

TUBERCULOCIDAL TESTING
using the methodology described in EN
14348
(PHASE 2, STEP 1)

TEKNON BIOCLEANSE CONCENTRATE
TK200

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MANUFACTURER

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TEST PRODUCT

Teknon Biocleanse Concentrate

TK 200

LOT NUMBER

Not stated

EXPIRY DATE

Not stated

TEST ORGANISMS

Mycobacterium tuberculosis H37 Rv NCTC 7146

EN 14348 states *Mycobacterium terrae* as the surrogate test organism for demonstrating tuberculocidal activity. However, Quadralene requested that the testing used *Mycobacterium tuberculosis*.

TEST METHOD AND VALIDATION

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

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 mandatory contact time of 60 mins.

Product test concentration

5%

Appearance product dilution

Clear Blue Solution

Contact time	5, 10, 15 and 60 minutes
Test temperature	20 ⁰ C
Interfering substance	Bovine albumin 0.03% clean conditions Bovine albumin 0.3% and sheep erythrocytes 0.3% dirty conditions
Inhibition method	Dilution/neutralization
Neutralizer	Tween 80 30g/l, Lecithin 3g/l, Sodium lauryl sulphate 4g/l. Tests were performed to establish the suitability of this neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms. This neutralizer was found to be suitable.

SUMMARY OF TEST METHODS

The test method involves mixing 1 ml of the test bacteria with 1 ml of soil and then adding 8 ml of disinfectant. After the required contact time, 1 ml is removed to 9 ml of recovery/neutralizer, which is then plated to detect surviving test bacteria.

RESULTS

TUBERCULOCIDAL ACTIVITY OF TEKNON BIOCLEANSE USING PHASE 2

STEP 1 SUSPENSION TEST EN 14348

Log₁₀ counts/reductions achieved

(Tests carried out in duplicate)

Test organism Myco. tuberculosis NCTC 7416	Log ₁₀ initial count	Contact time			
		5 mins	10 mins	15 mins	60 mins
Clean conditions	6.79	3.32	3.43	5.47	>5.79
Dirty conditions	6.79	3.26	3.16	5.56	>5.69

* A contact time of 60 mins is stated in EN 14348. However 5, 10 and 15 min contact times were commissioned by Quadralene Ltd as more relevant for in use conditions. The tests carried out were therefore, more stringent.

CONCLUSION

When tested using the methodology described in EN 14348, a 5% solution of Teknon Biocleanse at 20°C demonstrated a $>4 \log_{10}$ (99.99%) reduction with *Mycobacterium tuberculosis* in 15 mins under clean (0.03% albumin) and dirty (0.3% albumin) conditions. To satisfy the requirements for the test, at least a $4 \log_{10}$ reduction is required within 60 mins when the disinfectant is tested at its intended use dilution(s). Teknon Biocleanse when tested at 5%, therefore, satisfies the requirements of the test.

Performance under light (clean) and moderate to heavy (dirty) soiling was assessed. The presence of soil does not appear to affect the performance of the product.

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Christina Bradley
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Dr Adam P Fraise
Director