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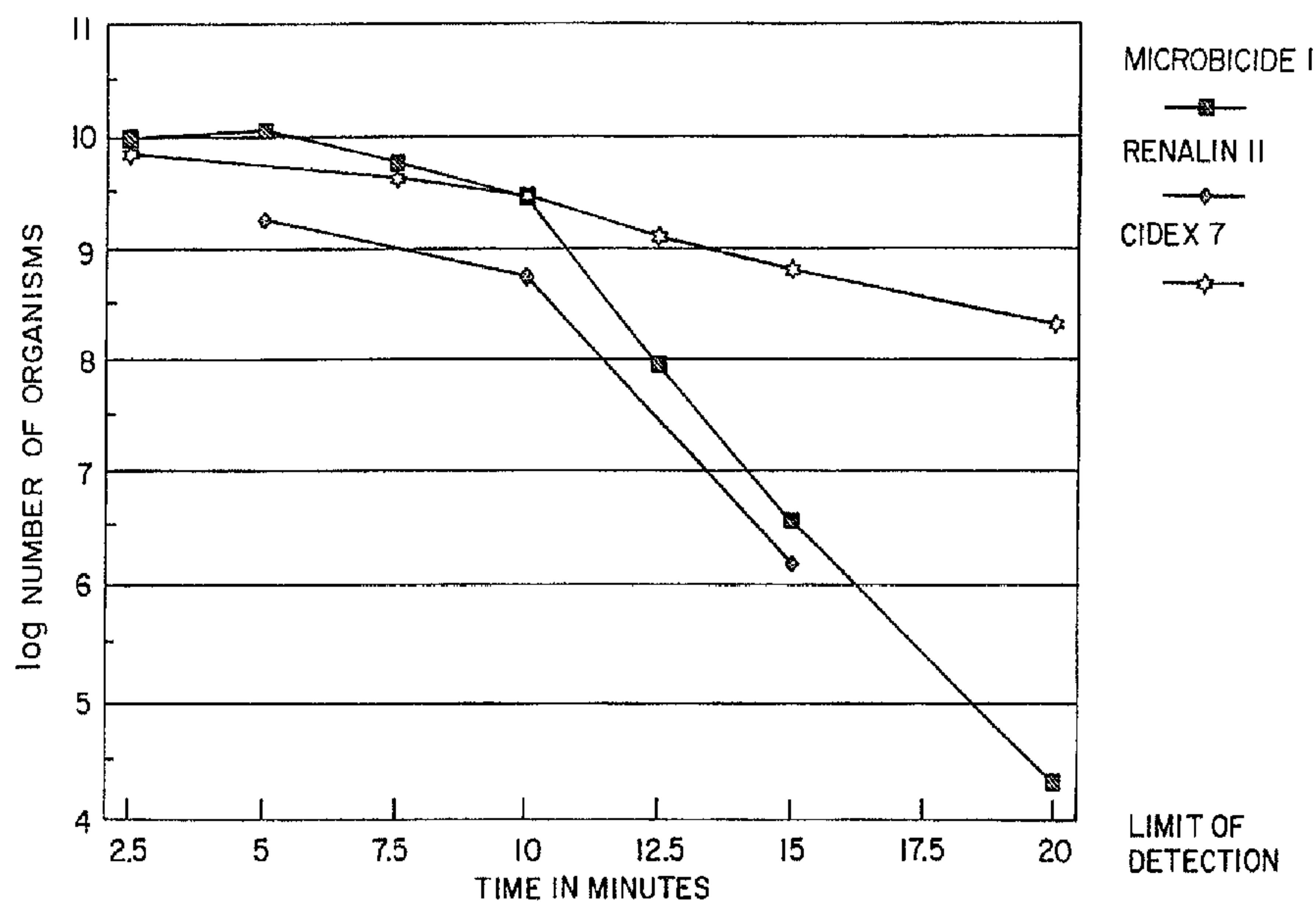
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(54) **STERILISANT A TEMPERATURE AMBIANTE POUR  
INSTRUMENTS MEDICAUX**

(54) **ROOM TEMPERATURE STERILANT FOR MEDICAL DEVICES**



(57) L'invention porte sur une composition antimicrobienne renfermant un ester d'acide formique, un oxydant, l'acide performique et de l'eau. L'invention présente également un prémélange pour l'obtention de la composition antimicrobienne en deux composantes. La première composante renferme l'ester de l'acide formique et la seconde composante contient l'oxydant. L'invention présente une autre méthode pour stériliser les dispositifs médicaux, incluant des modules de filtre dialyseur, où la composition antimicrobienne peut être diluée de 1:1 jusqu'à 1:12 avec de l'eau.

(57) Provided is an anti-microbial composition containing an ester of formic acid, an oxidizer, performic acid and water. Also provided is a premix for making the anti-microbial composition having two parts. One part contains the ester of formic acid and a second part contains the oxidizer. Another method is provided for making the anti-microbial composition in which the ester of formic acid is combined with the oxidizer and water. A further method is provided for sterilizing medical devices, including dialyzer filter modules, wherein the anti-microbial composition is capable of dilution of 1:1 to 1:12 with water.



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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/US96/18900 <b>(22) International Filing Date:</b> 25 November 1996 (25.11.96) <b>(30) Priority Data:</b> 08/565,995                      1 December 1995 (01.12.95)                      US <b>(71) Applicant:</b> MINNTECH CORPORATION [US/US]; 14605 28th Avenue North, Minneapolis, MN 55447 (US). <b>(72) Inventors:</b> HALL, Robert, T., II; 20175 Rhoda Avenue, Welch, MN 55089 (US). ONSTAD, Bradley, K.; 11531 Kentucky Avenue North, Champlin, MN 55316 (US). CARLSEN, Daniel, B.; Automato Instrumentation Inc., 7830 East Redfield Road #12, Scottsdale, AZ 85260 (US). <b>(74) Agent:</b> WRIGLEY, Barbara, A.; Minntech Corporation, 14605 28th Avenue North, Minneapolis, MN 55447 (US).	<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>	
<b>(54) Title:</b> ROOM TEMPERATURE STERILANT FOR MEDICAL DEVICES		
<b>(57) Abstract</b>  Provided is an anti-microbial composition containing an ester of formic acid, an oxidizer, performic acid and water. Also provided is a premix for making the anti-microbial composition having two parts. One part contains the ester of formic acid and a second part contains the oxidizer. Another method is provided for making the anti-microbial composition in which the ester of formic acid is combined with the oxidizer and water. A further method is provided for sterilizing medical devices, including dialyzer filter modules, wherein the anti-microbial composition is capable of dilution of 1:1 to 1:12 with water.		

ROOM TEMPERATURE STERILANT FOR MEDICAL DEVICESBACKGROUND OF THE INVENTION5      1. Field of the Invention

          The invention relates to a room  
temperature anti-microbial composition which  
includes an ester of formic acid, an oxidizer,  
performic acid, and water, a premix for making the  
10      anti-microbial composition, and a method for  
producing the anti-microbial composition, and a  
method for sterilizing medical devices utilizing the  
anti-microbial composition.

15      2. Background of Related Art

          Conventional methods of sterilizing  
medical devices have significant disadvantages. For  
example, the steam autoclave works well, but many  
instruments are sensitive to the high pressure and  
20      temperature required to achieve sterility. Ethylene  
oxide requires long exposure times in a vacuum, even  
longer aeration times, and the gas is highly toxic.  
Glutaraldehyde is a suspected carcinogen and can be  
corrosive to certain materials. In the field of  
25      medical devices which come in contact with a  
patient's blood stream, care must be taken to  
sterilize or reprocess these devices with  
biocompatible anti-microbial compositions.

          This is particularly true concerning  
30      catheters and blood filters such as dialyzers. Many  
of the aforementioned sterilizing techniques leave  
residues on the surfaces of the sterilized device  
which are toxic to the human body and may cause  
severe adverse patient reactions, such as skin  
35      rashes, hemolysis, and the like. Furthermore, if  
the dialyzer is to be reprocessed for reuse, it is  
particularly important that the anti-microbial  
composition be an effective biocide while remaining

biocompatible because any residual anti-microbial composition may elute from the dialyzer into the bloodstream of the dialyzed patient, again causing severe adverse patient reaction, which may  
5 exacerbate the condition of the patient already in renal failure.

#### SUMMARY OF THE INVENTION

10 An object of the present invention is to provide an easy to use room temperature anti-microbial composition.

A further object of the present invention is to provide an anti-microbial composition for  
15 sterilizing medical devices which overcomes the disadvantages of known methods of sterilizing medical devices.

The invention relates to an anti-microbial composition having improved anti-corrosive  
20 properties comprising an ester of formic acid, an oxidizer, performic acid and water.

A preferred embodiment of the invention relates to an anti-microbial composition having improved anti-corrosive properties comprising about  
25 .01 to about 10 wt.% of an ester of formic acid selected from the group consisting of ethyl formate, methyl formate, propyl formate, or mixtures thereof, about .01 to about 10 wt.% of an oxidizer, about .001 to about 5 wt.% of performic acid, and up to  
30 about 99.98% water.

The invention also relates to a premix for making the anti-microbial composition comprising two parts. One part comprises the ester of formic acid and a second part comprises the oxidizer.

35 The invention further relates to a method making the anti-microbial composition comprising the steps of combining the premix.

The invention also relates to a method of producing the anti-microbial composition comprising the steps of combining an ester of formic acid with an oxidizer and water.

5 The invention further relates to a method of sterilizing surfaces comprising contacting the surface with an anti-microbial composition diluted to a working concentration, the anti-microbial composition comprising from about .01 to about 10  
10 wt.% of an ester of formic acid selected from the group consisting of ethyl formate, or mixtures thereof, about .01 to about 10 wt.% of an oxidizer, about .001 to about 5 wt.% of performic acid, and up to about 99.98 % water.

15 A further embodiment of the invention relates to a method of sterilizing blood filters, such as dialyzers used as artificial kidneys, comprising contacting the dialyzers with the anti-microbial composition from about .01 to about 10  
20 wt.% of an ester of formic acid selected from the group consisting of ethyl formate, or mixtures thereof, about .01 to about 10 wt.% of an oxidizer, about .001 to about 5 wt.% of performic acid, and up to about 99.98 % water. The anti-microbial  
25 composition can be diluted to a working concentration by dilution from 1:1 to 1:12 with water.

30 BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1. illustrates the sporicidal effects of the anti-microbial composition according to the invention compared to two conventional  
35 anti-microbial compositions.

Fig. 2. illustrates the bactericidal effects of the anti-microbial composition according

to the invention compared to two conventional anti-microbial compositions.

5 Fig. 3. illustrates the net mass loss of brass after 24 hours of exposure as measured in Example 2.

10 Fig. 4. illustrates the concentration of performic acid in hard and deionized water over time as measured in Example 3.

15 Fig. 5. illustrates the concentration of hydrogen peroxide in hard and deionized water over time as measured in Example 3.

20 Fig. 6. illustrates the stability of hydrogen peroxide and performic acid in deionized water over time as measured in Example 3.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 The invention relates to an anti-microbial composition having improved anti-corrosive properties comprising an ester of formic acid, an oxidizer, performic acid and water.

30 Preferably, the anti-microbial composition comprises about .01 to about 10 wt.% of the ester of formic acid, about .01 to about 10 wt.% of an oxidizer, about .001 to about 5 wt.% of performic acid, and up to about 99.98 wt.% water. More preferably, the anti-microbial composition comprises about 2 to about 8 wt.% of the ester of formic acid, about 1 to 10 wt.% of an oxidizer, about .001 to about 1 wt.% of performic acid, and up to about 97  
35 wt.% of water.

Preferably, the ester of formic acid is an ester of ethyl formate, methyl formate, propyl

formate, or mixtures thereof. More preferably, the ester of formic acid is ethyl formate.

The oxidizer can be any oxidizer that is compatible with a performic acid based anti-microbial composition. Examples of such oxidizers include nonorganic oxidizing substances such as, hydrogen peroxide, sodium percarbonate, sodium periodate, sodium persulfate, ammonium persulfate, sodium perborate, sodium peroxide, calcium peroxide, silver (II) oxide, ozone, and chlorine dioxide. The oxidizers also include organic oxidizing substances, for example, diacyl peroxides, such as benzoyl peroxide, ketone peroxides, such as 2, 4-pentanedione peroxide, peroxydicarbonates, such as diisopropyl peroxydicarbonate, peroxyesters, such as t-butylperoxy maleic acid, dialkyl peroxides, such as dicumyl peroxide, hydroperoxides, such as t-butyl hydroperoxide, and peroxyketals, such as 2,2-di(t-butyl peroxy) butane.

Preferably, the oxidizer is hydrogen peroxide. More preferably, the oxidizer is urea hydrogen peroxide.

A preferred anti-microbial composition comprises ethyl formate in an amount of about 3.8 to about 4 wt.%, urea hydrogen peroxide in an amount of about 1 to about 8 wt.%, and about .001 to about 1 wt.% of performic acid.

The anti-microbial composition can also contain additives, such as, corrosion inhibitors and stabilizers.

Examples of corrosion inhibitors are 1,2,3-Benzotriazole, azimidobenzene and benzene azimide (collectively, COBRATEC 99™, PMC Specialties Group, Inc.) and the sodium hydroxide reaction products of an aliphatic alcohol and phosphorous pentoxide (VICTAWET™ 35B, Akzo Chemicals, Inc., Chicago, IL). The corrosion inhibiting properties

of VICTAWET™ 35B are disclosed in PCT/US90/01862,  
entitled "Anticorrosive Microbicide."

The stabilizers include those that  
stabilize the anti-microbial composition over time,  
5 and those that increase the concentration of  
performic acid, as well as other stabilizers.

The anti-microbial composition can be made  
in a concentrated form, dry or liquid, to be diluted  
with water before using.

10 Purifying the water is not required. When  
hard tap water is used, surprisingly, the  
concentration of performic acid in the anti-  
microbial composition is less likely to decrease or  
will increase at the expense of the oxidizer,  
15 compared to deionized water. This is a significant  
advantage, because tap water is more readily  
available and is less expensive than purified or  
deionized water. In particular, hard water  
containing calcium acts in this manner.

20 The invention also relates to a premix for  
making the anti-microbial composition comprising a  
first part comprising an ester of formic acid, and a  
second part comprising the oxidizer. The oxidizer  
and ester of formic acid include those described  
25 above. The anti-microbial composition can be formed  
by combining the first and second parts with water.

Preferably, the first part comprises an  
ester of ethyl formate, methyl formate, propyl  
formate, or mixtures thereof, and the second part  
30 comprises hydrogen peroxide.

Preferably, the amount of the ester of  
formic acid in the first part and the amount of  
oxidizer are such that when combined with water the  
resulting anti-microbial composition comprises about  
35 .01 to about 10 wt.% of the ester of formic acid,  
about .01 to about 10 wt.% of the oxidizer, about  
.001 to about 5 wt.% of performic acid, and up to  
about 99.98% water.



Each part of the premix can be in a dry or liquid form. For example, one or both parts of the premix can be diluted with water. Alternatively, one part can contain all of the required water so that when the other part is added no further water is required, or sufficient water is present in both parts so that when both parts are combined no further water is required.

The premix can also contain the above described additives in either or both of the parts.

The invention further relates to a method of making the anti-microbial composition comprising the steps of combining both parts of the pre-mix. If the pre-mix does not contain the required amount of water, water and the first and second parts can be mixed in any order.

Another embodiment of the invention relates to a method of producing the anti-microbial composition comprising the steps of combining the ester of formic acid with the oxidizer and water.

Preferably, sufficient amounts of water, ester of formic acid, and oxidizer are combined so that the resulting anti-microbial composition comprises about .01 to about 10 wt.% of the ester of formic acid, about .01 to about 10 wt.% of the oxidizer, about .001 to about 5 wt.% of performic acid, and up to about 99.98 wt.% water.

The anti-microbial composition can be used in place of conventional microbicides. The following is a partial list of uses for the anti-microbial composition. The uses of the anti-microbial composition is in no way intended to be limited to this list.

The anti-microbial composition can be used on skin, medical devices, and eating utensils.

The anti-microbial composition is particular useful for reprocessing used catheters which are sensitive to conventional anti-microbial

compositions. Preferably, when the anti-microbial composition is used to reprocess used catheters, the anti-microbial composition contains VICTAWET 35b. It is believed that the VICTAWET acts as a lubricant for the mechanical pump during reprocessing. The reprocessing method disclosed in U.S. Patent Nos. 4,721,123 and 5,310,524 are incorporated herein.

The anti-microbial composition is also particularly useful for sterilizing filter modules containing filter membranes in various forms, such as hollow fibers. Sterilization of filter modules using the anti-microbial composition of the present invention is particularly useful for reprocessing hollow fiber membrane dialyzers because not only are the dialyzers rendered microbe-free but the anti-microbial also removes proteinaceous blood components. Hollow fiber filter cartridges sterilized using the anti-microbial composition are suitable for re-use in a medial dialysis setting, such as for artificial kidney.

The invention will be further described by the following non-limiting examples.

#### EXAMPLE 1

Three tests were performed on samples of an anti-microbial composition according to the invention (hereinafter "Microbicide 1") made by combining 3.8 to 4% by weight of ethyl formate, 4% urea hydrogen peroxide, and the balance water. Performic acid was generated in an amount of about .001 to about .1 wt.%.

The anti-microbial composition was compared to two known microbicides, CIDEX 7 (Johnson and Johnson, Medical) and 1% RENALIN II (Minntech Corporation, published in PCT/US92/05877).

In the first test, the sporicidal and bactericidal activity of each anti-microbial composition was tested by placing  $\sim 1 \times 10^{10}$  Bacillus

subtilis spores into 10 ml of anti-microbial composition in a closed, but not sealed, test tube at room temperature (about 20°C). At exposure times of 2.5, 5, 7.5, 10, 12.5, 15, 17.5 and 20 minutes, 1 ml was removed and placed in a neutralizer solution to stop the sterilant action. The neutralizer solution comprised 1% Bacto-peptone (Difco), 1% sodium thiosulfate, and .025% catalase. The surviving spores were then serially diluted and plated to count.

Figure 1 illustrates the rate of kill by plotting the log number of surviving organisms vs. exposure time. Fig. 1 illustrates that the Microbicide 1 curve closely fits the 1% RENALIN II curve. Therefore, Microbicide 1 exhibits anti-microbial effects equal to or greater than 1% RENALIN II. Fig. 1 also illustrates that Microbicide 1 exhibits significantly greater anti-microbial effects than CIDEX 7, on the order of four logs, after 20 minutes.

The above test was repeated, except using methyl formate, butyl formate, or propyl formate in place of ethyl formate in the same molar concentration. After 20 minutes,  $5 \times 10^4$  bacteria were observed and after 60 minutes no bacterial were observed in the methyl formate solution. After 20 minutes, no bacterial were observed and after 60 minutes  $6 \times 10^4$  bacterial were observed in the propyl formate solution. The propyl formate solution was retested and no bacteria was observed after 20 and 60 minutes. Therefore, the bacteria observed after 60 minutes in the propyl formate solution was a procedural error. After 20 minutes,  $4.3 \times 10^7$  bacterial were observed and after 60 minutes  $3.3 \times 10^6$  bacteria were observed in the butyl formate solution.

A second test was performed by coating a petri dish (Falcon Corp.), containing an agar made

using tryptic soy (Difco Labs), with either  
Staphylococcus aureus, Pseudomonas aeruginosa, or  
E.coli. After the plates were dry, three wells were  
punched into the agar and filled to the top with  
5 either Microbicide 1, RENALIN II or CIDEX 7. The  
plates were then incubated for 48 hours at 37°C.  
The area around the well where no bacterial grew  
(zone of inhibition) was then measured and graphed.  
Figure 2 illustrates the results. The zones where  
10 no bacterial grew were significantly larger for the  
Microbicide 1 than they were for RENALIN II and  
CIDEX 7. This data illustrates that Microbicide 1  
kills significantly more organisms than either of  
RENALIN II or CIDEX 7, and that Microbicide 1 kills  
15 Pseudomonas spp. This is of considerable importance  
because CIDEX 7 has been reported to have difficulty  
in killing Pseudomonas spp. This test is similar to  
the test used for determining the relative  
effectiveness and/or resistance of microorganisms to  
20 antibiotics.

A third test was performed in which an  
AOAC 966.04 (1990) sporicidal test done on  
Clostridium sporogenes using suture loops as the  
carrier. The results are summarized in Table 1. All  
25 tests were run for 5 1/2 hours at 20°C. unless  
stated otherwise.

TABLE 1

	<u>Description:</u>	<u>Results</u> (negatives/#samples):
5	Microbicide 1	49/50
	1/2 concentration Microbicide 1	19/20
	Microbicide 1 pH 7	20/20
	Microbicide 1 in synthetic hard water	20/20
	Microbicide 1 in tap water	20/20
10	Microbicide 1 at 3 1/2 hours exposure	37/40
	Microbicide 1 2 1/2 hours exposure	20/20
	Microbicide 1 (double) <sup>1</sup> 12 min. exp.	19/20
	Microbicide 1 (double) <sup>1</sup> 20 min. exp.	20/20
	Microbicide 1 (double) <sup>2</sup> 12 min. exp.	17/20
15	Microbicide 1 (double) <sup>2</sup> 20 min. exp.	20/20
	Microbicide 1 (double) <sup>2</sup> 30 min. exp.	20/20

\* A tube is considered negative if no growth is observed after 21 days of incubating, heat shocking at 80°C. for 20 minutes and then incubating again for another 72 hours.

<sup>1</sup> Double the amount of urea hydrogen peroxide and ethyl formate, 2 wt.% COBRATEC 99, 50°C.

<sup>2</sup> Double the amount of urea hydrogen peroxide and ethyl formate, 50°C.

A difference of <5 is not statistically significant.

#### EXAMPLE 2

The corrosive effects of Microbicide 1 were tested using the same formulation of Microbicide 1 as used in Example 1, except where noted.

In the first test, the corrosive effects of Microbicide 1 and 1% RENALIN II on chrome plated Kerr dental mirrors. The Microbicide 1 formulation tested was the same as in Example 1 except that it did not include COBRATEC 99 and was adjusted to a pH7 using .1 N NaOH. The pH of Microbicide 1 before

adjusting was 3.8. The mirrors were soaked at room temperature (about 20°C) in a closed container (screw on lid) for a two week period in about 120 ml of Microbicide 1 or 1% RENALIN II. The solutions were changed daily by pouring out the used liquid and refilling with fresh.

This test was an appearance type of inspection process rather than a quantitative evaluation. Upon examination after the two week period, the mirrors soaked in Microbicide 1 had a significantly better appearance than the mirrors soaked in 1% RENALIN II. RENALIN II etched away the chrome layer, exposing the brass underneath. The brass was beginning to corrode which turned the 1% RENALIN II solution blue. The Microbicide 1 only slightly dulled the appearance of the chrome plating.

In the second test, the corrosion effects of Microbicide 1 and 3% RENALIN II on a naval brass coupons (approximately 12.3 gms) were tested. The Microbicide 1 tested was the same as in Example 1 except where noted.

Before testing, the brass coupons were cleaned to remove oils, dirt, etc., by placing the coupons in a glass tray containing acetone and sonicating for about 5 minutes, removing the coupons with forceps, rinsing with deionized water, and then air drying. The coupons were then weighed (Wt1).

The method used to test the corrosion effects is outlined in the ASTM G1-90, (1992) Vol.3.02, pp.-35-38. Each naval brass coupon was soaked in about 120 ml of test solution for a time period of 24 hours in a plastic specimen cup.

The rate of corrosion was measured using the mass lost during the 24 hour soak period as follows. The naval brass coupons were removed from the test liquids, rinsed thoroughly with deionized water, dried and weighed (Wt2). The corrosion products were then removed from the tested coupons. All of

the tested coupons and one blank coupon were submerged in 10% sulfuric acid for 2 minutes while sonicating. The coupons were then rinsed thoroughly with deionized water, air dried and weighed (Wt3).  
 5 Each coupon was placed on the back of a modified test tube rack in between two glass slides on each side of the coupon. A weighted SCOTCH BRITE pad (3M Corp.) was wrapped around each coupon and the coupon was rubbed 10 times each way with the pad, allowing  
 10 the weight of the pad to be the only downward force exerted on the coupons. Both sides of the coupons were rubbed with the pad. All of the coupons were then placed in 10% sulfuric acid and sonicated for 2minutes. The coupons were then rinsed, air dried  
 15 and weighed (Wt4). The coupons were immersed in sulfuric acid and rubbed with the pad as described above until the weight loss of the tested coupons was almost equal to the amount lost by the blank coupon. The weight loss of the tested coupons will  
 20 not be equal to the amount lost by the blank coupon, but they will usually be within about .001 g of each other. Each weight was measured after air drying as (Wt<sup>n</sup>).

The corrosion rate was calculated using the  
 25 following formula:

corrosion rate (mm/yr)=(KxW)/(AxTx D) where:

A=area of coupon in cm<sup>2</sup> to nearest .1

cm<sup>2</sup> (std=28.7 cm<sup>2</sup>)

K=a constant (8.76x10<sup>4</sup>)

30 T=time of exposure in hours to the nearest .25 hours.

W=the mass lost in g, to the nearest 1mg corrected for the mass lost during cleaning (initial weight-Wt<sup>n</sup> of treated coupon) minus (Initial weight-Wt<sup>n</sup> of blank coupon).

D=density in g/cm<sup>3</sup> of material tested (naval brass c-464 - 8.41 g/cm<sup>3</sup>).

The results are shown in Table 2 and Figure 3.

TABLE 2

	<u>SUBSTANCE TESTED:</u>	<u>CORROSION</u>
5	<u>RATE:</u>	
	Microbicide 1 pH 7, 2x concentrate	.57 mm/yr
	Microbicide 1 pH 7	1.40
10	mm/yr	
	Microbicide 1 pH 7, w/.1% COBRATEC 99	.061
	mm/yr	
	Microbicide 1 w/.1% COBRATEC 99	.094
	mm/yr	
15	Microbicide 1 w/.17% COBRATEC 99	.035
	mm/yr	
	Microbicide 1 w/.1% VICTAWET 35B	.77 mm/yr
	Microbicide 1 w/.1% VICTAWET 58	.34 mm/yr
	Microbicide 1 pH 7, w/.1% sodium nitrite	1.26 mm/yr
20	Microbicide 1 pH 7.8, w/.1% sodium nitrite	1.24
	mm/yr	
	Cath <sub>x</sub>	1.10 mm/yr
	3% RENALIN II	4.13 mm/yr

25 The addition of small amounts of COBRATEC 99 significantly reduced the corrosion rate of brass.

In the third test, the corrosion effects of Microbicide 1 and 1% RENALIN on dental burrs and carbon steel scalpel blades was tested. The  
 30 Microbicide 1 and 1% RENALIN II, and the test procedures, were the same as used in the first test of Example 2, except where noted. Microbicide 1 made the burrs tarnish in 24 hours, but the addition of the COBRATEC 99 (.2%) almost eliminated this  
 35 problem. To compare, 1% RENALIN etched the burr away. The scalpel blades showed no signs of corrosion from Microbicide 1, with or without COBRATEC. 1% RENALIN performed equally well as



Microbicide 1 . However, deionized water (deionized using a mixed bed deionizing system) rusted the blades.

5        EXAMPLE 3

          The stability of Microbicide 1 was tested. Formulas 599-81-18 through 599-81-20 used a 1 quart bottle (Twin City Bottle), with vented caps, which was filled with the test solution and the lid  
10        screwed on. The 1 quart bottles were stored in a closed cabinet at room temperature (about 20°C). All of the other formulas used 30 gm glass vials, which were filled with the test solution and the  
15        lids screwed on. The vials were stored on an open bench top under fluorescent light at room temperature (about 20°C). The formulas with a "T" at the end signifies that the test solution was stored at 50°C instead of 20°C.

          The test solution, length of time tested and  
20        the test results are shown in Table 3. The synthetic hard water used was made by the method described in Official Methods of Analysis, Germicidal and Detergent Sanitizing Action of Disinfectants (Final Action) 960.09 page 139  
25        "Synthetic Hard Water" (Section E).

          The results are also shown in Figures 4-6. Fig.4 illustrates the concentration of performic acid in hard and deionized water over time. Fig.5 illustrates the concentration of hydrogen peroxide  
30        in hard and deionized water over time. Fig. 6 illustrates the stability of hydrogen peroxide and performic acid in deionized water over time.

EXAMPLE 4

35        The anti-microbial composition of the present invention for dialyzer reprocessing was tested. The initial amount of components in the anti-microbial composition of the present invention

for sterilizing/reprocessing can be in the range  
from about 1 to 10 wt.% of an ester of formic acid  
selected from the group consisting of ethyl formate,  
methyl formate, propyl formate and mixtures thereof;  
5 from about 1 to 10 wt.% of an oxidizer; from about  
.001 to .1 wt.% performic acid and up to about 99.98  
wt.% water. Preferably, the initial amount of the  
ester of formic acid is about 2 to about 7 wt.% and  
the oxidizer is from about 3 to 9 wt.% with the  
10 remainder water. More preferably, the initial  
amount of the ester of formic acid is about 2 to 4  
wt.% and the oxidizer is about 4 to 8 wt.% and most  
preferably, the ester of formic acid is about 2.2  
wt.% and the oxidizer is about 7 wt.% (hereinafter  
15 abbreviated as "Microbicide 2" for notation purposes  
only).

For dialyzer sterilizing/reprocessing,  
Microbicide 2 can be diluted from about 1:1 to about  
1:12, and preferably between 1:5 and 1:6 with water.  
20 It is to be understood that in order to remain an  
effective anti-microbial agent, the anti-microbial  
composition for dialyzer reprocessing is diluted  
such that the oxidizer final working concentration  
is between about 0.1 to about 2.0 wt.%.

25 The dialyzer hollow fiber filter units  
(PRIMUS® 1000 high flux polysulfone dialyzers by  
Renal Systems, Division of Minntech Corporation)  
were first steam sterilized prior to any  
reprocessing. Dialyzers were reprocessed or  
30 sterilized using Microbicide 2 were compared to  
dialyzers reprocessed using another anti-microbial  
composition of hydrogen peroxide, acetic acid and  
peracetic acid, namely, RENALIN® (Minntech  
Corporation). Dialyzers were attached to an  
35 automated dialyzer reprocessor, namely RENATRON®  
(Minntech Corporation), wherein the anti-microbial  
composition tested was diluted per RENATRON®  
protocol, about 1:5, with water. The diluted anti-

microbial composition was then cycled through the dialyzer filter so that the diluted anti-microbial composition flows through the hollow fibers in the dialyzer. Performance parameters for dialyzers reprocessed with Microbicide 2 and RENALIN® were compared.

In particular, the following performance measurements were taken on dialyzers reprocessed with either Microbicide 2 or RENALIN®.

Specifically, water permeability, or flux, measured as  $\text{ml}/\text{min}\cdot\text{cm}^2\cdot\text{mmHg}$  and  $\text{Na}^+$  clearance, as an estimate for plasma urea clearance measured as  $\text{ml}/\text{min}$ , were performed on reprocessed dialyzers. Baseline pretreatment measurements were taken prior to any reprocessing. Performance measurements were taken on reprocessed dialyzers after 10 treatments, or reprocessing cycles on the RENATRON®, and after 20 treatments. Also, after 20 treatments, the reprocessed dialyzers were evaluated for BSA rejection, as an indicator for albumin rejection during dialysis. The following table summarizes the results.

Table 4

Number of Exposures to Anti-Microbial Composition

	<u>0</u>	<u>10</u>	<u>20</u>
<u>Microbicide</u> <u>2<sup>1</sup></u>			
Flux	23.95 +/- 2.33	31.88 +/- 4.08	30.05 +/- 3.15
Clearance	171.35 +/- 3.81	168.67 +/- 4.08	163.27 +/- 4.74
BSA Rejection			99.90 +/- 0.04
<u>RENALIN®<sup>2</sup></u>			
Flux	23.90 26.00	35.90 28.60	28.20 35.50
Clearance	178.70 158.90	161.47 178.10	171.24 177.17
BSA Rejection			99.89 99.88

<sup>1</sup>Six steam sterilized dialyzers were reprocessed using Microbicide 2 which was diluted about 1:5 with water during reprocessing in the RENATRON®.

<sup>2</sup>Two steam sterilized dialyzers were reprocessed using RENALIN® so that about a 3.5% RENALIN® solution in water passed through the dialyzer during reprocessing in the RENATRON®.

Comparison between the performance measurements taken from the dialyzers reprocessed using Microbicide 2 and those taken from the dialyzers using a conventional reprocessing anti-microbial composition indicate that the performance of Microbicide 2 reprocessed dialyzers is substantially similar to the performance of the conventionally reprocessed dialyzers.

TABLE 3

FORMULA #	DATE	FORMULATION	WATER TYPE				INTEGRATION #			
		EF,g	U/P,g	50%H2O2	DI,g	TAP,g	HARD,g	DATE	%H2O2	%PFA
599-56-1	10/7/93	0.44	1.2		20			10/7/93	2.09	0.0089
599-56-3	10/8/93	0.44	1.2		20			10/8/93	2.11	0.0073
599-56-4	10/11/93	0.44	1.2		20			10/11/93	2.08	0.0065
599-56-5	10/11/93	0.44	1.2		20			10/11/93	2.08	0.0154
599-56-6	10/12/93	0.44	1.2		20			10/12/93	1.91	0.0113
599-56-7	10/15/93	0.44	1.2		20			10/15/93	2.08	0.0154
599-57-11	10/8/93	0.88	1.2		20			10/8/93	2.11	0.0105
599-57-12	10/8/93	0.44	1.2		20			10/8/93	3.83	0.0089
599-64-13-H	10/25/93	0.44	1.2				20 500PPM Ca	10/26/93	2.3	0.0211
599-64-14-H	10/25/93	0.52	1.2				20 500PPM Ca	10/26/93	2.11	0.0130
599-65-15-T	10/26/93	0.44	1.2			20		10/26/93	2.06	0.0122
599-65-16-T	10/26/93	0.44	1.2			20		10/26/93	2.07	0.0105
599-65-17-T	10/26/93	0.88	2.4			20		10/26/93	2.86	0.0105
599-65-18-T	10/26/93	0.88	2.4			20		10/26/93	3.9	0.0178
599-65-19-T	10/26/93	0.22	1.2			20		10/26/93	2.08	0.0049
599-65-20-T	10/26/93	0.22	1.2			20		10/27/93	2.06	0.0162

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FORMULA #	DATE	FORMULATION				WATER TYPE			ITERATION #	
		EF,g	U/P,g	50%H2O2	DI,g	TAP,g	HARD,g	DATE	%H2O2	%PFA
599-66-13	10/29/93	0.22	0.6		20				1.08	0.0057
599-66-14	10/29/93	0.22	0.6		20				1.07	0.0008
599-66-15	10/29/93	0.22	0.6		20				1.08	0.0081
599-66-16	10/29/93	0.22	0.6		20				1.09	0.0041
599-80-1	11/18/93	0.44	1.2		20				2.06	0.0113
599-80-2	11/18/93	0.44	1.2		20				2.08	0.0122
599-80-3	11/18/93	0.44	1.2		20				2.07	0.0105
599-80-4	11/18/93	0.44	1.2		20				2.08	0.0081
599-80-5	11/18/93	0.44	1.2		20		20 500PPM			
599-80-6	11/18/93	0.44	1.2		20		20 500PPM		2.02	0.0251
599-80-7	11/18/93	0.44	1.2		20		20 500PPM		2.09	0.0130
599-80-8	11/18/93	0.44	1.2		20		20 500PPM		2.07	0.0154
599-80-9	11/18/93	0.44	1.2		20		20 1000PPM		2.07	0.0113
599-80-10	11/18/93	0.44	1.2		20		20 1000PPM		1.95	0.0113
599-81-11-Ca	11/19/93	0.44	1.2		20		20 500PPM CaCl2		2.05	0.0138
599-81-42-Ca	11/19/93	0.44	1.2		20		20 500PPM CaCl2		2.06	0.0186
599-81-13-Bi	11/19/93	0.44	1.2		20		20 .22g/L BICARB		2.06	0.0097

FORMULA #	DATE			FORMULATION			WATER TYPE			TITRATION #		
	EF,g	U/P,g	50%H2O2	DI,g	TAP,g	HARD,g	DATE	%H2O2	%PFA			
599-81-14-Bi	0.44	1.2				.22g/L BICARB	11/22/93	2.02	0.0122			
599-81-15-Bc	0.44	1.2			.22g/L BICARB	11/22/93	2.06	0.0178				
599-81-16-Bc	0.44	1.2			.22g/L BICARB	11/22/93	2.05	0.0178				
599-81-17	0.44	1.2		1 quart			11/22/93	2.11	0.0130			
599-81-18	0.44	1.2		1 quart			11/22/93	2.14	1.2231			
599-81-19	1.32	3.6		1 quart			11/22/93	5.28	0.0502			
599-81-20	1.32	3.6		1 quart			11/22/93	5.26	0.0292			
599-83-21	1.8	4.8		20 g			11/23/93	6.72	0.0340			
599-83-22	1.8	4.8		20 g			11/23/93	6.67	0.0292			
599-83-23	1.8	4.8			20 500PPM		11/23/93	5.88	0.0446			
599-83-24	1.8	4.8			20 500PPM		11/23/93	6.75	0.0470			
599-83-25	1.8	4.8			20 1000PPM		11/23/93	6.7	0.0446			
599-83-26	1.8	4.8			20 1000PPM		11/23/93	6.79	0.0494			
599-83-27	1.8	4.8			20 1000PPM Ca		11/23/93	6.72	0.0462			
599-83-28	1.8	4.8			20 1000PPM Ca		11/23/93	6.73	0.0494			
599-83-29	1.8	4.8		20 g			11/23/93	6.72	0.0429			
599-83-30	0	4.8		20 g			11/23/93	6.9	0.0089			

FORMULA #	DATE	FORMULATION				WATER TYPE			TITRATION #1		
		EF,g	U/P,g	50%H2O2	DI,g	TAP,g	HARD,g	DATE	%H2O2	%PFA	
599-83-31	11/23/93	1.8	0		20 g			11/23/93	0.004	0.0032	
534-28-1	2/15/94	0.44	1.2		20 g			2/15/94	mixing time and temperature		
534-29-1	2/15/94	0.44		0.8	18.76			2/17/94	2.12	0.0073	
534-29-1T	2/15/94	0.44		0.8	18.76			2/17/94	2.12	0.0073	
534-29-2	2/15/94	0.88		0.8	18.32			2/17/94	2.25	0.0275	
534-29-2T	2/15/94	0.88		0.8	18.32			2/17/94	2.25	0.0275	
534-29-3	2/15/94	0.44		1.6	17.96			2/17/94	4.2	0.0219	
534-29-3T	2/15/94	0.44		1.6	17.96			2/17/94	4.2	0.0219	
534-29-4	2/15/94	0.88		1.6	17.52			2/17/94	4.32	0.0259	
534-29-4T	2/15/94	0.88		1.6	17.52			2/17/94	4.32	0.0259	
534-29-5	2/15/94	1.76		1.6	16.64			2/17/94	4.5	0.0243	
534-29-5T	2/15/94	1.76		1.6	16.64			2/17/94	4.5	0.0243	
534-29-6	2/15/94	0.44		3.2	16.36			2/17/94	8.26	0.0284	
534-29-6T	2/15/94	0.44		3.2	16.36			2/17/94	8.26	0.0284	
534-29-7	2/15/94	0.88		3.2	15.92			2/17/94	8.35	0.0251	
534-29-7T	2/15/94	0.88		3.2	15.92			2/17/94	8.35	0.0251	
534-29-8	2/15/94	1.76		3.2	15.04			2/17/94	8.64	0.0267	



FORMULA #	DATE	FORMULATION	WATER TYPE			TITRATION #					
			EF,g	U/P,g	50%H2O2	DI,g	TAP,g	HARD,g	DATE	%H2O2	%PFA
534-29-8T	2/15/94		1.76	-	3.2	15.04			2/17/94	8.64	0.0267
534-29-9	2/15/94		1.76		3.2	15.04			2/17/94	8.6	0.0535
534-29-9T	2/15/94		1.76		3.2	15.04			2/17/94	8.6	0.0535
534-29-10	2/15/94		3.52		3.2	13.28			2/17/94	9.63	0.0599
534-29-10T	2/15/94		3.52		3.2	13.28			2/17/94	9.63	0.0599
534-29-11	2/15/94		8		52	0			2/17/94	44.9	0.2349
534-29-11T	2/15/94		8		52	0			2/17/94	44.9	0.2349
534-29-12	2/15/94		6		54	0			2/17/94	46.8	0.5249
534-29-12T	2/15/94		6		54	0			2/17/94	46.8	0.5249
534-29-13	2/15/94		4		56	0			2/17/94	46.1	0.2584
534-29-13T	2/15/94		4		56	0			2/17/94	46.1	0.2584
534-29-14	2/15/94		2		58	0			2/17/94	49.8	0.1393
534-29-14T	2/15/94		2		58	0			2/17/94	49.8	0.1393
534-29-15	2/15/94		10		50	0			2/17/94	45.6	0.4755
534-29-15T	2/15/94		10		50	0			2/17/94	45.6	0.4755
534-29-16	2/15/94		1.76		3.2	7.04		8g 1000PPM	2/17/94	8.48	0.0275
534-29-16T	2/15/94		1.76		3.2	7.04		8g 1000PPM	2/17/94	8.48	0.0275

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FORMULA #	DATE	FORMULATION	WATER TYPE				TITRATION #1			
		EF,g	U/P,g	50%H2O2	DI,g	TAP,g	HARD,g	DATE	%H2O2	%PFA
524-29-17	2/15/94	1.76		3.2	9.04		6g 1000PPM	2/17/94	8.61	0.0543
524-29-17T	2/15/94	1.76		3.2	9.04		6g 1000PPM	2/17/94	8.61	0.0543
524-29-18	2/15/94	1.76		3.2	11.04		4g 1000PPM	2/17/94	8.52	0.0697
524-29-18T	2/15/94	1.76		3.2	11.04		4g 1000PPM	2/17/94	8.52	0.0697
524-29-19	2/15/94	1.76		3.2	13.04		2g 1000PPM	2/17/94	8.58	0.0680
524-29-19T	2/15/94	1.76		3.2	13.04		2g 1000PPM	2/17/94	8.58	0.0680
529-29-20	2/15/94	1.76		3.2	14.04		1g 1000PPM	2/17/94	8.57	0.0680
529-29-20T	2/15/94	1.76		3.2	14.04		1g 1000PPM	2/17/94	8.57	0.0770
529-29-21	2/15/94	1.76		3.2	6.8		10g 1000PPM	2/17/94	6.98	0.0770
529-29-21T	2/15/94	1.76		3.2	6.8		10g 1000PPM	2/17/94	6.98	0.0648
529-29-22	2/15/94	0		3.2	16.8			2/17/94	8.14	0.0648
529-29-22T	2/15/94	0		3.2	16.8			2/17/94	8.14	0.0356
529-29-23	2/15/94	0.44		0.8	18.72	.04g COBRATEC 99		2/17/94	2.18	0.0356
529-29-23T	2/15/94	0.44		0.8	18.72	.04g COBRATEC 99		2/17/94	2.18	0.0186
529-29-24	2/15/94	0.44		1.2	20			2/17/94	2.09	0.0186
529-29-24T	2/15/94	0.44		1.2	20			2/17/94	2.09	0.0154
529-29-25	2/15/94	0.44		1.2	20			2/17/94	2.09	0.0170

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FORMULA #	DATE	FORMULATION					WATER TYPE			TITRATION #1		
		EF,g	U/P,g	50%H2O2	DI,g	TAP,g	HARD,g	DATE	%H2O2	%PFA		
529-29-25T	2/15/94	0.44		1.2	20			2/17/94	2.09	0.0170		
529-29-26	2/15/94	0		3.2	16.8			2/17/94	8.66	0.0348		
529-29-26T	2/15/94	0		3.2	16.8			2/17/94	8.66	0.348		

FORMULA #	TITRATION #2				TITRATION #3				TITRATION #4			
	DATE	%H2O2	%PFA	DATE	%H2O2	%PFA	DATE	%H2O2	%PFA	DATE	%H2O2	%PFA
599-56-1	10/8/93	2.06	0.0154	10/11/93	2.07	0.0146	10/12/93	2.08	0.0162			
599-56-3	10/11/93	2.09	0.0122	10/11/93	2.1	0.0122	10/12/93	2.1	0.0154			
599-56-4	10/12/93	2.08	0.0138	10/14/93	2.07	0.0162	10/25/93	1.99	0.0041			
599-56-5	10/12/93	2.07	0.0113	10/14/93	2.07	0.0138	10/15/93	2.06	0.0186			
599-56-6	10/14/93	1.92	0.0130	10/25/93	1.86	0.0122	2/15/94	1.49	0.0105			
599-56-7	10/25/93	2.04	0.0219	2/15/94	1.64	0.0146						
599-57-11	10/8/93	2.15	0.0122	10/12/93	2.08	0.0162	10/14/93	2.04	0.0130			
599-57-12	10/8/93	3.84	0.0073	10/12/93	3.78	0.0122	10/14/93	3.75	0.0105			
599-64-13-H	10/26/93	2.09	0.0518	10/26/93	2.03	0.0154	10/26/93	2.04	0.0138			
599-64-14-H	11/2/93	2.03	0.0186	11/18/93	1.84	0.0194	2/15/94	1.41	0.0535			
599-65-15-T	10/27/93	2.03	0.0122	11/2/93	1.99	0.0049	11/18/93	1.85	0.0032			
599-65-16-T	11/2/93	1.99	0.0049	11/18/93	1.85	0.0073	2/15/94	1.42	0.0186			
599-65-17-T	10/27/93	3.81	0.0259	11/2/93	3.6	0.0113	11/18/93	3.13	0.0146			
599-65-18-T	11/2/93	3.63	0.0170	11/18/93	31.5	0.0122	2/15/94	2.25	0.0105			
599-65-19-T	10/26/93	2.06	0.0097	2/15/94	1.72	0.0211						
599-65-20-T	2/15/94	1.67	0.0041									

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FORMULA #	TITRATION #2				TITRATION #3				TITRATION #4			
	DATE	%H2O2	%PFA	DATE	%H2O2	%PFA	DATE	%H2O2	%PFA	DATE	%H2O2	%PFA
599-66-13	11/2/93	1.08	0.0081	2/15/94	0.93	0.0348						
599-66-14	11/2/93	1.08	0.0081	2/15/94	0.94	0.0235						
599-66-15	11/2/93	1.09	0.0041	2/15/94	0.96	0.0203						
599-66-16	11/2/93	1.09	0.0057	2/15/94	0.94	0.0251						
599-80-1	11/22/93	2.04	0.0073	2/15/94	1.59	0.0105						
599-80-2	11/22/93	2.07	0.0162	2/15/94	1.65	0.0113						
599-80-3	11/22/93	2.05	0.0097	2/15/94	1.64	0.0243						
599-80-4	11/22/93	2.06	0.0154	2/15/94	1.61	0.0170						
599-80-6	11/22/93	1.99	0.0146	2/15/94	1.56	0.0834						
599-80-7	11/22/93	2.06	0.1539	2/15/94	1.56							
599-80-8	11/22/93	2.04	0.0170	2/15/94	1.54	0.0656						
599-80-9	11/22/93	2.03	0.0154	2/15/94	1.4	0.0810						
599-80-10	11/22/93	1.94	0.0178	2/14/94	1.39	0.0640						
599-81-11-Ca	2/14/94	1.6	0.0397									
599-81-42-Ca	2/14/94	1.58	0.0413									
599-81-13-Bi	2/14/94	1.64	0.0130									
599-81-14-Bi	2/14/94	1.66	0.0130									

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FORMULA #	ITERATION #2				ITERATION #3				ITERATION #4			
	DATE	%H2O2	%PFA		DATE	%H2O2	%PFA		DATE	%H2O2	%PFA	
599-81-15-Bc	2/14/94	106	0.0664									
599-81-17	2/14/94	1.69	0.0105									
599-81-18	2/14/93	1.5	0.0243									
599-81-19	2/14/93	3.13	0.1134	2/15/94	3.15	0.0284						
599-81-20	2/14/93	3.22	0.0486	2/15/94	3.2	0.0275		2/15/94	3.16	0.0308		
599-83-21	12/3/93	5.58	0.0308	2/14/94	3.79	0.0365						
599-83-22	12/3/93	5.38	0.0373	2/14/94	3.66	0.0340						
599-83-23	12/3/93	4.97	0.0624	2/14/94	3.26	0.0421						
599-83-24	12/3/93	5.49	0.0632	2/14/94	3.69	0.0365						
599-83-25	12/3/93		0.0923	2/14/94	3.39	0.0421						
599-83-26	12/3/93	5.41	0.0899	2/14/94	3.51	0.0713						
599-83-27	12/3/93	5.63	0.0729	2/14/94	3.74	0.0421						
599-83-28	12/14/93	3.74	0.0365									
599-83-29	12/14/93	3.76	0.0348									

FORMULA #	TITRATION #5				TITRATION #6				TITRATION #7			
	DATE	%H2O2	%PFA		DATE	%H2O2	%PFA		DATE	%H2O2	%PFA	
599-56-1	10/14/93	2.04	0.0138		10/15/93	2.02	0.0154		10/25/93	1.96	0.0073	
599-56-3	10/14/93	2.08	0.0138		10/25/93	1.99	0.0081		10/27/93	1.98	0.0146	
599-56-4	10/27/93	2	0.0073		2/15/94	1.52	0.0186					
599-56-5	10/25/93	1.98	0.0275		10/25/93	1.97	0.0267		10/27/93	1.98	0.0454	
599-57-11	10/25/93	1.86	0.0130		2/15/94	0.95	0.0235					
599-57-12	10/25/93	3.59	0.0113		2/15/94	1.36	0.0194					
599-64-13-H	10/27/93	2.04	0.0178		11/2/93	2	0.0178		11/18/93	1.82	0.0203	
599-65-15-T	2/15/94	1.43	0.0065									
599-65-17-T	2/15/94	2.24	0.0089									

FORMULA #	TITRATION #8				TITRATION #9				TITRATION #10			
	DATE	%H2O2	%PFA		DATE	%H2O2	%PFA		DATE	%H2O2	%PFA	
599-56-1	10/27/93	1.94	0.0081		11/2/93	1.89	0.0146		11/8/93	1.78	0.0065	
599-56-3	2/15/94	1.44	0.0316									
599-56-5	10/29/93	1.95	0.0356		11/2/93	1.92	0.0267		11/18/93	1.81	0.0292	
599-64-13-H	2/15/94	1.38	0.0332									

FORMULA #	TITRATION #11		
	DATE	%H2O2	%PFA
599-56-5	2/15/94	1.4	0.0243



While the invention has been described in detail with reference to specific embodiments thereof, it will be appreciated to one of ordinary skill in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

WHAT IS CLAIMED IS:

1. A method of sterilizing a filter module with an anti-microbial composition comprising contacting the filter module with an anti-microbial composition comprising from about .01 to about 10.0 wt.% of an ester of formic acid; from about .01 to about 10.0 wt.% of an oxidizer; from about 0.001 to about 5.0 wt.% performic acid and up to about 99.98 wt.% water.

2. A method of sterilizing a filter module according to claim 1, wherein the ester of formic acid is selected from the group consisting of ethyl formate, methyl formate, propyl formate, and mixtures thereof.

3. A method of sterilizing a filter module according to claim 1, wherein the oxidizer is hydrogen peroxide.

4. A method of sterilizing a filter module according to claim 2, wherein the ester of formic acid is ethyl formate.

5. A method of sterilizing a filter module according to claim 2, wherein the ester of formic acid is ethyl formate and the oxidizer is hydrogen peroxide.

6. A method of sterilizing a filter module according to claim 5, wherein the ethyl formate is in an amount from about .02 to about 5.0 wt.%; hydrogen peroxide is in an amount from about .02 to about 5.0 wt.%; performic acid is in an amount from about 0.001 to about 1.0 wt.%; and up to about 99.98 wt.% water.

7. A method of sterilizing a filter module according to claim 1 further comprising diluting the anti-microbial composition from about 1:1 to about 1:12 with water prior to contacting the filter module with the anti-microbial composition.
8. A method of sterilizing a filter module according to claim 1, wherein the ester of formic acid is in an amount of about 2.2 wt.%; the oxidizer is in an amount of about 7.0 wt.% and water is in an amount of about 90.8 wt.%.
9. A method of sterilizing a filter module according to claim 8, wherein the ester of formic acid is selected from the group consisting of ethyl formate, methyl formate, propyl formate, and mixtures thereof.
10. A method of sterilizing a filter module according to claim 8, wherein the oxidizer is hydrogen peroxide.
11. A method of sterilizing a filter module according to claim 9, wherein the ester of formic acid is ethyl formate.
12. A method of sterilizing a filter module according to claim 9, wherein the ester of formic acid is ethyl formate and the oxidizer is hydrogen peroxide.
13. A method of sterilizing a filter module according to claim 12, wherein the anti-microbial composition is capable of dilution with water such that the oxidizer is present in an amount between about 0.1 to about 2.0 wt.%.

14. A method of sterilizing a filter module with an anti-microbial composition comprising:

(a) providing an anti-microbial composition comprising from about .01 to about 10.0 wt.% of an ester of formic acid; from about .01 to about 10.0 wt.% of an oxidizer; from about 0.001 to about 5.0 wt.% performic acid and up to about 99.98 wt.% water;

(b) diluting the anti-microbial composition from about 1:1 to about 1:12 with water; and

(c) contacting the filter module with a diluted anti-microbial composition from step (b).

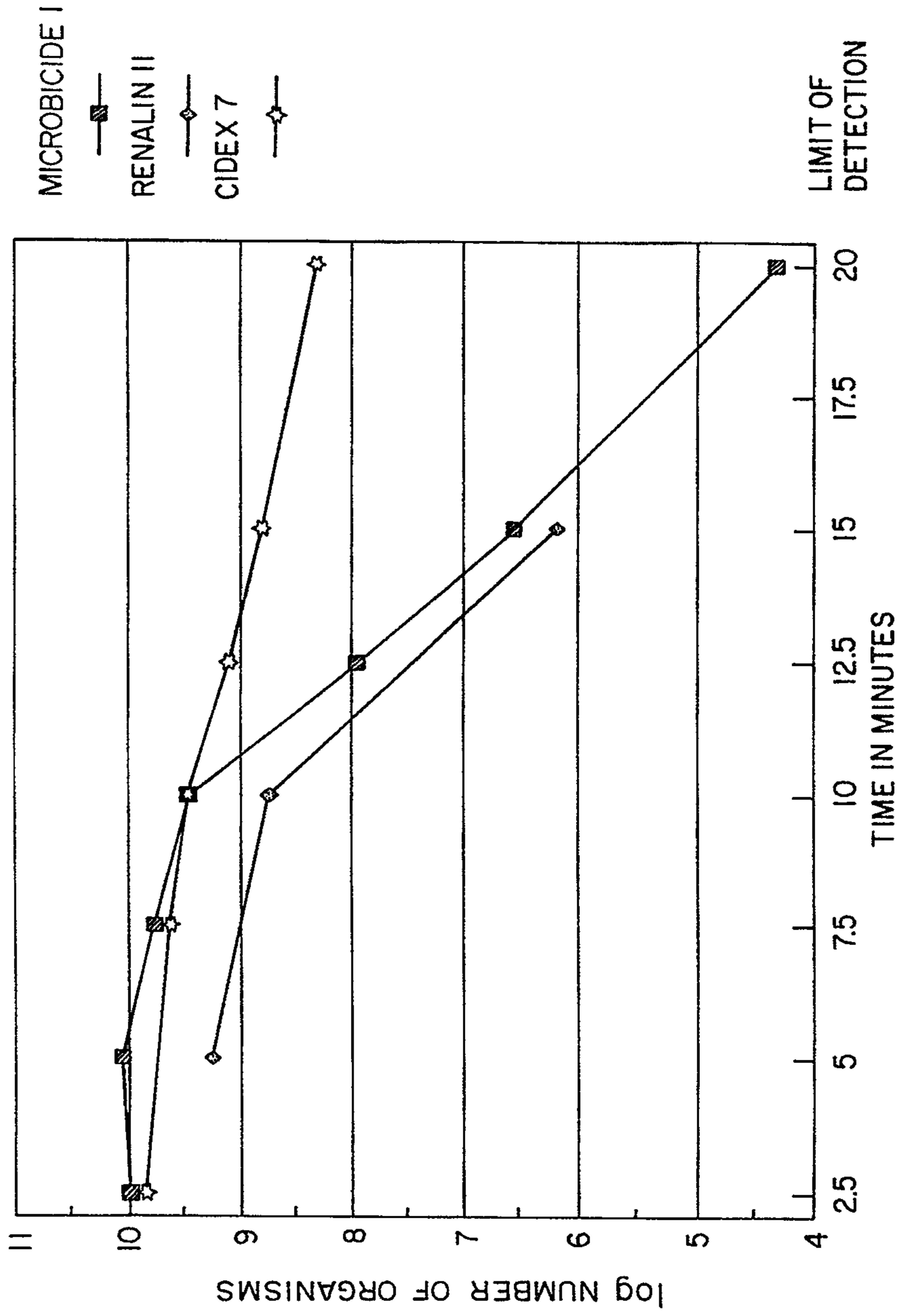
15. A method of sterilizing a filter module with an anti-microbial composition according to claim 14, wherein the diluted anti-microbial composition from step (b) is characterized as including the oxidizer in an amount between about 0.1 to about 2.0 wt.%.

16. A method of sterilizing a filter module with an anti-microbial composition comprising contacting the filter module with an anti-microbial composition comprising:

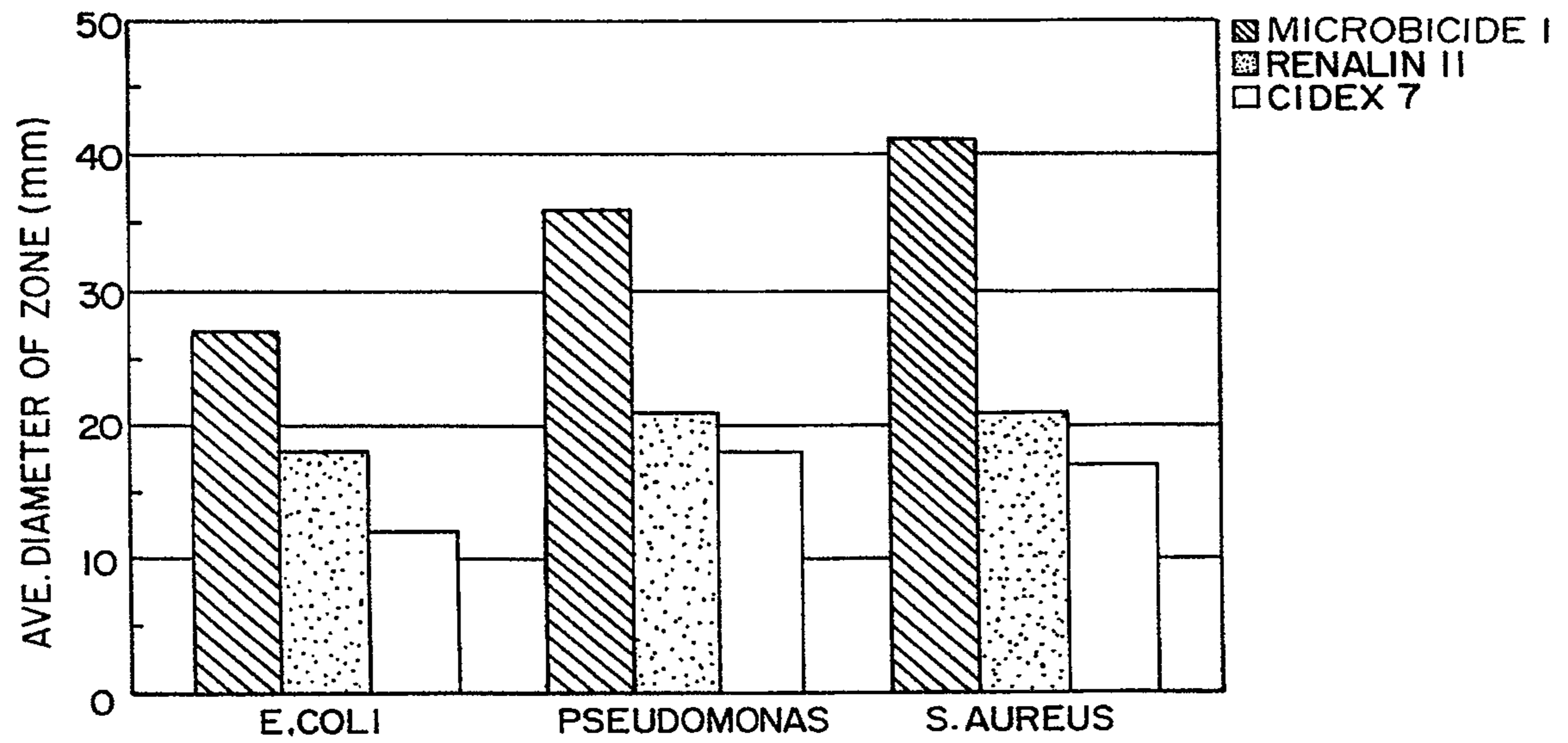
(i) combining a sufficient amount of an ester of formic acid, an oxidizer and water to provide from about 0.01 to about 10.0 wt.% of the ester of formic acid, from about 0.01 to about 10.0 wt.% of the oxidizer, from about 0.001 to about 5.0 wt.% of performic acid and up to about 99.98 wt.% water; and

(ii) diluting the anti-microbial composition from 1:1 to about 1:12 with water.

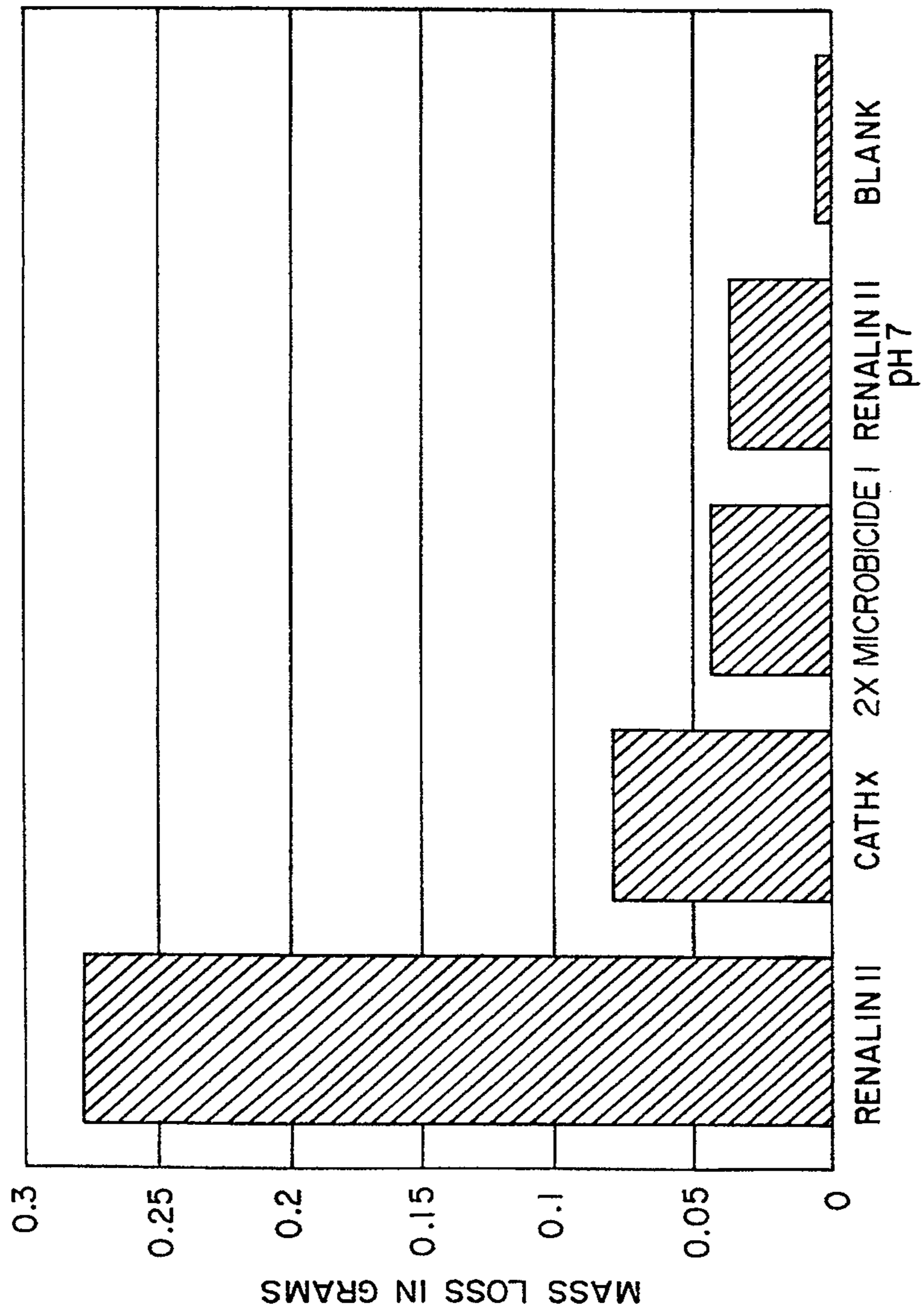
Fig. 1



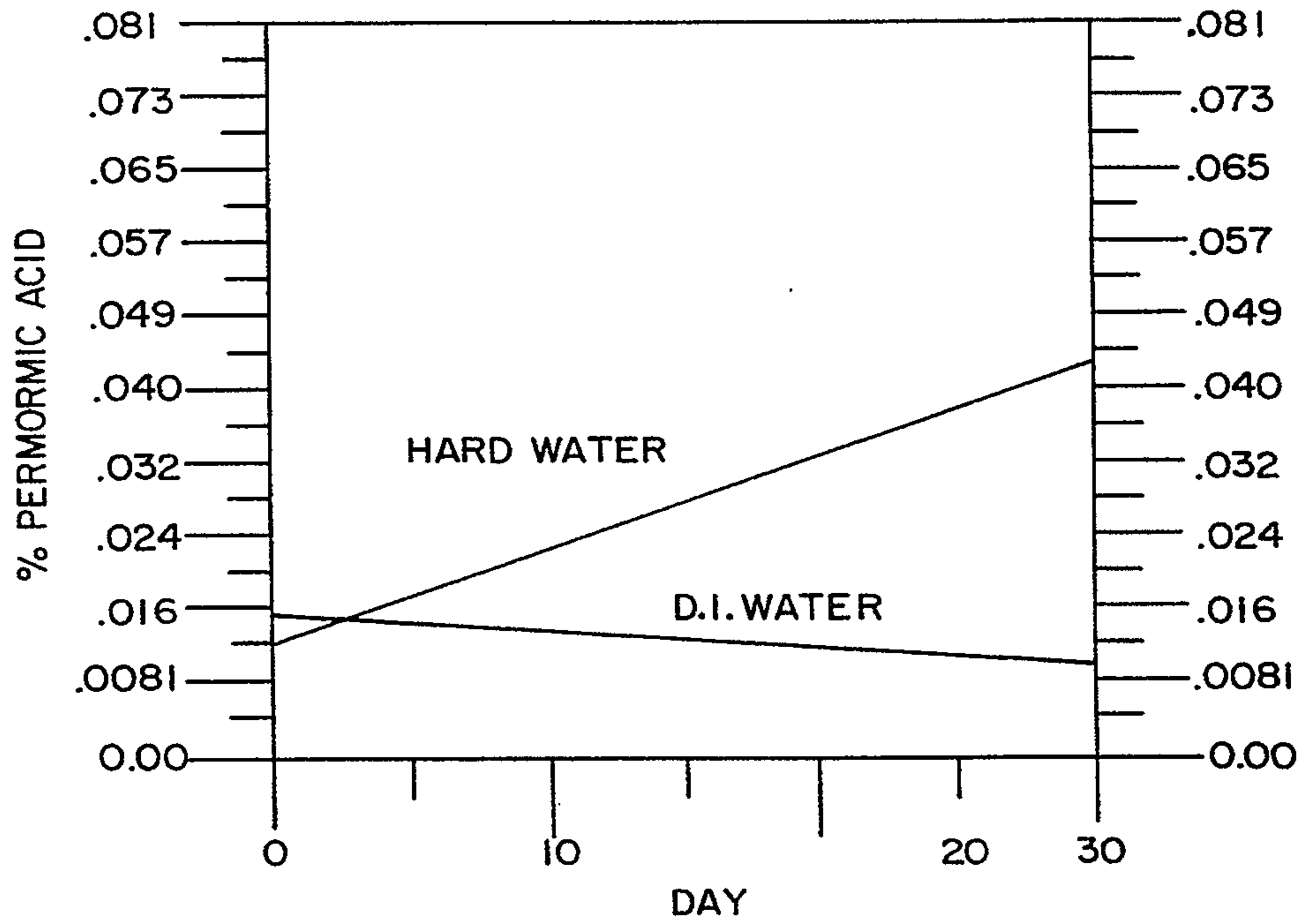
*Fig. 2*



*Fig. 3*

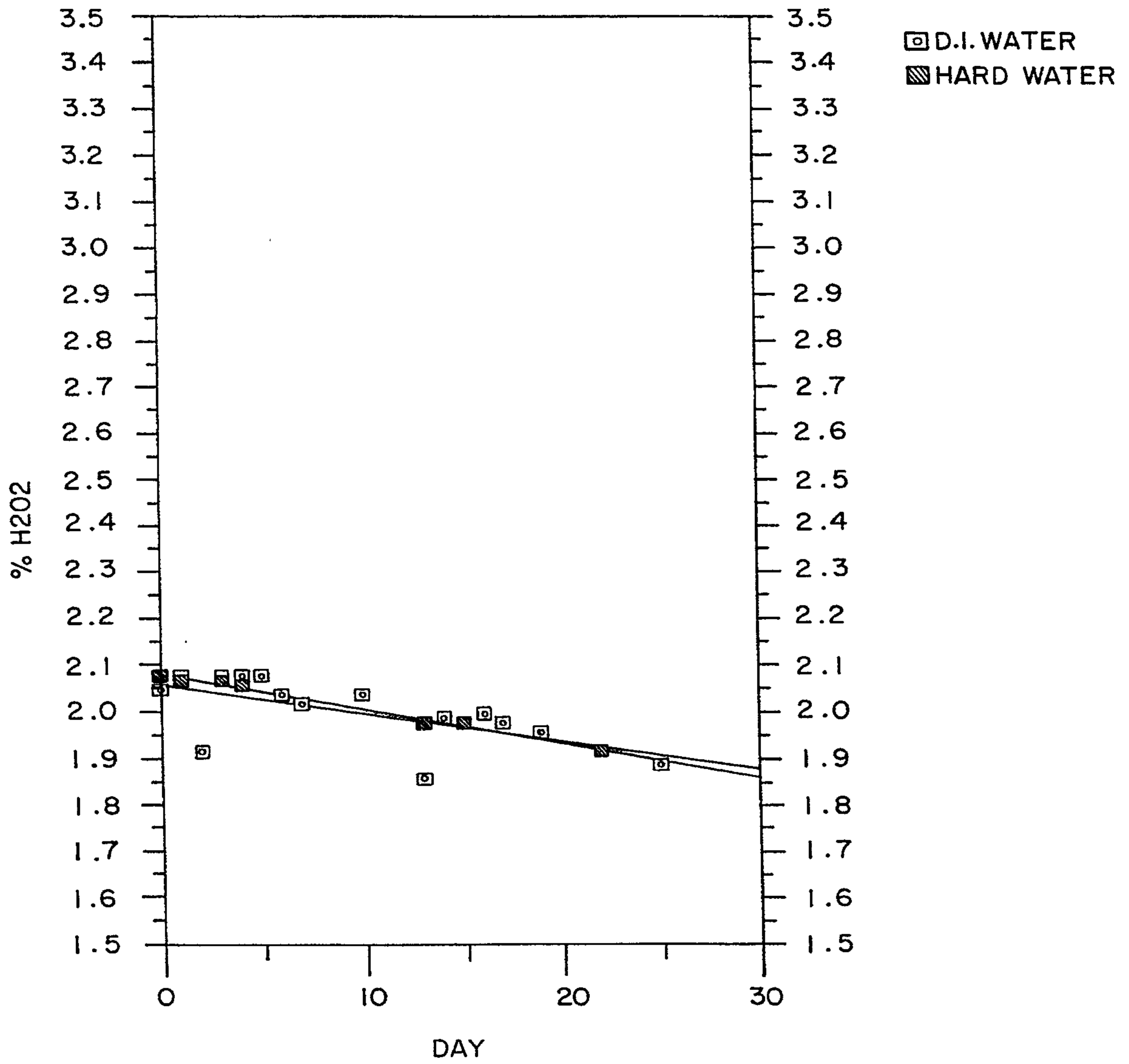


*Fig. 4*





*Fig. 5*



**Fig. 6**

