



FINAL REPORT

KILL TIME STUDY

PROTOCOL NO. 200509407-01

LABORATORY NO. 288171A.1 AMENDED

PREPARED FOR:

BILL MOELLER
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KILL TIME STUDY

LABORATORY NUMBER:	288171A.1 Amended
PROTOCOL NUMBER:	200509407-01
SAMPLE SOURCE:	American Biotech Labs
SAMPLE IDENTIFICATION:	Sample 1: ASAP-AGX-32, Sample 2: 7ppm modified to 32 ppm, Sample 3: 10 ppm modified to 32 ppm produced by the new method, Sample 4: 100 ppm new method (105.1ppm actual), and Sample 5: ASAP Solution 10 ppm
DEVIATIONS:	Yes; refer to text
DATA ARCHIVE LOCATION:	Sequentially by lab number
PROTOCOL APPROVAL DATE:	06 Apr 2005
SAMPLE RECEIVED DATE:	29 Mar 2005
LAB PHASE START DATE:	06 Apr 2005
LAB PHASE COMPLETION DATE:	31 May 2005
REPORT ISSUE DATE:	31 May 2005
STUDY COMPLETION DATE:	10 Jun 2005
AMENDMENT JUSTIFICATION:	09 Sep 2005
TOTAL NUMBER OF PAGES:	10

AMENDMENT JUSTIFICATION:

At the request of the sponsor, the organisms were separated into A and B reports. The A report contains the yeast and mold and the B report contains the bacteria.

REFERENCES:

AOAC International. 2000. Official Methods of Analysis. Volume I, Chapter 6, Disinfectants. AOAC International, Gaithersburg, MD.

Manual of Clinical Microbiology, 6th ed. American Society for Microbiology, Washington D.C.

United States Pharmacopeia 28 & National Formulary 23. 2005. United States Pharmacopeial Convention, Inc., Rockville, MD.

SAMPLE PREPARATION:

Samples were tested as received without any additional dilution or manipulation.



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ACCEPTANCE CRITERIA:

Positive controls must demonstrate a titer of $\geq 10^5$ CFU/mL. Negative controls must not show any growth of the test organism. Percent neutralization for each dilution of product must be $\geq 70\%$.

Negative controls did not show growth of the test organism.

RESULTS:

All testing was performed in accordance with protocol #200509407-01 except for deviations noted. *C. albicans* was incubated for an additional 7.2 hours beyond the 5 days specified in protocol; however, colonies were still countable. The percent reduction and log reduction results for each disinfectant concentration can be found in Table 1-4. The percent neutralization recoveries are shown in Table 5.

ESTIMATED STATEMENT OF UNCERTAINTY:

The samples analyzed were not collected by the laboratory and therefore the representative nature of the samples is not included in the uncertainty assessment. The uncertainty of this test is based on the standard deviation of the Nelson Laboratories, Inc.'s general plate count proficiency test data. The combined standard uncertainty is 0.05 log units. The expanded uncertainty for plate count, at a 95% confidence level, is 0.10 log units.



Bryan E. Wilson, B.S. RM(NRM)
Study Director



Amended Report Date

KH/smp

TABLE 1. Results
Trichophyten mentagrophytes ATCC #9533

SAMPLE IDENTIFICATION	EXPOSURE INTERVALS	AVERAGE CONTROL TITER (CFU/mL)	AVERAGE RECOVERED (CFU/mL)	PERCENT REDUCTION (%)	LOG ₁₀ REDUCTION
Sample 1: ASAP-AGX-32	10 minutes	4.8 x 10 ⁶	8.5 x 10 ⁴	98.2	1.75
Sample 2: 7ppm modified to 32 ppm	10 minutes	4.8 x 10 ⁶	7.0 x 10 ⁴	98.5	1.84
Sample 3: 10 ppm modified to 32 ppm produced by the new method	10 minutes	4.8 x 10 ⁶	2.3 x 10 ⁵	95.3	1.33
Sample 4: 100 ppm new method (105.1ppm actual)	10 minutes	4.8 x 10 ⁶	<2.0 x 10 ¹	>99.99958	>5.38
Sample 5: ASAP Solution 10 ppm	10 minutes	4.8 x 10 ⁶	1.5 x 10 ⁶	69	0.51

TABLE 2. Results
Stachybotrys charatum ATCC #9182

SAMPLE IDENTIFICATION	EXPOSURE INTERVALS	AVERAGE CONTROL TITER (CFU/mL)	AVERAGE RECOVERED (CFU/mL)	PERCENT REDUCTION (%)	LOG ₁₀ REDUCTION
Sample 1: ASAP-AGX-32	10 minutes	1.0 x 10 ⁵	<2.0 x 10 ¹	>99.981	>3.71
Sample 2: 7ppm modified to 32 ppm	10 minutes	1.0 x 10 ⁵	<2.0 x 10 ¹	>99.981	>3.71
Sample 3: 10 ppm modified to 32 ppm produced by the new method	10 minutes	1.0 x 10 ⁵	<2.0 x 10 ¹	>99.981	>3.71
Sample 4: 100 ppm new method (105.1ppm actual)	10 minutes	1.0 x 10 ⁵	<2.0 x 10 ¹	>99.981	>3.71
Sample 5: ASAP Solution 10 ppm	10 minutes	1.0 x 10 ⁵	2.0 x 10 ²	99.81	2.71

TABLE 3. Results
Candida albicans ATCC #10231

SAMPLE IDENTIFICATION	EXPOSURE INTERVALS	AVERAGE CONTROL TITER (CFU/mL)	AVERAGE RECOVERED (CFU/mL)	PERCENT REDUCTION (%)	LOG ₁₀ REDUCTION
Sample 1: ASAP-AGX-32	10 minutes	2.0 x 10 ⁶	<2.0 x 10 ¹	>99.9990	>5.00
Sample 2: 7ppm modified to 32 ppm	10 minutes	2.0 x 10 ⁶	<2.0 x 10 ¹	>99.9990	>5.00
Sample 3: 10 ppm modified to 32 ppm produced by the new method	10 minutes	2.0 x 10 ⁶	<2.0 x 10 ¹	>99.9990	>5.00
Sample 4: 100 ppm new method (105.1ppm actual)	10 minutes	2.0 x 10 ⁶	<2.0 x 10 ²	>99.990	>4.00
Sample 5: ASAP Solution 10 ppm	10 minutes	2.0 x 10 ⁶	6.0 x 10 ²	99.970	3.52

TABLE 4. Results
Aspergillus niger ATCC #16404

SAMPLE IDENTIFICATION	EXPOSURE INTERVALS	AVERAGE CONTROL TITER (CFU/mL)	AVERAGE RECOVERED (CFU/mL)	PERCENT REDUCTION (%)	LOG ₁₀ REDUCTION
Sample 1: ASAP-AGX-32	10 minutes	1.9 x 10 ⁶	2.5 x 10 ⁵	87	0.89
Sample 2: 7ppm modified to 32 ppm	10 minutes	1.9 x 10 ⁶	8.9 x 10 ⁴	95.4	1.34
Sample 3: 10 ppm modified to 32 ppm produced by the new method	10 minutes	1.9 x 10 ⁶	7.7 x 10 ⁴	96.0	1.40
Sample 4: 100 ppm new method (105.1ppm actual)	10 minutes	1.9 x 10 ⁶	~4.7 x 10 ¹	~99.9976	~4.62
Sample 5: ASAP Solution 10 ppm	10 minutes	1.9 x 10 ⁶	6.2 x 10 ⁵	68	0.49

TABLE 5. Neutralization

SAMPLE IDENTIFICATION	ORGANISM	AVERAGE CONTROL COUNTS (CFU)	AVERAGE SAMPLE COUNTS (CFU)	PERCENT NEUTRALIZATION (%)
Sample 1: ASAP-AGX-32	<i>A. niger</i>	68	64	94
	<i>C. albicans</i>	36	28	78
	<i>T. mentagrophytes</i>	21	21	98
	<i>S. chartarum</i>	31	38	122
Sample 2: 7ppm modified to 32 ppm	<i>A. niger</i>	68	70	103
	<i>C. albicans</i>	36	36	101
	<i>T. mentagrophytes</i>	21	21	102
	<i>S. chartarum</i>	31	38	120
Sample 3: 10 ppm modified to 32 ppm produced by the new method, 10 ppm	<i>A. niger</i>	68	67	99
	<i>C. albicans</i>	36	39	109
	<i>T. mentagrophytes</i>	21	21	98
	<i>S. chartarum</i>	31	44	140

Note: The percent neutralization was calculated using a validated computer spreadsheet program. The numbers shown in the control and sample recovery column were rounded for formatting of report.

TABLE 5. Neutralization (Cont.)

SAMPLE IDENTIFICATION	ORGANISM	AVERAGE CONTROL COUNTS (CFU)	AVERAGE SAMPLE COUNTS (CFU)	PERCENT NEUTRALIZATION (%)
Sample 4: 100 ppm new method (105.1ppm actual)	<i>A. niger</i>	68	68	100
	<i>C. albicans</i>	39	58*	149
	<i>T. mentagrophytes</i>	21	24	114
	<i>S. chartarum</i>	31	36	116
Sample 5: ASAP Solution	<i>A. niger</i>	68	67	99
	<i>C. albicans</i>	36	49	136
	<i>T. mentagrophytes</i>	21	19	92
	<i>S. chartarum</i>	31	35	112

* Neutralized in second dilution (10^2). All others neutralized in first dilution (10^1).

Note: The percent neutralization was calculated using a validated computer spreadsheet program. The numbers shown in the control and sample recovery column were rounded for formatting of report.



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