

**VIRUCIDAL EFFICACY TESTS
EN 14476 (PHASE 2, STEP 1)
CLINELL SPORICIDAL WIPES**

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MANUFACTURER

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TEST PRODUCT

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 VIRUSES

Non-enveloped RNA virus Picornavirus group – poliovirus type 1, LSc-2ab

Non-enveloped DNA virus Adenovirus group – adenovirus type 5, strain Adenoid
75, ATCC VR-5

TEST METHOD AND VALIDATION

EN 14476:(2005) Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants used in the human medicine. (Phase 2, step 1).

Copies available from BSI, 389 Chiswick High Road, London W4 4AL.

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 log₁₀ reduction in the obligatory contact time of 60 mins. Additional contact times may be selected.

PRODUCT TEST CONCENTRATION

Not Applicable

APPEARANCE PRODUCT

Clear 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. The cytotoxic effect to the cells was determined as described in section 6.6.4.

SUMMARY OF TEST METHOD

The disinfectant was extracted from the wipes in accordance with the manufacturers' instructions, 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.

EN 14476: - This test method involves mixing 1 ml of the test virus with 1 ml of soil (0.3% albumin – clean conditions or 3% albumin with 3% freshly triple washed and spun sheep erythrocytes – dirty conditions), and then adding 8 ml of the test disinfectant. After the required contact time, 0.5 ml is removed to 4.5 ml of Eagles Minimal Essential Medium (MEM) plus 2% foetal calf serum which is then sampled to detect surviving test virus.

RESULTS

VIRUCIDAL ACTIVITY USING PHASE 2 STEP 1 SUSPENSION TEST EN 14476

Log₁₀ counts/reductions achieved in 5, 10, 15 and 60 minutes at 20°C

(Tests carried out in duplicate – figures expressed are the mean of two test results)

| log TCID ₅₀ after | | | | | | | | | |
|------------------------------|-------------------|-------------------------------------|------------|------------|----------------|--|----------------|----------------|----------------|
| Test virus | | Clean conditions (0.03% albumin) | | | | Dirty conditions (0.3% albumin/0.3% sheep erythrocytes) | | | |
| | | 5min | 10 min | 15 min | 60min | 5min | 10 min | 15 min | 60min |
| Adenovirus | Pre count | 5.3 | 5.7 | 5.3 | 5.1 | 5.3 | 5.7 | 5.3 | 5.1 |
| | Post count | 0.7 | 0.7 | 0.7 | 0.7 | 0.7 | 0.7 | 0.9 | <0.5 |
| | Log RF | 4.6 | 5.0 | 4.6 | 4.4 | 4.6 | 5.0 | 4.4 | >4.6 |
| Poliovirus | Pre count | 5.3 | 5.9 | 5.9 | 5.7 | 5.3 | 5.9 | 5.9 | 5.7 |
| | Post count | 2.3 | 2.5 | 1.9 | <1.5 | 2.1 | <1.5 | <1.5 | <1.5 |
| | Log RF | 3.0 | 3.4 | 4.0 | >4.2 | 3.2 | >4.4 | >4.4 | >4.4 |

CONCLUSION

When tested in accordance with EN 14476 (2005), the disinfectant contained within the 'Clinell Sporocidal Wipes A57' successfully satisfies the requirements of the test ie possesses virucidal activity at 20°C when tested under clean conditions (0.03% albumin) and dirty conditions (0.3% albumin and 0.3% sheep erythrocytes). A $>4 \log_{10}$ (99.999%) reduction was achieved with both test viruses ie adenovirus and poliovirus within the mandatory contact time of 60 mins.

A $>4 \log_{10}$ reduction with adenovirus was achieved in 5 mins under clean conditions and 10 minutes under dirty conditions and a 15 min contact time with poliovirus under clean and and 10 mins under dirty conditions.

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

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