml water). Surviving test bacteria were detected by plating onto Tryptone Soya Agar supplemented with 7% v/v sheep blood, 0.1% w/v lecithin and 0.5% v/v Tween 80, and incubated anaerobically for 3 -5 days.

REQUIREMENT

The test requirements for EN 13704 (Phase 2 Step 1 sporicidal test) is for a 3 log₁₀ reduction in 60 minutes.

RESULTS

SPORICIDAL ACTIVITY OF DUO MAX + UNDER CLEAN AND DIRTY CONDITIONS

(All tests carried out in duplicate)

Log ₁₀ Initial Count (Challenge)	Contact Time	Log ₁₀ Reduction Achieved					
		Clean Conditions (0.03% Albumin)			Dirty Conditions (0.3% Albumin plus 0.3% Sheep erythrocytes)		
		Test 1	Test 2	Mean	Test 1	Test 2	Mean
6.10	5 min	>5.10	>5.10	>5.10	>5.10	>5.10	>5.10
	60 min	>5.10	>5.10	>5.10	>5.10	>5.10	>5.10

CONCLUSION

Tests carried out with Duo Max + demonstrated a $>5 \log_{10}$ reduction against spores of *Clostridium difficile* at 20°C under clean and dirty (0.03% w/v albumin; 0.3% w/v albumin and 0.3% v/v sheep erythrocytes) conditions.

Published EN tests for sporicidal activity i.e. EN 13704 have a requirement for a 3 $\log_{10}$ reduction in 60 minutes. This was achieved after both contact times ie 5 and 60 mins and under clean and dirty conditions. Therefore, Duo Max + meets the test criteria.

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

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