EEE BRANCH REVIEW

DATE: IN _____ OUT _____ IN _____ OUT _____ IN 6/7/78 OUT 9/15/78

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 34292-1

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED 3-22-78

DATE OF SUBMISSION 3-20-78

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCTS(S): I, (D,) H, F, N, R, S Industrial Antimicrobial

DATA ACCESSION NO(S). 233856

PRODUCT MGR. NO. 31 (Tavano)

PRODUCT NAME(S) Dow Corning 5700 Antimicrobial Agent

COMPANY NAME Dow Corning Corporation

SUBMISSION PURPOSE Amendment with data (new use on disposable hospital surgical gowns and drapes)

CHEMICAL & FORMULATION Concentrate for manufacturing use only.

Active Ingredient:

3-(Trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride 42%

200.0 Introduction

200.1 Use(s):

The product is registered as a bacteriostat, algistat, and fungistat for manufacturing use as a preservative for unfinished textile fibers, fabrics, and threads.

Claims have also been accepted for its use in a finished article, socks, to prevent deterioration and discoloration caused by fungi and to inhibit odor causing bacteria.

The purpose of the current submission is to extend the claims to include finished disposable hospital surgical gowns and drapes (surgical gowns, operating room gowns, non-absorbant towels, surgical drapes, clean room apparel), as follows:

Disposable Hospital Surgical Gowns and Drapes..... Treated with Dow Corning 5700 Antimicrobial Agent (1) exhibit broad spectrum antimicrobial activity against gram negative and gram positive micro-organisms (2) reduces the number of viable organisms deposited on its surface (3) will retard and reduce penetration of an aqueous microbial challenge (4) to provide a durable, non-leachable antimicrobial treatment, (5) to provide hygienic freshness (6) to resist the development of bacterial odors (7) to retain its freshness by resisting the growth of odor causing bacteria (8) for chemical protection to resist odors.

200.2 Background Information:

It should be noted that this review addresses only the specific data which are the subject of this proposed amendment. No attempt has been made in this review to reevaluate previously submitted data or previously accepted claims or other proposed amendments for added uses which are also under consideration for this product.

201.0 Data Summary

201.1.1 Brief Description of Tests:

(A) "Antibacterial Activity of Textiles Treated With Dow Corning 5700 Antimicrobial Agent Following Gamma Radiation Sterilization". Reference E-3067-45, dated 3-20-78.

(B) "Antibacterial Activity of Nylon-Reinforced Nonwoven Textile Treated with Dow Corning 5700 Antimicrobial Agent". Reference E-3067-134, dated 3-20-78.

(C) "Antibacterial Activity of Nylon-Reinforced Nonwoven Textile Treated with Dow Corning 5700 Antimicrobial Agent Against Odor-Causing Bacteria". Reference E-3067-138, dated 3-20-78.

(D) "Effectiveness of Nylon-Reinforced Nonwoven Textile Treated with Dow Corning 5700 Antimicrobial Agent In Retarding and Reducing Penetration of an Aqueous Microbial Challenge". Reference E-3302-75, dated 3-20-78.

(E) "Antibacterial Activity of Nylon-Reinforced Nonwoven Textile Treated with Dow Corning 5700 Antimicrobial Agent". Reference E-3302-96, dated 3-20-78.

All of the above tests were apparently conducted by Dow Corning Corporation, Midland, MI, although the identity of the investigators was not provided. All reports are dated 3-20-78; test dates were not provided. All tests were included in Accession No. 233856.

201.1.1 Data Summaries:

(A) E-3067-45

PURPOSE

To determine the antimicrobial activity of various textiles treated with Dow Corning 5700 antimicrobial agent after being exposed to different levels of gamma radiation during a sterilization process.

TEST MATERIALS

Cotton/polyester sheeting, two-ply polyester nonwoven fabric, and fourply polyester nonwoven fabric were treated with Dow Corning 5700 antimicrobial agent at 0.3% wt./wt. pickup of active ingredient. The samples were exposed to different levels of gamma radiation.

MICROBIOLOGICAL METHODS

Dow Corning 5700 antimicrobial agent treated fabric and untreated control fabric (sterilized and non-sterilized) were tested according to modified AATCC Method 100-1974 (CTM-0829) against Klebsiella pneumoniae ATC 4352. This method was previously furnished and is included with the review by Technical Support Section (Efficacy), Disinfectants Branch, RD, dated 8-11-78, for the application for amended registration of EPA Reg. No. 34292-1 for use on carpets dated 5-5-77.

RESULTS

The bacterial counts from treated and untreated fabric obtained by CTM-0829 are presented in Table I attached.

SUMMARY

Procedural detail was lacking with respect to the following:

(1) The method of treatment of the fabric samples with the product and the procedure for sterilization of the samples by gamma radiation were not described.
(2) The relationship between the fabric samples tested and the finished items intended for treatment (surgical gowns, surgical drapes, etc.) was not delineated.
(3) The number of samples inoculated and the volume of inoculum per sample were not indicated.
(4) Raw data (actual counts) were not included.
(5) The effectiveness of Letheen broth as a neutralizer for the active ingredient was

not documented.

Assuming that the above mentioned information could be provided, the test results indicate that reduction of numbers of K. pneumoniae was observed when liquid inocula were placed on treated (0.3% a.i.) fabric samples for 6 hours at 37°C and kept under wet conditions, i.e. in a screw-capped bottle with the cap screwed on tightly to prevent evaporation. Irradiation of the samples prior to testing did not appear to affect these bacteriostatic properties except to a small extent at the highest level employed (3.6 M. rad). Untreated, non-irradiated and irradiated control fabrics supported survival of the inoculum for the 6 hour period under the test conditions.

The test did not address the proposed claim for the product for prevention of odor; the causative agent(s) of the odor problem; or the conditions likely to be encountered in actual use of the finished items.

(B) E-3067-134

PURPOSE

To determine the antimicrobial activity of a nonwoven textile treated with Dow Corning 5700 antimicorbial agent before and after gamma radiation sterilization. The activity is measured against three different bacteria.

TEST MATERIALS

A finished nonwoven textile treated with Dow Corning 5700 antimicrobial agent and an unfinished untreated control nonwoven textile were received from Convertors Division of American Hopsital Supply for use in this study. The textile samples included non-sterilized samples and samples that had been sterilized with gamma radiation (2 M. rad).

MICROBIOLOGICAL METHODS

Dow Corning 5700 antimicrobial agent treated nonwoven textile and untreated control nonwoven textile (non-sterilized and sterilized) were tested according to modified AATCC Method 100-1974 (CTM-0829)* against each of the following bacteria:

1)	Klebsiella pneumoniae	ATCC 4352
2)	Pseudomonas aeruginosa	ATCC 15442
3)	Staphylococcus aureus	ATCC 6538

RESULTS

The bacterial counts from treated and untreated nonwoven textiles obtained by CTM-0829 are presented in Table II attached.

SUMMARY

The same procedural details are lacking as indicated for the tests in 201.1.1 (A) above. In addition, the treatment level of the product on the fabric was not specified, and the difference between "finished" and "unfinished" fabric was not defined. *See 201.1.1 (A) concerning the referenced method.

Assuming that the above details could be provided, the tests show results which are similar to those obtained in 201.1.1 (A) above with the three test bacteria, K. pneumoniae, P. aeruginosa, and S. aureus at a contact time of 3 hours at 37°C. In these tests, however, the bacteriostatic properties of the treated fabric appear to be slightly enhanced in the treated material which had been irradiated. No explanation for this result was offered. No untreated, irradiated controls were employed.

The test did not address the claim for odor control; the causative agents thereof; or actual use conditions.

(C) E-3067-138

PURPOSE

To determine the antimicrobial activity of a nonwoven textile treated with Dow Corning 5700 antimicrobial agent before and after gamma radiation sterilization. The activity is measured against isolates recovered from human subjects. This study is submitted in support of the claim that "a nylon-reinforced nonwoven textile treated with Dow Corning 5700 antimicrobial agent inhibits the growth of odor-causing bacteria".

TEST MATERIALS

A finished nonwoven textile treated with Dow Corning 5700 antimicrobial agent and an unfinished untreated control nonwoven textile were received from Convertors Division of American Hospital Supply for use in this study. The textile samples included non-sterilized samples and samples that had been sterilized with gamma radiation (2 M. rad).

MICROBIOLOGICAL METHODS

Dow Corning 5700 antimicrobial agent treated nonwoven textile and untreated control non-woven textile (non-sterilized and sterilized) were tested according to modified AATCC Method 100-1974 (CTM-0829) against each of the bacterial isolates from the study titled "Identification of Bacteria Isolated from the Axillary Region of the Human Body".

RESULTS

The bacterial counts from treated and untreated nonwoven textiles obtained by CTM-0829 are presented in Table III attached.

SUMMARY

The same procedural details are lacking as indicated for the tests in 201.1.1 (A) and (B) above.

Assuming that the above details could be provided, the test results indicate that

numbers reduction (bacteriostasis) was achieved against Micrococcus lutea, Staphylococcus epidermidis, and K. pneumoniae at a contact time of 3 hours at 37°C in a manner and under conditions analogous to that described in 201.1.1 (A) and (B) above. All observations were similar.

Although the bacteria employed in the test were isolated from the axillary region of human subjects, it was not shown that these organisms were the cause of odor in/on the tested fabric or on any of the end articles intended to be treated. Actual conditions of use were not addressed in the testing.

(D) E-3302-75

PURPOSE

To determine the ability of nylon-reinforced nonwoven textile treated with Dow Corning 5700 antimicrobial agent (before and after sterilization by gamma radiation) to retard and reduce aqueous challenges of three strains of bacteria. This study is submitted in support of the claim that "nylon-reinforced nonwoven textile treated with Dow Corning 5700 will retard and reduce penetration of an aqueous microbial challenge".

TEST MATERIALS

Finished nonwoven textile treated with Dow Corning 5700 antimicrobial agent and unfinished untreated control nonwoven textile were received from Convertors Division of American Hospital Supply for use in this study. The textiles included non-sterilized samples and samples that had been sterilized by gamma radiation (2 M. rad).

MICROBIOLOGICAL METHODS

Dow Corning 5700 antimicrobial agent treated finished textiles (sterilized and non-sterilized) and unfinished untreated control

textiles were tested to determine their ability to reduce the penetration of an aqueous microbial challenge by means of a New Brunswick Ecolo-Gen Mixed Culture apparatus, Model E-40, as shown in Figure 1. Textile samples were placed in an aerosalization chamber (see Figure II), uniformly sprayed with a suspension of a known bacteria and dried at 25°C for three hours. The samples were then placed in the Ecolo-Gen apparatus with the sprayed sides facing the central chamber. The side and central chambers were filled with Tryptic Soy Broth. At time intervals of zero, 1, 2 and 3 hours the four side chambers were sampled and plated in order to obtain a count of how many viable organisms had passed through each textile.

RESULTS

The bacterial counts from the finished treated textile and unfinished untreated control obtained by the above method are presented in Table IV attached.

SUMMARY

Essentially the same procedural details are lacking in this study as were indicated for the tests in 201.1.1 (A), (B), and (C) above.

Additional deficiencies were found with regard to the design, conduct, and/or reporting of the study, such as the following:

(1) The test design appears faulty. The stated objective of the test was to evaluate penetration of an aqueous microbial challenge through treated and untreated test fabric. However, the bacterial inoculum was applied by aerosol (liquid inoculum ?) and allowed to dry for three hours prior to initiation of the Ecolo-Gen (penetration) phase of the study. Neither the initial inoculum applied by aerosol or the survivors after three hours of drying on the fabric were enumerated.

This drying period provided considerable contact time between the inoculum and the antimicrobial treatment, so that any comparisons thereafter with untreated fabric appear meaningless for the stated purpose of the test.

Secondly, in the Ecolo-Gen phase of the study, filling both the central chamber and side chambers with broth permits only an estimate of diffusion of bacteria through the fabric (in equilibrium with broth on both sides), not penetration of the aqueous microbial challenge. The porosity of the test fabric to aqueous media was not mentioned. The rate of flow of the liquid thorugh the fabric would determine the contact time between the antimicrobial and the bacterial challenge. If the fabric porosity were such as to allow penetration of the contaminated liquid within seconds or minutes, then the testing intervals of 1-3 hours were totally unrealistic.

(2) The description of the Ecolo-Gen device was not adequate. It is assumed (perhaps wrongly) that the device contained a barrier to bacterial migration from the side chamber (containing the inoculated fabric) to the central chamber, and that it would only allow passage of bacteria through the fabric and into the side chamber. If this is not the case, bacteria could freely cross-contaminate the central chamber as well as the other side chambers. Whatever the mechanics of the system, a more logical approach to testing would appear to be inoculation of the fabric with liquid bacterial challenge or (in the absence of a barrier to the central chamber) inoculation of the central chamber itself, allowing the inoculum to penetrate the fabric and flow into the side chamber (left empty), then sample and enumerate the bacteria in the effluent.

In absence of substantial clarification and/or justification for the study, as performed, no evaluation of the results can be made. No relationship can be seen between the intent of the study and the claim for control of odor causing bacteria.

(E) E-3302-96

PURPOSE

To determine the antimicrobial activity of nylon-reinforced nonwoven textile treated with Dow Corning 5700 antimicrobial agent before and after gamma radiation sterilization. The activity is measured against three strains of bacteria. This study is submitted in support of the claim that "nylon-reinforced nonwoven textile treated with Dow Corning 5700 antimicrobial agent will reduce the number of viable organisms deposited on a surface".

TEST MATERIALS

A finished nonwoven textile treated with Dow Corning 5700 antimicrobial agent and an unfinished untreated control textile were received from Convertors Division of American Hospital Supply for use in this study. The textiles included non-sterilized samples and samples that had been sterilized by gamma radiation (2 M. rad).

MICROBIOLOGICAL METHODS

Dow Corning 5700 antimicrobial agent treated finished textiles (sterilized and non-sterilized) and unfinished untreated control textiles were tested to determine the reduction of viable organisms deposited on their surfaces. The samples were placed on wire racks in an aerosolization chamber (see Figure 1). A known strain of bacteria was aerosolized and uniformly sprayed over the samples. Each sprayed sample was then placed in a petri dish and dried at 25°C and 50%

relative humidity for a prescribed period of time, ranging from zero to two hours. At the end of these times, all viable organisms were extracted from the samples by shaking each sample for one minute in a screw-cap bottle containing Letheen Broth. The bottles were then diluted and plated in order to obtain a count of the number of viable bacteria remaining on each sample.

RESULTS

The bacterial counts from the finished treated textile and unfinished untreated control obtained by the above method are presented in Table V attached.

SUMMARY

The same details are lacking in this study as for the tests in 201.1.1 (A), (B), (C), and (D). It is assumed that these details might be able to be provided.

The results suggest that bacteriostatic activity of treated fabric is less evident than that shown in previous studies [201.1.1 (A), (B), and (C)]. This is apparently due to the fact that some concession to realism was made, however small. The test bacteria were applied by aerosol to the fabric samples and allowed to dry in petri dishes at 25°C and 50% relative humidity. Although the initial inoculum is not known, the only test bacterium to survive in significant numbers for the test duration was S. aureus. The test procedure more closely approximates actual use conditions than previous studies employing liquid inoculum on fabrics in a closed jar (saturated moisture) at 37°C.

Although the results indicate that minimal bacteriostatic activity may be exhibited by the treated fabric for periods up to 2 hours under the test conditions, the benefit or function which was provided was not demonstrated. The results cannot be related to the claim for control of odor causing bacteria.

202.0 Recommendations

202.2 Efficacy Not Supported by the Data Submitted:

The submitted data do not support effectiveness of the product for controlling development of bacterial odors, or for any other claim, in the treatment of disposable hospital gowns, drapes, and/or related items intended for use in the operating room.

The intent of the proposed treatment of single-use disposable surgical apparel appears clearly unrelated to any unproven and unlikely problem of odor causing bacteria. The only conceivable function of treatment of such items with an antimicrobial, claimed or implied, would be to provide some measure of protection to patients and/or operating room personnel against transmission and/or exposure to infectious microorganisms from the items in question while in use during surgical procedures. The only level of effectiveness which could be considered in this critical pattern of use would be elimination of the target infectious microorganisms on/in treated items, i.e., "self-sterilization" or "self-disinfection", within a relatively short time under simulated use conditions. Efficacy at the mitigating level, i.e., "bacteriostasis", which might be expected to be provided by the proposed treatment, could not be considered for this pattern of use.

202.3 Additional Data Required to Support Efficacy:

There is no basis for prescribing efficacy data requirements for the product in the proposed pattern of use. No rational foundation has been proposed or documented for effectiveness against odor causing bacteria under the conditions of use for the treated items. The only conceivable benefit for treatment of prepackaged, sterile, disposable hospital gowns, drapes, and related items would be to provide effectiveness against pathogenic microorganisms while in use during surgical procedures. Such claims, overt or implied, are unacceptable and cannot be considered for

residual bacteriostatic treatments for this critical pattern of use.

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9-15-78
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TABLE I

ANTIMICROBIAL ACTIVITY OF DOW CORNING® 5700 ANTIMICROBIAL AGENT
TREATED FABRICS AFTER GAMMA RADIATION STERILIZATION

Samples	Radiation Level (M. rad)	Number of Bacteria Remaining At		% Reduction
		0 Time	6 Hours	
Cotton/Polyester Sheeting:				
Control	0	45,500	35,000	
Treated	0	80,000	100	99.8
Control	1.85	64,500	20,000	
Treated	1.85	84,500	0	100
Two-ply Nonwoven Polyester:				
Control	0	360,000	285,000	
Treated	0	340,000	300	99.9
Control	1.85	300,000	145,000	
Treated	1.85	435,000	0	100
Control	3.6	300,000	205,000	
Treated	3.6	325,000	1,200	99.6

TABLE I (Continued)

Samples	Radiation Level (M. rad)	Number of Bacteria Remaining at 0 Time	Number of Bacteria Remaining at 6 Hours	% Reduction
Four-Ply Nonwoven Polyester:				
Control	0	405,000	75,000	
Treated	0	370,000	100	99.9
Control	1.85	430,000	>3,000,000	
Treated	1.85	385,000	400	99.9
Control	3.6	410,000	950,000	
Treated	3.6	330,000	12,500	96.6

TABLE II

ANTIMICROBIAL ACTIVITY OF DOW CORNING® 5700 TREATED NONWOVEN TEXTILE

Sample	Organism	Number of Bacteria Remaining At: 0 Time	3 Hours	% Reduction
Unfinished Untreated Control	*Klebsiella pneumoniae*	146,000	575,000	
Finished Treated Textile		191,000	4,350	97.4
Sterilized Finished Treated Textile		170,000	0	100
Unfinished Untreated Control	*Pseudomonas aeruginosa*	92,500	48,000	
Finished Treated Textile		118,000	5,900	94.8
Sterilized Finished Treated Textile		127,000	0	100
Unfinished Untreated Control	*Staph aureus*	110,500	81,000	
Finished Treated Textile		102,500	15,600	85.4
Sterilized Finished Treated Textile		105,500	2,750	97.4

TABLE III

ANTIMICROBIAL ACTIVITY OF DOW CORNING® 5700 ANTIMICROBIAL AGENT TREATED NONWOVEN TEXTILE AGAINST BACTERIA ISOLATED FROM THE AXILLARY REGION

Sample	Organism	Number of Bacteria Remaining at: 0 Time	3 Hours	% Reduction
Unfinished untreated control	*Micrococcus lutea*	55,500	53,500	
Finished treated textile		66,500	15,300	72.8
Sterilized finished treated textile		47,000	5,400	90.4
Unfinished untreated control	*Staph epidermidis*	58,000	37,000	
Finished treated textile		59,000	7,250	86.7
Sterilized finished treated textile		46,000	250	99.5
Unfinished untreated control	*Klebsiella pneumoniae*	98,500	940,000	
Finished treated textile		123,000	33,500	71.4
Sterilized finished treated textile		129,500	13,350	88.6

FIGURE 1 – NEW BRUNSWICK GROWTH CHAMBER MODEL E-40

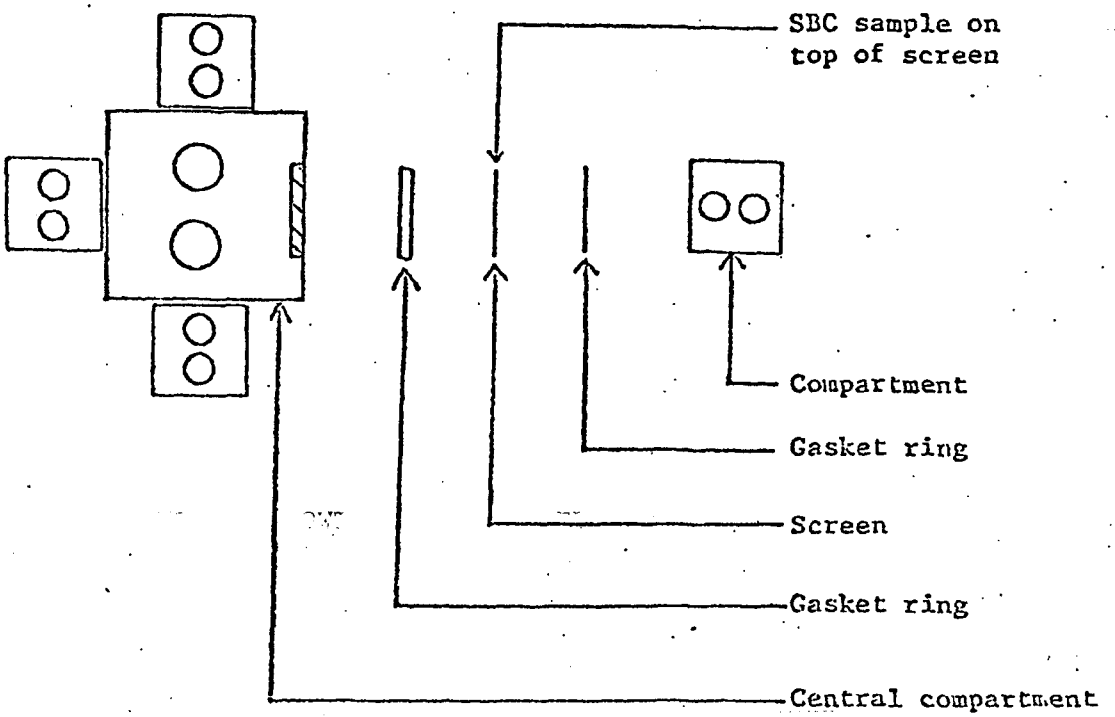

Fig. 2 Aerosol spray chamber. (A) sterile cotton air filter; (B) spray head assembly; (C) aerosol chamber; (D) position of test materials; (E) wire sample-support; (F) disinfectant tray.

30 cm
C
A
B
D
E
F

TABLE IV

BIOBARRIER EFFECTIVENESS OF DOW CORNING® 5700 ANTIMICROBIAL AGENT
TREATED NONWOVEN TEXTILES AGAINST KNOWN BACTERIA

Sample	Organism	Number of Bacteria per ml. at 0 Time	1 Hour	2 Hours	3 Hours
Unfinished Untreated Control	Staphylococcus aureus	0	17	130	960
Finished Treated Textile	ATCC 6538	0	0	0	10
Finished Treated Textile		0	0	0	12
Sterilized Treated Textile		0	0	0	0
Unfinished untreated control	Pseudomonas aeruginosa	0	48	104	80
Finished treated textile	ATCC 15442	0	4	1	5
Finished treated textile		0	0	2	2
Sterilized treated textile		0	0	1	1
Unfinished untreated control	Pseudomonas aeruginosa	400	455	510	495
Finished treated textile	ATCC 15442	0	0	0	0
Sterilized finished treated textile		1	10	19	18
Unfinished untreated control	Klebsiella pneumoniae	0	0	4	18
Finished treated textile	ATCC 4352	0	0	0	0
Finished treated textile		0	0	0	0
Sterilized finished treated textile		0	0	1	0
Unfinished untreated control	Staphylococcus aureus	1	15	80	440
Finished treated textile	ATCC 6538	1	7	18	26

TABLE V

ANTIMICROBIAL ACTIVITY OF DOW CORNING® 5700 ANTIMICROBIAL AGENT
TREATED NONWOVEN TEXTILE

Sample	Organism	Number of Bacteria per Test Swatch Remaining At 0 Time	1 Hour	2 Hours	% Red.
Unfinished untreated control	Staphylococcus aureus	>300,000	230,000	245,000	>18.3
Finished treated textile	ATCC 6538	>300,000	117,000	52,500	>82.5
Sterilized Finished treated textile		>300,000	162,500	84,500	>71.8
Unfinished untreated control	Klebsiella pneumoniae	201,500	173,500	7,300	>97.1
Finished treated textile	ATCC 4352	>300,000	3,500	730	>99.7
Sterilized finished treated textile		>300,000	650	400	>99.8
Unfinished untreated control	Corynebacterium xerosis	1,080	270	670	31.6
Finished treated textile	ATCC 373	880	80	70	92.9