

TUBERCULOCIDAL EFFICACY TEST

EN 14348 – PHASE 2 STEP 1

**HYCOLIN CLEANER DISINFECTANT
(COVGUARD CONCENTRATE)**

COVENTRY CHEMICALS Ltd

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MANUFACTURER

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TEST PRODUCT

Hycolin Disinfectant Cleaner (also known as Covguard Concentrate)

Ingredients – alkyl dimethyl benzyl ammonium chloride, fatty alcohol ethoxylate and tetrasodium EDTA

Batch number: Not Stated

Lot number: Not Stated

STORAGE CONDITIONS

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

TEST ORGANISMS

Mycobacterium tuberculosis NCTC 7416

The prescribed test organism in EN 14348 is *Mycobacterium terrae*. However, testing against *M. tuberculosis* was requested.

TEST METHOD AND VALIDATION

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

PRODUCT TEST CONCENTRATION

5%

APPEARANCE PRODUCT

Light blue solution

CONTACT TIMES

5, 10, 15 and 60 minutes

TEST TEMPERATURE

20 °C

INTERFERING SUBSTANCE

Clean conditions - 0.03 % albumin (final concentration)

Dirty conditions - 0.3 % albumin (final concentration) plus 3% washed sheep erythrocytes

INHIBITION METHOD

Dilution/neutralization

NEUTRALIZER

Tween 80 (30g/L); Sodium Lauryl Sulphate (4g/L); Lecithin (3g/ 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 (method described in EN 14348).

SUMMARY OF TEST METHOD

The EN 14348 test method involves mixing 1 ml of the test bacteria with 1 ml of soil (0.3% or 3% albumin) and then adding 8 ml of test disinfectant. After the required contact time, 1 ml is removed to 9 ml of recovery broth (8ml neutralizer and 1ml diluent), which is then plated onto 7H11 selective media, to detect surviving test bacteria.

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 60 minutes.

RESULTS

TUBERCULOCIDAL ACTIVITY OF 5% HYCOLIN CLEANER DISINFECTANT (COVGUARD CONCNETRATE) USING PHASE 2 STEP 1 SUSPENSION TEST EN 14348

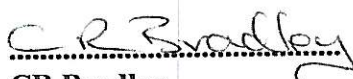
(All tests carried out in duplicate)


Log ₁₀ Initial Count (Challenge)	Contact Time	Log ₁₀ Reduction Achieved					
		Clean Conditions (0.03 % Albumin)			Dirty Conditions (0.3 % Albumin)		
		Test 1	Test 2	Mean	Test 1	Test 2	Mean
7.70	5 mins	2.53	2.36	2.45	2.22	2.31	2.27
	10 mins	2.53	2.38	2.45	2.44	2.29	2.32
	15 mins	2.40	2.40	2.40	2.29	-	2.29
	60 mins	5.10	4.92	5.01	4.62	4.53	4.53

CONCLUSION

To comply with the requirements of EN14348 a $>4 \text{ Log}_{10}$ reduction of the test bacteria within 60 minutes is required. Hycolin Cleaner Disinfectant (Covguard Concentrate) tested at 5% meets this requirement and passes the test.

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


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CR Bradley
Laboratory Manager


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Dr AP Fraise
Director