

SPORICIDAL EFFICACY TEST
Clinell Sporicidal Wipes

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MANUFACTURER

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TEST PRODUCTS

‘Clinell Sporidal Wipes’ A57

Ingredients – sodium percarbonate and tetra acetyl ethylene diamine.

Clinell sporicidal wipes comprise of a dry cellulose based non-woven Airtex, laminated together with EVA adhesive and the powdered particles of the active ingredients stated above.

Batch number: Not Stated

Lot number: Not Stated

STORAGE CONDITIONS

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

TEST ORGANISMS

Bacillus subtilis var niger NCTC 10073 (UK chemical sterilization validation test strain).

TEST METHOD AND VALIDATION

European phase 2 tests to establish sporicidal activity have not yet been agreed. The suspension test used here was first described by *Babb JR, Bradley CR, Ayliffe GAJ (1980) Sporicidal activity of glutaraldehydes and hypochlorites and other factors influencing their selection for the treatment of medical equipment. Journal of Hospital Infection 1: 63-75.*

TEST CONCENTRATION

Not Applicable

APPEARANCE PRODUCT

Clear solution

CONTACT TIMES

30 seconds, 1, 2 and 5 minutes

TEST TEMPERATURE

20 °C

INTERFERING SUBSTANCE

Bovine albumin:-

1 % Horse serum (dirty conditions)

INHIBITION METHOD

Dilution/neutralization

NEUTRALIZER

Tween 80 (30g/L); Sodium lauryl sulphate (4g/L); Lecithin (3g/ L); Saponin (30g/L); Histidine (1g/L) and Sodium thio-sulphate (5g/L).

Tests were performed to establish the suitability of this neutralizer in inhibiting the activity of the disinfectant without being toxic to the test organisms.

SUMMARY OF TEST METHOD

No standard test method exists for wipes therefore the following test was carried out on the disinfectant impregnated into the wipes. The disinfectant was extracted from the wipes in accordance to manufacturers' instruction, immediately prior to testing.

The disinfectant was extracted by soaking a wipe of approx 30cm by 20 cm with 75ml of standard hard water. Wearing gloves, the wipe was squeezed to release the solution. The solution was allowed to be reabsorbed on to the wipe and the process repeated three more times. This solution was then used for testing.

A suspension of *Bacillus subtilis var niger* containing $> 10^8$ spores/ ml, was heat shocked (80°C for 1 min) to eliminate non-sporing organisms.

The test method involves adding 1 ml of the test organism to 9 ml of disinfectant. The mixture was gently swirled to mix and, at the specified time intervals, 1 ml was removed into added to 9 ml of recovery/neutralizer broth. This was mixed thoroughly and 10 fold diluted in quarter strength Ringers solution. The recovery broths and dilutions were plated onto tryptone soya agar plates, incubated for 18 hours at 37°C and examined for surviving test organisms.

The test was repeated in the presence of 10% horse serum (dirty conditions). This gives a final concentration of 1% horse serum in the disinfectant/spore mixture.

RESULTS

Sporicidal Activity Of The Disinfectant In ‘Clinell Sporidical Wipes A57’

(All tests carried out in duplicate)

Log ₁₀ Initial Count (Challenge)	Contact Time	Log ₁₀ Reduction Achieved					
		Clean Conditions			Dirty Conditions (1% serum)		
		Test 1	Test 2	Mean	Test 1	Test 2	Mean
7.75	1 min	>6.75	>6.75	> 6.75	5.54	6.97	6.25
	2 mins	>6.75	>6.75	> 6.75	>6.75	>6.75	> 6.75
	5 mins	>6.75	>6.75	> 6.75	>6.75	>6.75	> 6.75
	10 mins	>6.75	>6.75	> 6.75	>6.75	>6.75	> 6.75
	20 secs	>6.75	>6.75	> 6.75	>6.75	>6.75	> 6.75
	30 min	>6.75	>6.75	> 6.75	>6.75	>6.75	> 6.75
	60 mins	>6.75	>6.75	> 6.75	>6.75	>6.75	> 6.75

A >6 log₁₀ reduction is required for satisfactory sporicidal activity.

CONCLUSION

The disinfectant in the 'Clinell Sporocidal Wipes A57' successfully satisfies the requirements of the test, i.e. at least a $> 6 \text{ Log}_{10}$ reduction when the disinfectant is tested at its intended use dilution.

This was successfully achieved within 5 minutes under both clean and dirty conditions and therefore the disinfectant in the 'Clinell Sporocidal Wipes A57' achieves satisfactory sporicidal efficacy.

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

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