



Abbott Analytical



Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Sample(s): One sample of Remuvit Concentrate

Received from: Klenitise Ltd. 14 Cherry Grove, Sketty, Swansea, SA2 8AS

Date received: 16 May 2011 **Date tested:** 18 May 2011

Certificate no: 11E.040S-KR.CLE **Certificate date:** 20 May 2011

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Analysis required: EN 13704, Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in human medicine, veterinary field, and food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)

Product stored at: Room temperature

Active substance: Not declared

Test conditions: Dirty

Interfering substance: 3.0g/l bovine albumin +
3.0ml/l sheep erythrocytes

Product test concentration: 20% v/v

Product diluent used during test: Sterile hard water 300mg/l CaCO₃

Contact time: 60 minutes

Test temperature: 20°C ± 0.5°C

Neutralising solution: 30g/l polysorbate 80, 3g/l lecithin,
1g/l histidine, 1g/l cysteine

Incubation temperature: 30°C ± 1°C

Identification of bacterial strain(s) used: *Bacillus subtilis* ATCC 51189
(was *globigii*)
Bacillus cereus ATCC 12826

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Test results:

| Test Organism | <i>Bacillus globigii</i> | | <i>Bacillus cereus</i> | |
|-----------------------------------------|--------------------------------|---------|--------------------------------|---------|
| Validation Suspension (N _v) | Vc1 258 | Vc2 300 | Vc1 236 | Vc2 268 |
| | $\bar{x} = 279$ | | $\bar{x} = 252$ | |
| Experimental Control (A) | Vc1 272 | Vc2 260 | Vc1 222 | Vc2 204 |
| | $\bar{x} = 266 \geq 0.5N_{v0}$ | | $\bar{x} = 213 \geq 0.5N_{v0}$ | |
| Neutraliser Control (B) | Vc1 284 | Vc2 246 | Vc1 216 | Vc2 235 |
| | $\bar{x} = 265 \geq 0.5N_{v0}$ | | $\bar{x} = 226 \geq 0.5N_{v0}$ | |
| Method Validation (C) | Vc1 270 | Vc2 254 | Vc1 206 | Vc2 228 |
| | $\bar{x} = 262 \geq 0.5N_{v0}$ | | $\bar{x} = 217 \geq 0.5N_{v0}$ | |
| Test Suspension | 10 ⁻⁴ Vc1 208 | Vc2 234 | Vc1 186 | Vc2 244 |
| | 10 ⁻⁵ Vc1 35 | Vc2 43 | Vc1 24 | Vc2 27 |
| (N) | $\bar{w} = 2.36 \times 10^6$ | | $\bar{w} = 2.19 \times 10^6$ | |
| (N ₀ = 0.1N) | lg N = 6.37 | | lg N = 6.34 | |
| | lg N ₀ = 5.37 | | lg N ₀ = 5.34 | |
| Results 10 ⁰ | Vc1 <14 | Vc2 <14 | Vc1 <14 | Vc2 <14 |
| | 10 \bar{x} < 140 | | 10 \bar{x} < 140 | |
| (Na) | lg Na < 2.15 | | lg Na < 2.15 | |
| (R) | lg R > 3.23 | | lg R > 3.19 | |
| Pass: lg R \geq 3 | PASS | | PASS | |

Vc = plate count per ml

\bar{x} = average of Vc1 and Vc2

\bar{w} = weighted mean of \bar{x}

R = reduction (lg R = lg N₀ - lg Na)

Conclusion:

This batch of Remuvit Concentrate, when diluted to 20% v/v, passes the requirements of EN 13704 for sporicidal activity in 60 minutes at 20°C under dirty conditions against the reference organisms detailed.

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