FIG. 1

Group	Cationic Segment Length	Cationic:Hydrophobic Block Length Ratio	Approximate MW (Da)
I. Long Cationic Segment	200-400	1.5 to 15	>32,000
II. Medium Cationic Segment	100-199	1.5 to 15	16,000 to 32,000
III. Short Cationic Segment	10-99	1.5 to 15	<16,000

FIG. 2

Group	Cationic Segment (Plurality of cationic amino acid units)		Hydrophobic Segment (Plurality of hydrophobic amino acid units)	
	Cationic Amino Acid Selection	**Lengths**	**Hydrophobic Amino Acid Selection**	**Cationic:hydrophobic Segment Length Ratio**
I. Long Cationic Segment ≥200 amino acid units with a plurality of cationic amino acid units	Lysine (K)	200-400	Alanine (A) Phenylalanine (F) Glycine (G) Isoleucine (I) Leucine (L) Methionine (M) Proline (P)	1.5 to 15
	Arginine (R)	200-400		
	Histidine (H)	200-400		
	Ornithine(O)	200-400		
II. Medium Cationic Segment 100 to 199 amino acid units with a plurality of cationic amino acid units	Lysine (K)	100-199	Alanine (A) Phenylalanine (F) Glycine (G) Isoleucine (I) Leucine (L) Methionine (M) Proline (P)	1.5 to 15
	Arginine (R)	100-199		
	Histidine (H)	100-199		
	Ornithine(O)	100-199		
III. Short Cationic Segment 10 to 99 amino acid units with a plurality of cationic amino acid units	Lysine (K)	10-99	Alanine (A) Phenylalanine (F) Glycine (G) Isoleucine (I) Leucine (L) Methionine (M) Proline (P)	1.5 to 15
	Arginine (R)	10-99		
	Histidine (H)	10-99		
	Ornithine(O)	10-99		

FIG. 3

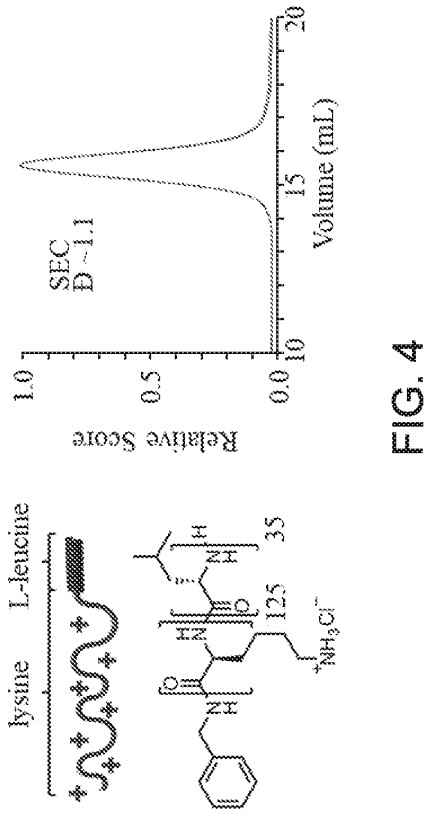

Relative Score
1.0
0.5
0.0
SEC
Đ ~1.1
10
15
20
Volume (mL)
lysine
L-leucine
35
125
$^{+}NH_3Cl^{-}$

FIG. 4

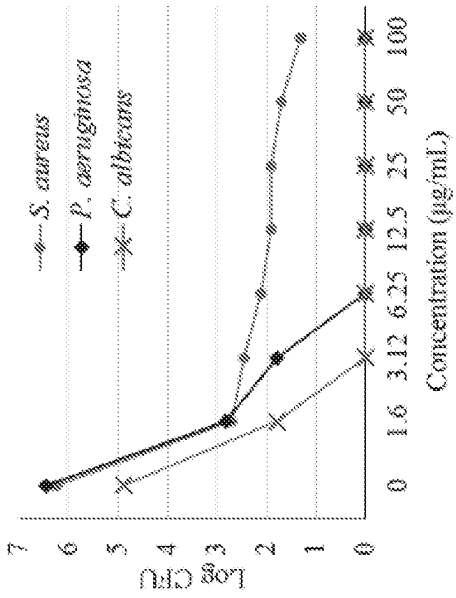

S. aureus
P. aeruginosa
C. albicans
Log CFU
0
1
2
3
4
5
6
7
0
1.6
3.12
6.25
12.5
25
50
100
Concentration (μg/mL)

FIG. 5

	Microbe	% CFU Reduction
Gram positive	*S. aureus*	99.99%
	MRSA*	99.98%
	Vancomycin-resistant *E. faecium* (VRE)*	100%
	S. pyogenes	99.74%
Gram negative	*A. baumannii**	100%
	MDR *A. baumannii**	100%
	ESBL *E. coli**	100%
	K. pneumoniae	100%
	ESBL, KPC *K. pneumoniae**	100%
	P. aeruginosa	100%
	MDR *P. aeruginosa**	100%
Anaerobe	MDR *B. fragilis**	99.80%
Fungi	*C. albicans*	100%
	Fluconazole-resistant *C. albicans**	100%

FIG. 6

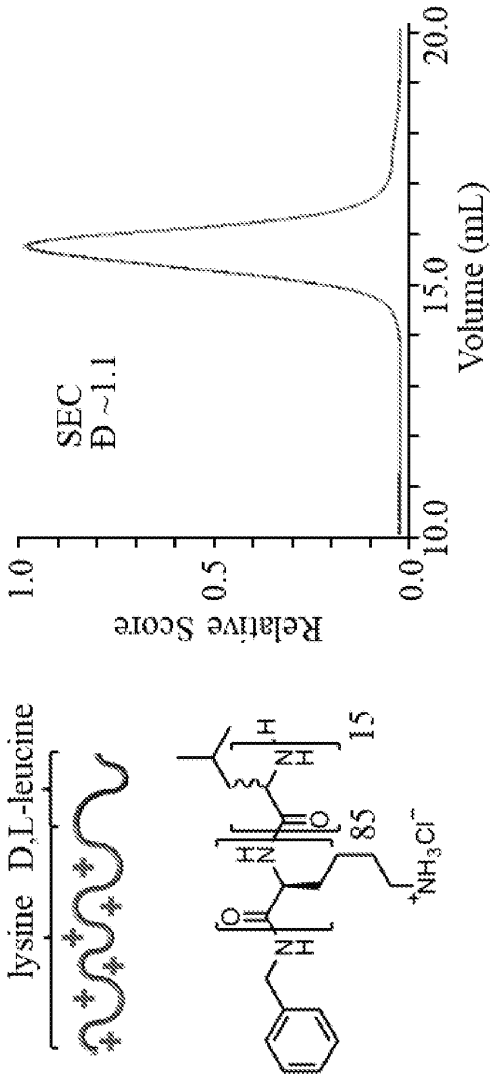

lysine D,L-leucine
85
15
Relative Score
1.0
0.5
0.0
10.0
15.0
20.0
Volume (mL)
SEC
Đ ~1.1

FIG. 7

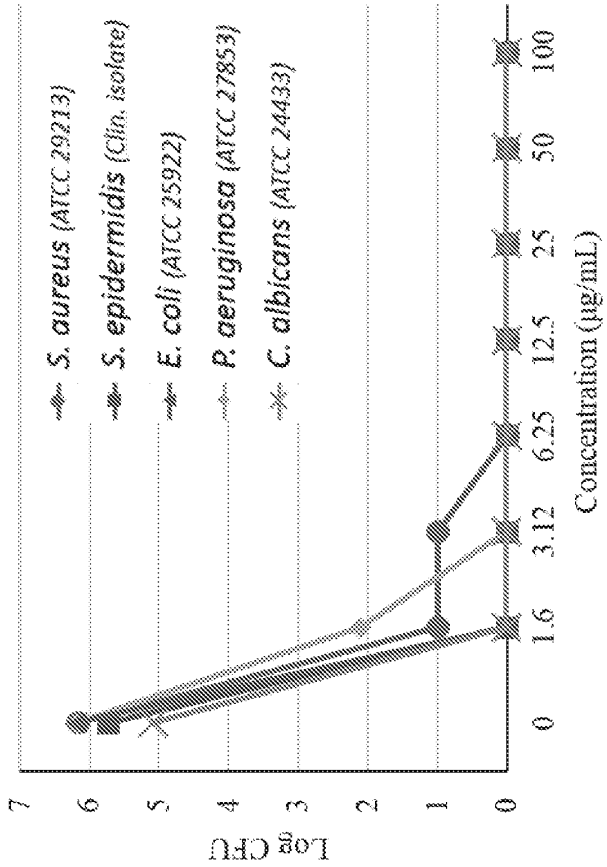

S. aureus (ATCC 29213)
S. epidermidis (Clin. isolate)
E. coli (ATCC 25922)
P. aeruginosa (ATCC 27853)
C. albicans (ATCC 24433)
Log CFU
7
6
5
4
3
2
1
0
0
1.6
3.12
6.25
12.5
25
50
100
Concentration (µg/mL)

FIG. 8

	Microbe	Microbes (t=0 min)	Microbes (t=60 min)	% CFU Reduction
Gram positive	*S. mitis*	1,260,000	0	100%
	MRSA*	1,380,000	0	100%
	Vancomycin-resistant *E. faecium* (VRE)*	955,000	0	100%
	S. progenes	2,630,000	60	99.99%
Gram negative	*A. baumannii**	1,450,000	0	100%
	MDR *A. baumannii**	2,000,000	0	100%
	ESBL *E. coli**	1,480,000	0	100%
	K. pneumoniae	2,190,000	0	100%
	ESBL, KPC *K. pneumoniae**	1,450,000	200	99.99%
	P. aeruginosa	2,190,000	0	100%
	MDR *P. aeruginosa**	2,190,000	0	100%
Anaerobe	MDR *B. fragilis**	776,000	0	100%
Fungi	*C. albicans*	115,000	0	100%
	Fluconazole-resistant *C. albicans**	100,000	0	100%

FIG. 9

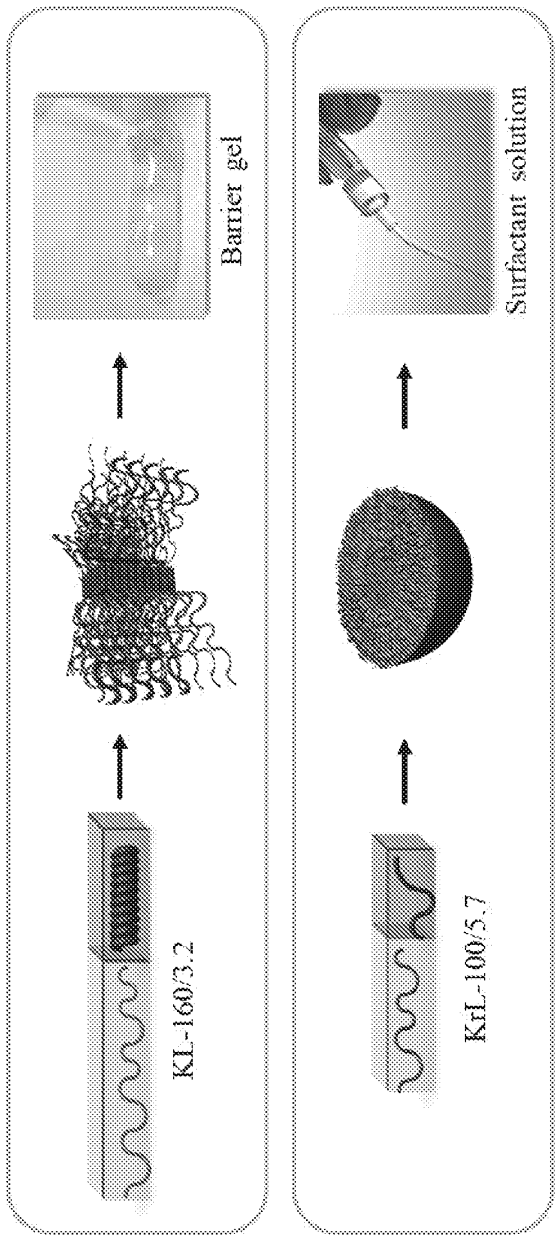


FIG. 10

Molecular Type	Polypeptide Designation	Lot	CAC (μg/mL)
Polylysine	K-100	79	1,600
Lysine + L-leucine	KL-130/3.3-RAN	80	2,700
	KL-170/3.3	111	8
	KL-160/3.2	BAC003	19
	KL-150/2.0	74	2
	KL-140/2.5	99	8
	KL-140/2.5	73	1
	KL-130/3.3	72	6
	KL-120/5.0	71	21
	KL-120/2.5	BAC004	10
Lysine + D,L-leucine	KrL-170/3.3	104	4
	KrL-160/3.2	BAC001	34
	KrL-140/2.5	78	6
	KrL-130/3.3	77	4
	KrL-120/5.0	93	130
	KrL-120/5.0	94	51
	KrL-120/5.0	76	14
	KrL-100/5.7	BAC002	160

FIG. 11

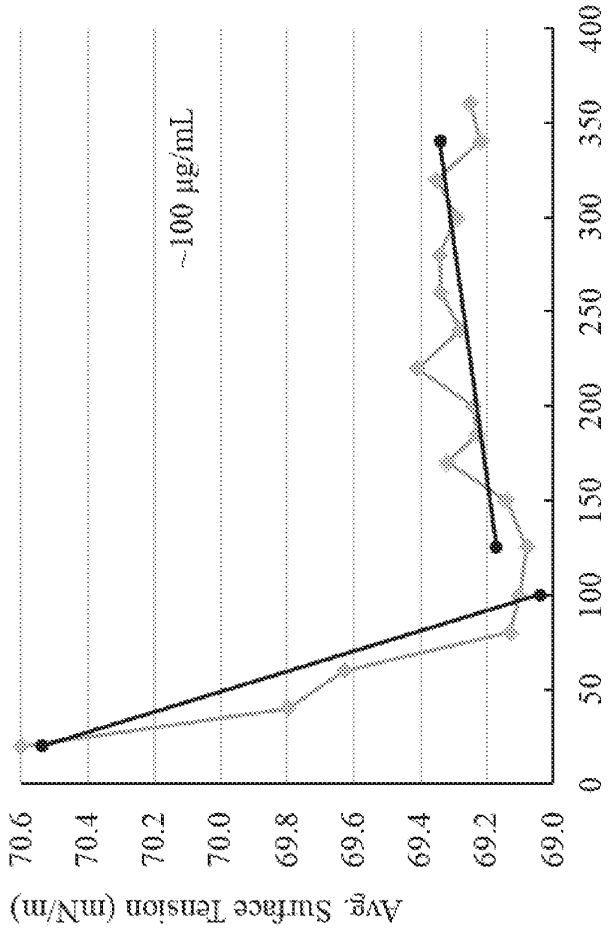
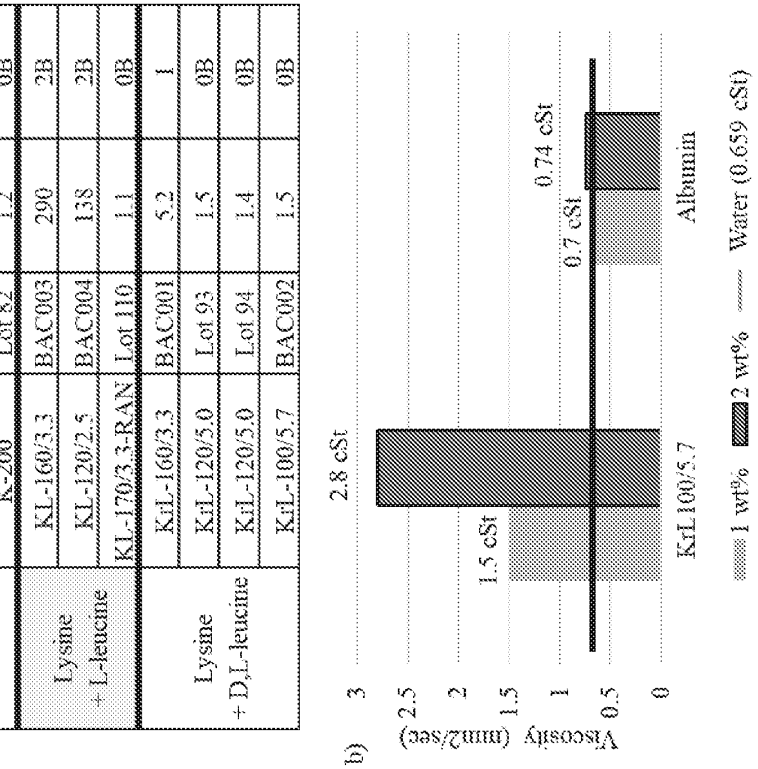

Avg. Surface Tension (mN/m)
70.6
70.4
70.2
70.0
69.8
69.6
69.4
69.2
69.0
0
50
100
150
200
250
300
350
400
Concentration (µg/mL)
~100 µg/mL

FIG. 12

a)

Molecular Type	Polypeptide Designation	Lot	Viscosity (cSt)	Ubbelohde Size
Polylysine	Water	-	0.71	0
	K-100	Lot 79	0.86	0B
	K-200	Lot 82	1.2	0B
Lysine + L-leucine	KL-160/3.3	BAC003	290	2B
	KL-120/2.5	BAC004	138	2B
	KL-170/3.3-RAN	Lot 110	1.1	0B
Lysine + D,L-leucine	KrL-160/3.3	BAC001	5.2	1
	KrL-120/5.0	Lot 93	1.5	0B
	KrL-120/5.0	Lot 94	1.4	0B
	KrL-100/5.7	BAC002	1.5	0B

b)



FIGS. 13A-B

Molecular Type	Polypeptide Designation	Lot	Viscosity (cSt)	Ubbelohde Size
Lysine + L-leucine	KL-160/3.3	BAC003	17	1B
	KL-120/2.5	BAC004	9	1

FIG. 14

Molecular Type	Polypeptide Designation	Lot	Viscosity (cSt)		Ubbelohde Size
			1wt%	2wt%	
Lysine + L-leucine	KL-160/3.2	D-303-18A	24.8	-	1B
	KL-100/5.7	D-301-67-03	5.53	15.17	1, 1B
Lysine + D,L-leucine	KrL-160/3.3	BAC001	5.0	20.7	1, 1B
	KrL-110/4.0	D-301-37-05	2.78	6.45	0B, 1C

FIG. 15

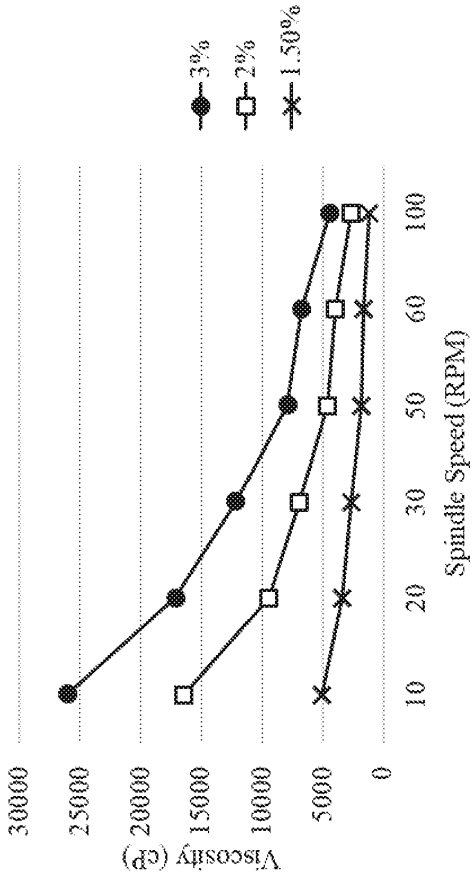
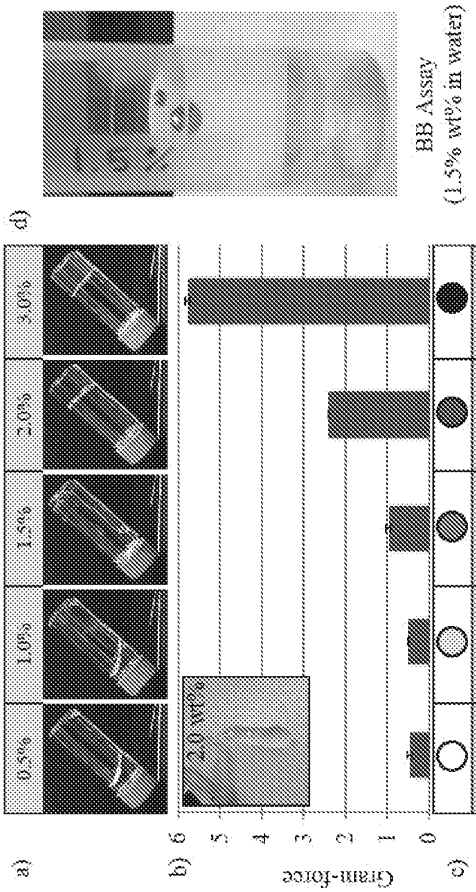

3%
2%
1.50%
Viscosity (cP)
30000
25000
20000
15000
10000
5000
0
10
20
30
50
60
100
Spindle Speed (RPM)

FIG. 16



FIGS. 17A-D

Non-ionic excipients
Dextrose
Mannitol
Glycerol
Xylitol
Sorbitol
Propylene glycol
Non-ionic surfactants

FIG. 18

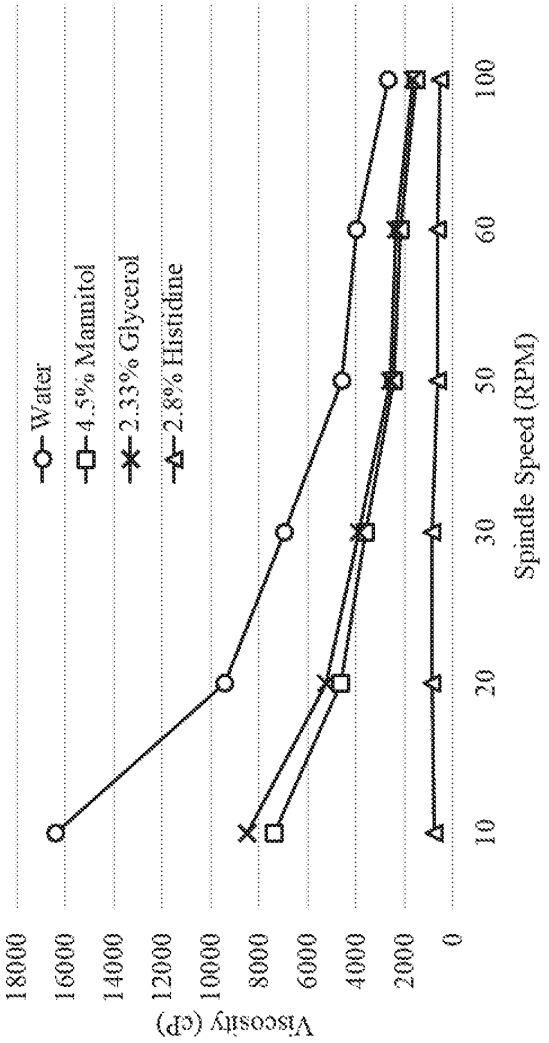

Water
4.5% Mannitol
2.33% Glycerol
2.8% Histidine
Viscosity (cP)
18000
16000
14000
12000
10000
8000
6000
4000
2000
0
10
20
30
50
60
100
Spindle Speed (RPM)

FIG. 19

Polypeptide Designation	Lot	Viscosity (cSt) @ 1wt%		
		Water	Saline (0.9%)	Xylitol (4.4%)
KL-100/5.7	D-301-67-03	5.53	1.50	5.94
KL-110/4.0	D-301-37-05	2.78	1.69	3.14

FIG. 20

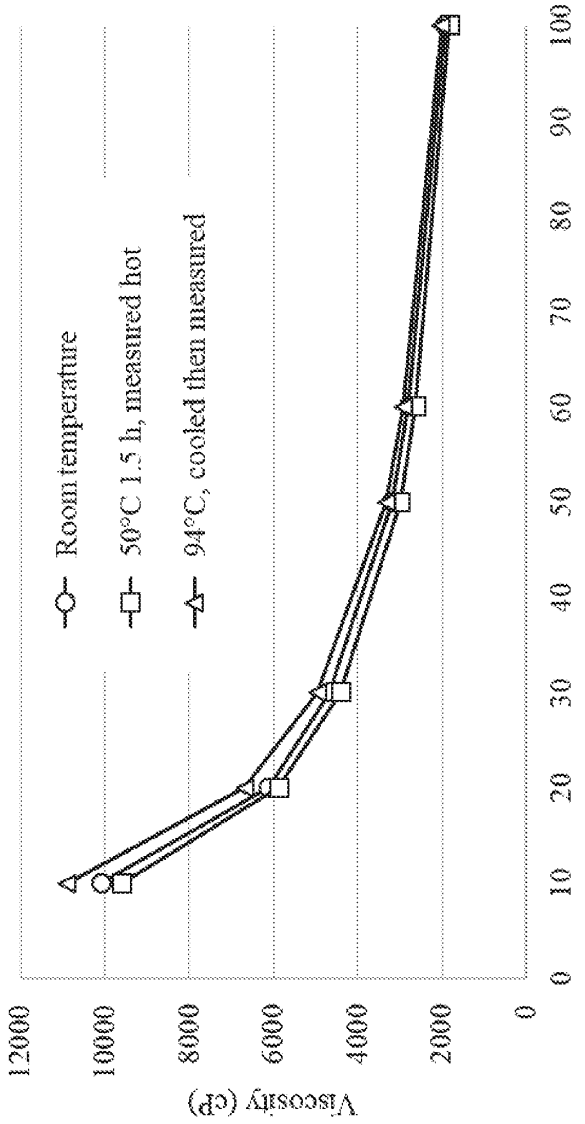

Viscosity (cP)
12000
10000
8000
6000
4000
2000
0
0
10
20
30
40
50
60
70
80
90
100
Shear Rate (RPM)
Room temperature
50°C 1.5 h, measured hot
94°C, cooled then measured

FIG. 21

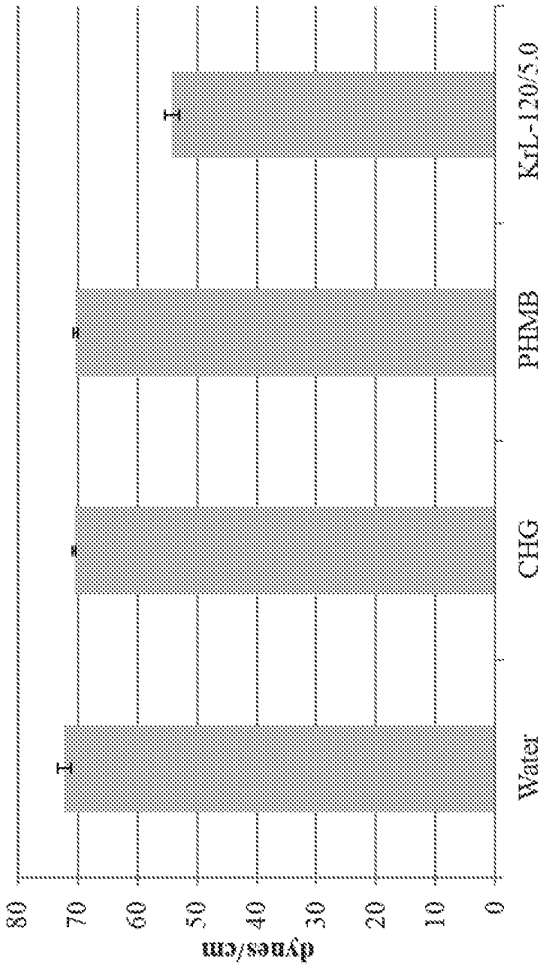
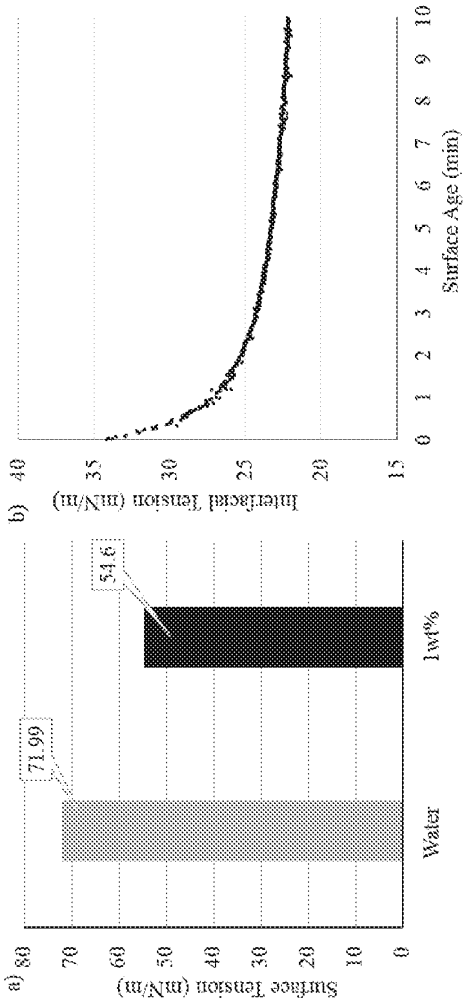


FIG. 22

Synthetic Cationic Polypeptide(s)	Lot	Surface Tension (dynes/cm)
Water	-	72.2
KL-120/5.0	71	68.8
KL-130/3.3	72	71.5
KL-140/2.5	73	72.4
KL-150/2.0	74	72.3
KrL-120/5.0	76	54.2
KrL-130/3.3	77	59.1
KrL-140/2.5	78	60.1
KrL-150/6.5	92	65.7
KrL-170/3.3	104	57.8

FIG. 23


a)
Surface Tension (mN/m)
80
70
60
50
40
30
20
10
0
71.99
54.6
Water
1wt%
b)
Interfacial Tension (mN/m)
40
35
30
25
20
15
0 1 2 3 4 5 6 7 8 9 10
Surface Age (min)

FIGS. 24A-B

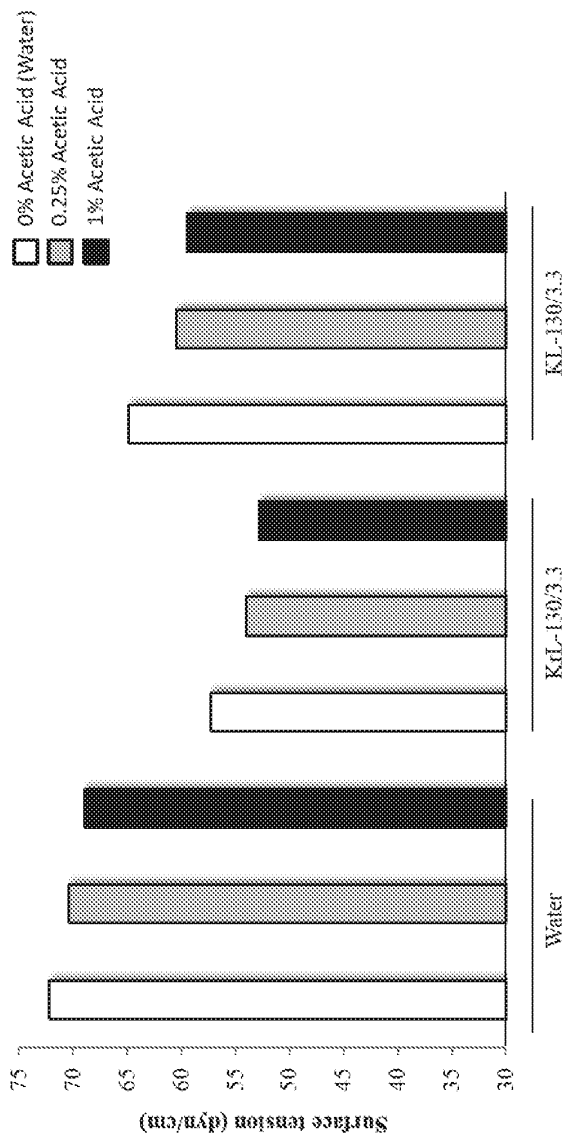

0% Acetic Acid (Water)
0.25% Acetic Acid
1% Acetic Acid
Surface tension (dyn/cm)
75
70
65
60
55
50
45
40
35
30
Water
KdL-130/3.3
KL-130/3.3

FIG. 25

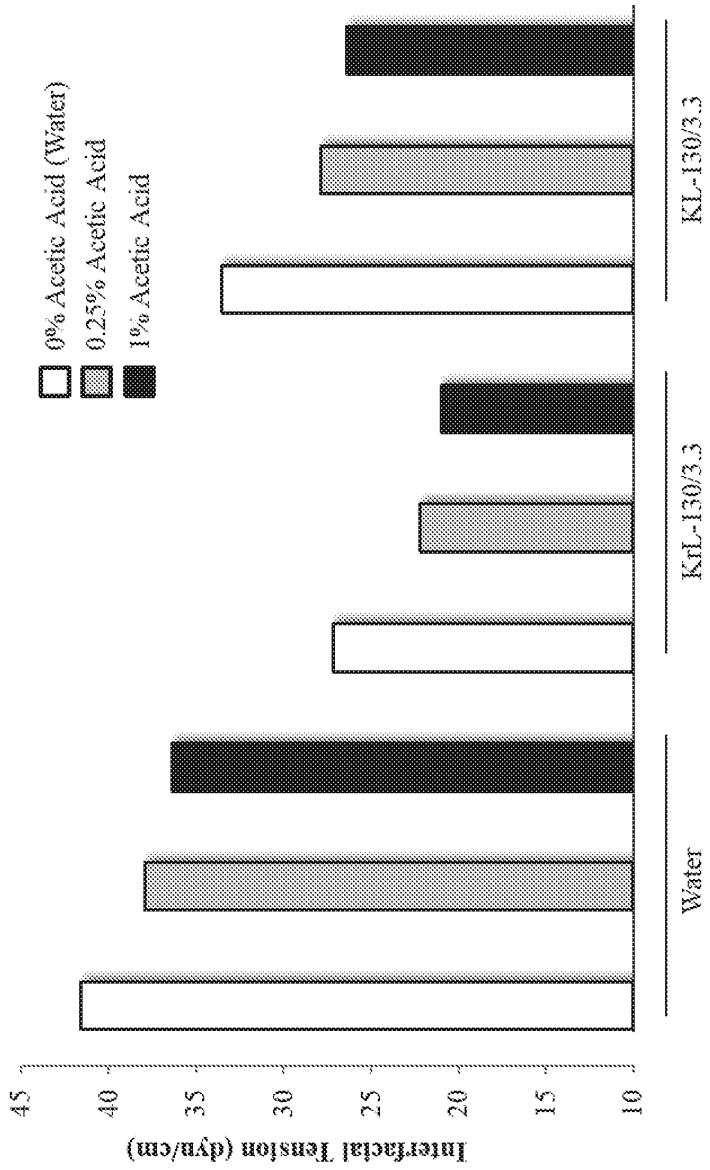
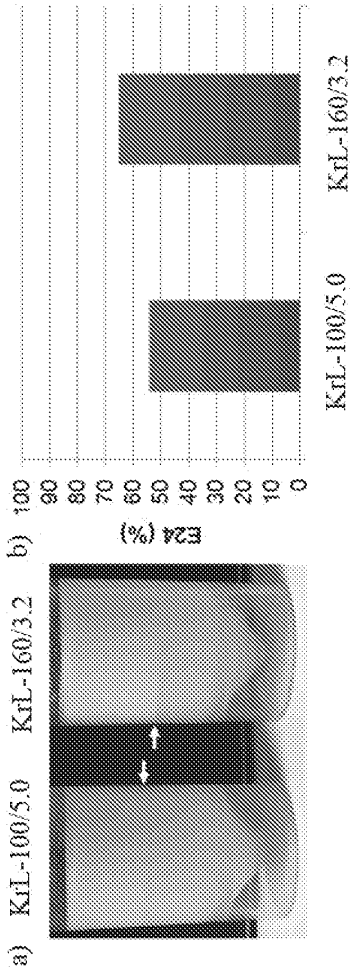

0% Acetic Acid (Water)
0.25% Acetic Acid
1% Acetic Acid
Interfacial Tension (dyn/cm)
45
40
35
30
25
20
15
10
Water
KrL-130/3.3
KL-130/3.3

FIG. 26



FIGS. 27A-B

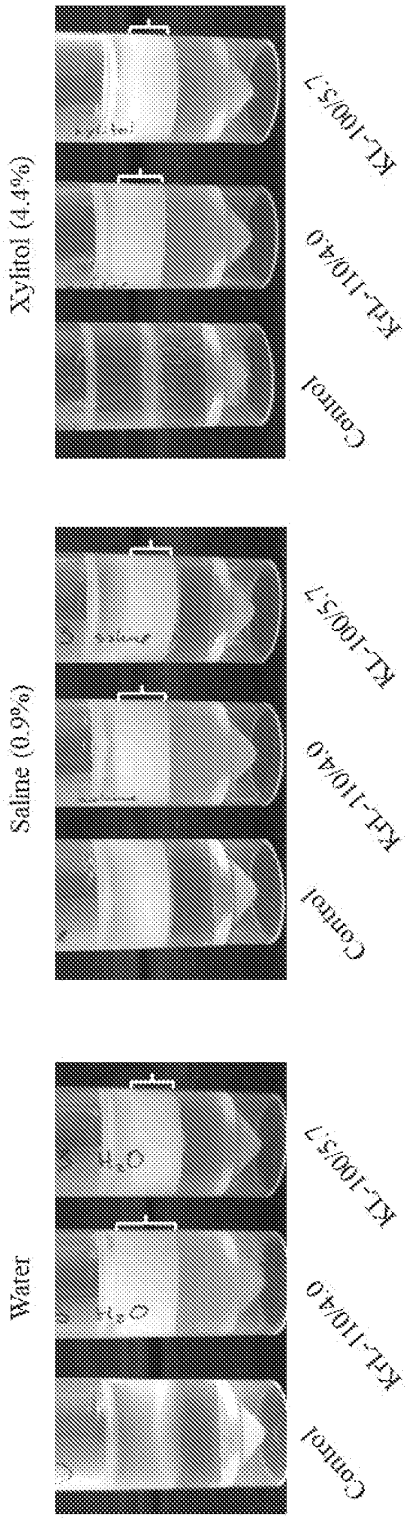


FIG. 28

Synthetic Cationic Polypeptide(s)	Concentration (mg/mL)	Formulation (+ water)	Score		Response Category
			Intact Skin	Abraded Skin	
KL-140/2.5 (Lot 73)	10	-	0	0	Negligible
	20	-	0	0	Negligible
	5	10 mg/mL HEC	0	0	Negligible
	10	5 mg/mL HEC	0.06	0	Negligible
KrL-120/5.0 (Lot 76)	10	-	0	0	Negligible
		2 mg/mL P407	0	0	Negligible
		5 mg/mL HEC	0	0	Negligible
		30 mg/mL PEG400	0	0	Negligible

FIG. 29

KL-140/2.5 (Lot 73), 1wt%		
Animal #	Challenge Scores	
	24h	48h
12497	0	0
12501	0	0
12503	0	0
12508	0	0
12514	0	0
12519	0	0
12520	0	0
12522	0	0
12525	0	0
12529	0	0
12532	0	0

KL-120/5.0 (Lot 93) 1wt%		
Animal #	Challenge Scores	
	24h	48h
12450	0	0
12451	0	0
12452	0	0
12453	0	0
12454	0	0
12455	0	0
12456	0	0
12458	0	0
12459	0	0
12460	0	0
12461	0	0

Scale	Patch test reaction
0	No visible change
1	Discreet or patchy erythema
2	Moderate and confluent erythema
3	Intense erythema and swelling

FIG. 30

Synthetic Cationic Polypeptide(s)	Concentration (mg/mL)	Dosage (mg/kg)	Response
KL-140/2.5 (Lot 76)	20	160	No abnormalities noted
	5	40	No abnormalities noted
	1.25	10	No abnormalities noted
	0.31	2.5	No abnormalities noted
	0.078	0.625	No abnormalities noted
KrL-120/5.0 (Lot 76)	20	160	No abnormalities noted
	5	40	No abnormalities noted
	1.25	10	No abnormalities noted
	0.31	2.5	No abnormalities noted
	0.078	0.625	No abnormalities noted

FIG. 31

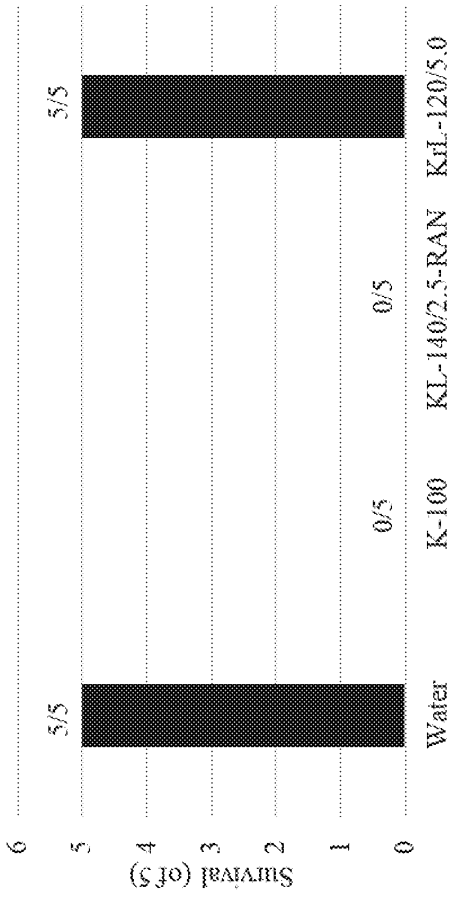


FIG. 32

Synthetic Cationic Polypeptide(s)	Concentration (mg/mL)	Dosage (mg/kg)	Formulation	Survival
KrL-130/3.3 (Lot 77)	20	800	Water	5/5
	5	200		5/5
	1.25	50		5/5
	0.31	12.5		5/5
Saline	-	-	-	5/5

FIG. 33

Synthetic Cationic Polypeptide(s)	Concentration (mg/mL)	Dosage (mg/kg)	Formulation	Survival
KrL-120/5.0 (Lot 93)	20	800	Water	0/0
	5	200		0/0
	1.25	50		5/5
KrL-120/5.0 (Lot 94)	20	800	Water	5/5
	5	200		5/5
	1.25	50		5/5

FIG. 34

Synthetic Cationic Polypeptide(s)	Concentration (mg/mL)	Dosage (mg/kg)	Formulation	Survival
KL-170/3.3 (Lot 86)	10	400	Water	5/5
	2.5	100		5/5
	0.63	25		5/5
	0.16	6.25		5/5
KL-140/2.5 (Lot 73)	10	400	Water	5/5
	2.5	100		5/5
	0.63	25		5/5
	0.16	6.25		5/5
Water	-	-	-	5/5

FIG. 35

Synthetic Cationic Polypeptide(s)	Concentration (mg/mL)	Dosage (mg/kg)	Formulation	Survival
KL-140/2.5 (Lot 73)	10	400	Water	5/5
	2.5	100		5/5
	0.63	25		5/5
	0.16	6.25		5/5
	5	200	10 mg/mL HEC	3/5
	1.25	50	2.5 mg/mL HEC	5/5
	0.31	12.5	0.625 mg/mL HEC	5/5
	0.08	3.125	0.156 mg/mL HEC	5/5
	2	80	15 mg/mL HEC	2/5
	0.5	20	3.75 mg/mL HEC	4/5
	0.125	5	0.937 mg/mL HEC	5/5
	0.031	1.25	0.234 mg/mL HEC	5/5
Water	-	-	-	5/5

FIG. 36

Synthetic Cationic Polypeptide(s)	Concentration (mg/mL)	Dosage (mg/kg)	Formulation	Survival
KrL-120/5.0 (Lot 94)	20	800	Water	5/5
	5	200		5/5
	1.25	50		5/5
	20	800	Normal Saline	5/5
	5	200	4x dilution above	5/5
	1.25	50	4x dilution above	5/5
	20	800	½ Normal Saline	4/5
	5	200	4x dilution above	4/5
	1.25	50	4x dilution above	5/5
	20	800	5 mg/mL T20 + 1 glu/cham	3/5
	5	200	4x dilution above	5/5
	1.25	50	4x dilution above	5/5
	20	800	5 mg/mL T20 + 5 glu/cham	4/5
	5	200	4x dilution above	5/5
	1.25	50	4x dilution above	5/5

FIG. 37

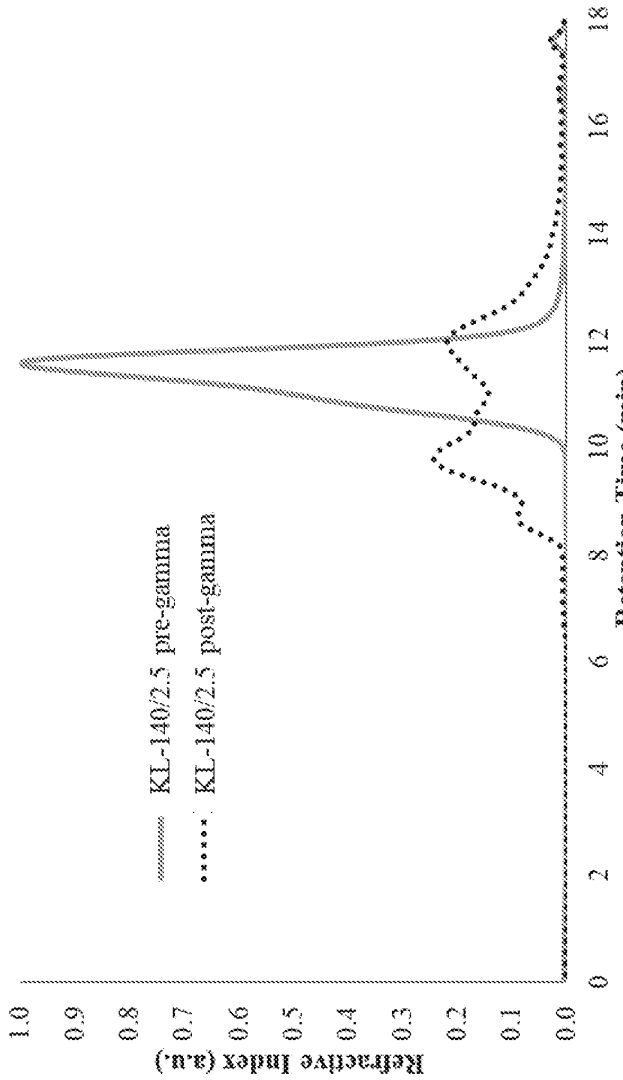

KL-140/2.5 pre-gamma
KL-140/2.5 post-gamma
Refractive Index (a.u.)
1.0
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
2
4
6
8
10
12
14
16
18
Retention Time (min)

FIG. 38

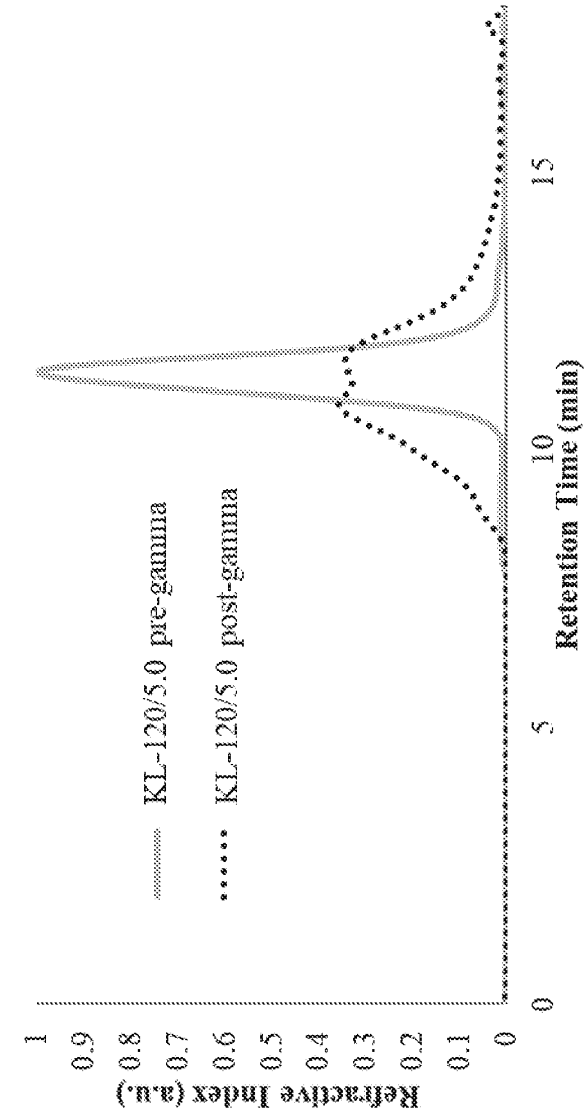

Refractive Index (a.u.)
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
5
10
15
Retention Time (min)
KL-120/5.0 pre-gamma
KL-120/5.0 post-gamma

FIG. 39

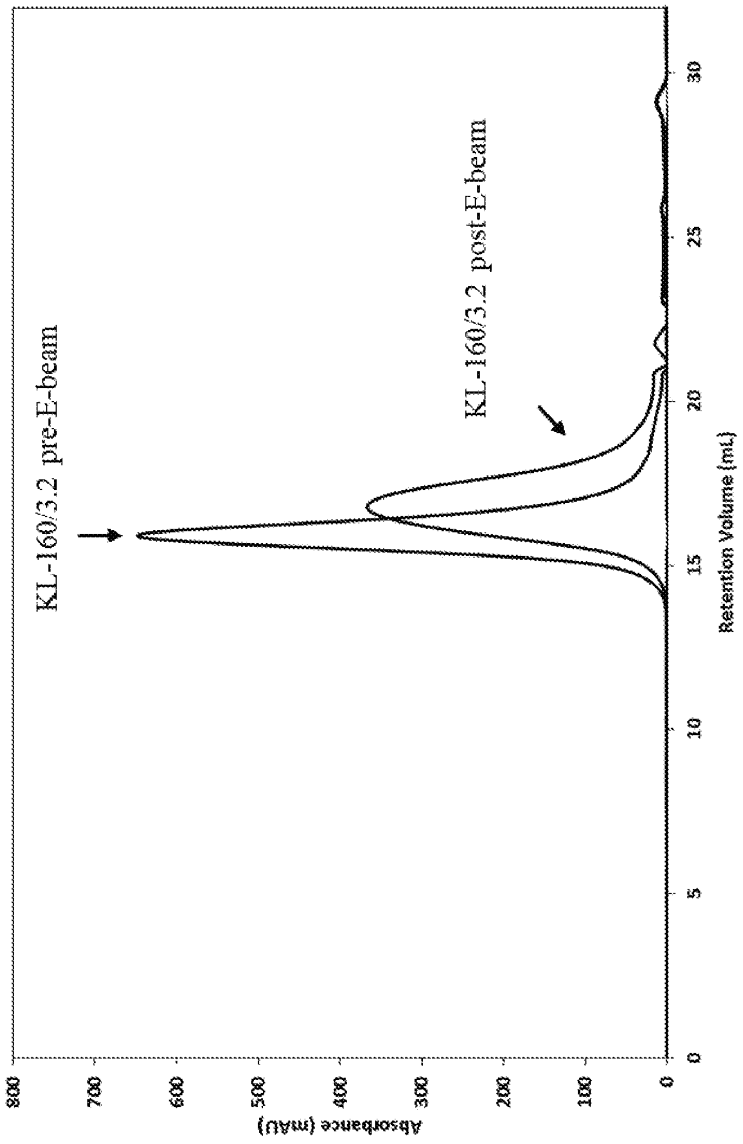

KL-160/3.2 pre-E-beam
KL-160/3.2 post-E-beam
Absorbance (mAU)
Retention Volume (mL)
800
700
600
500
400
300
200
100
0
0
5
10
15
20
25
30

FIG. 40

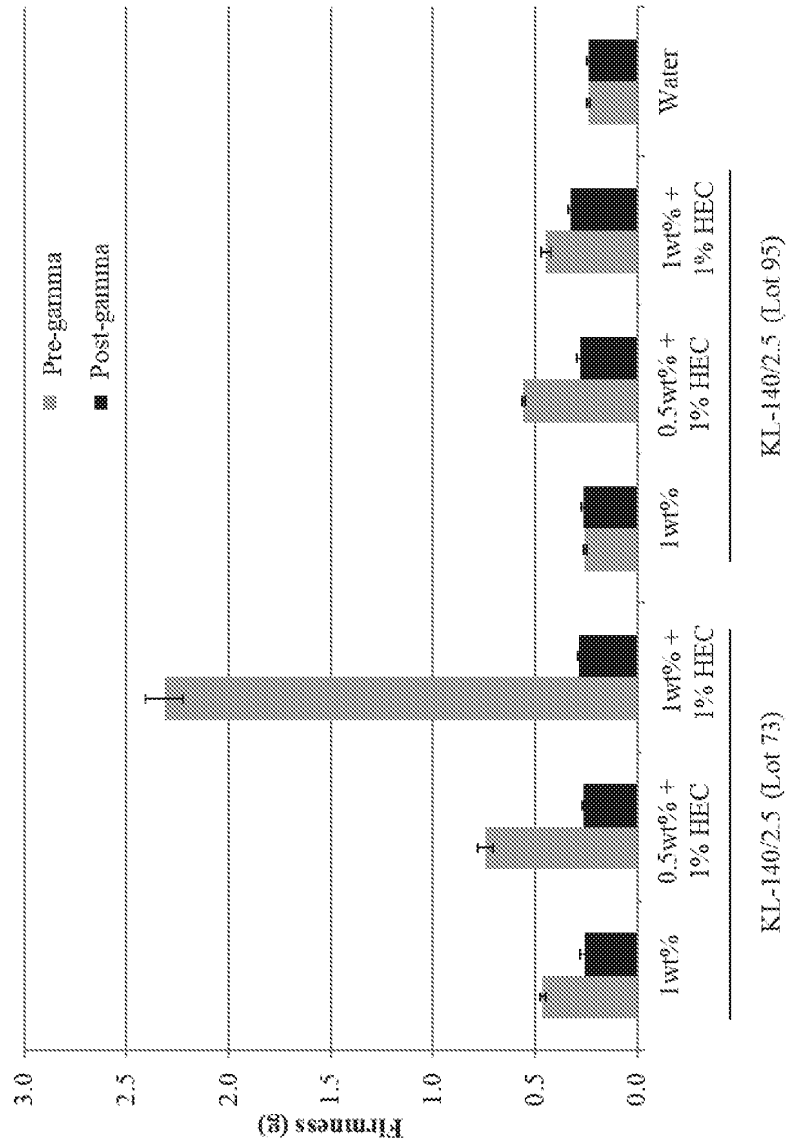

Pre-gamma
Post-gamma
Firmness (g)
3.0
2.5
2.0
1.5
1.0
0.5
0.0
1wt%
0.5wt% + 1% HEC
1wt% + 1% HEC
1wt%
0.5wt% + 1% HEC
1wt% + 1% HEC
Water
KL-140/2.5 (Lot 73)
KL-140/2.5 (Lot 95)

FIG. 41

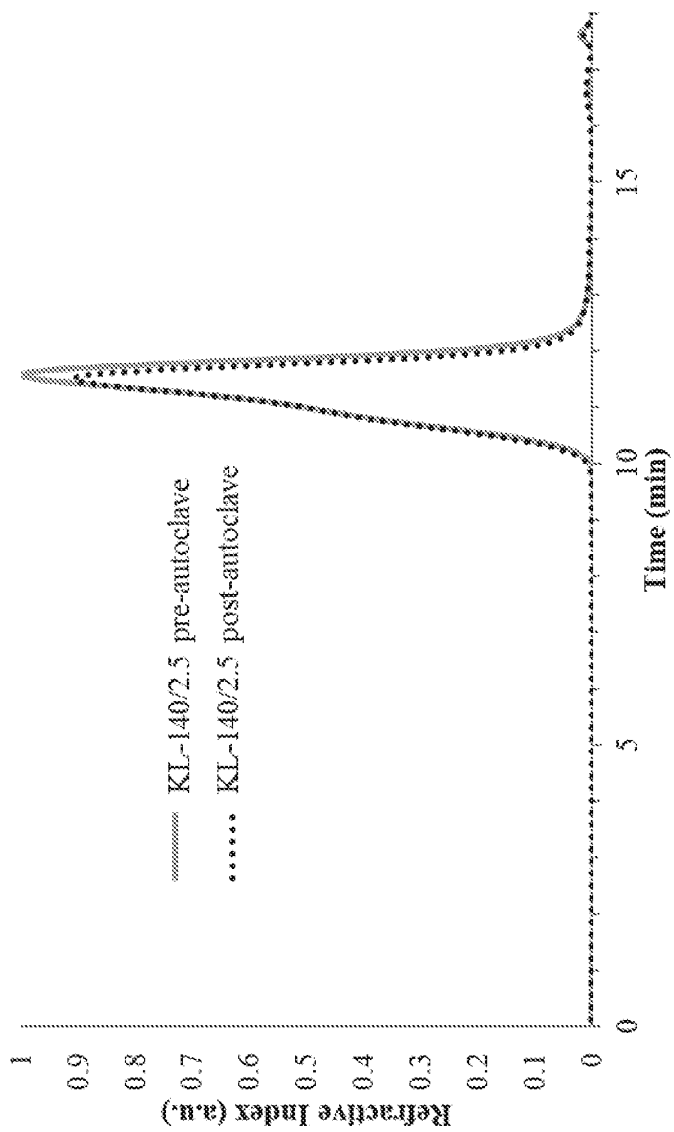

KL-140/2.5 pre-autoclave
KL-140/2.5 post-autoclave
Refractive Index (a.u.)
Time (min)
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1
0
5
10
15

FIG. 42

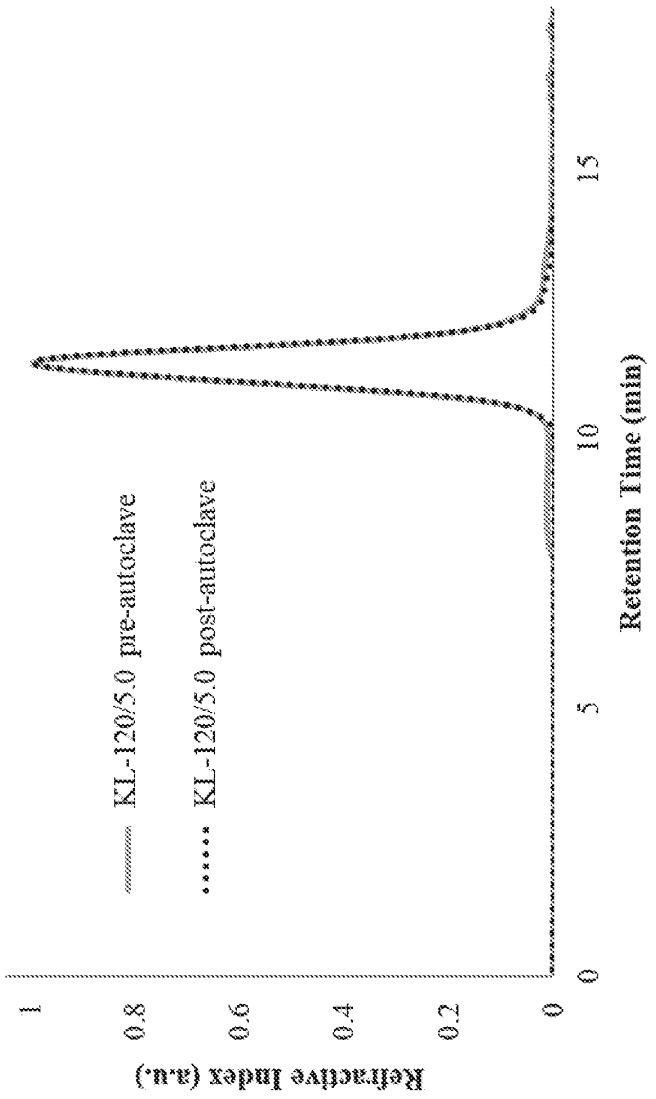

KL-120/5.0 pre-autoclave
KL-120/5.0 post-autoclave
Refractive Index (a.u.)
1
0.8
0.6
0.4
0.2
0
0
5
10
15
Retention Time (min)

FIG. 43

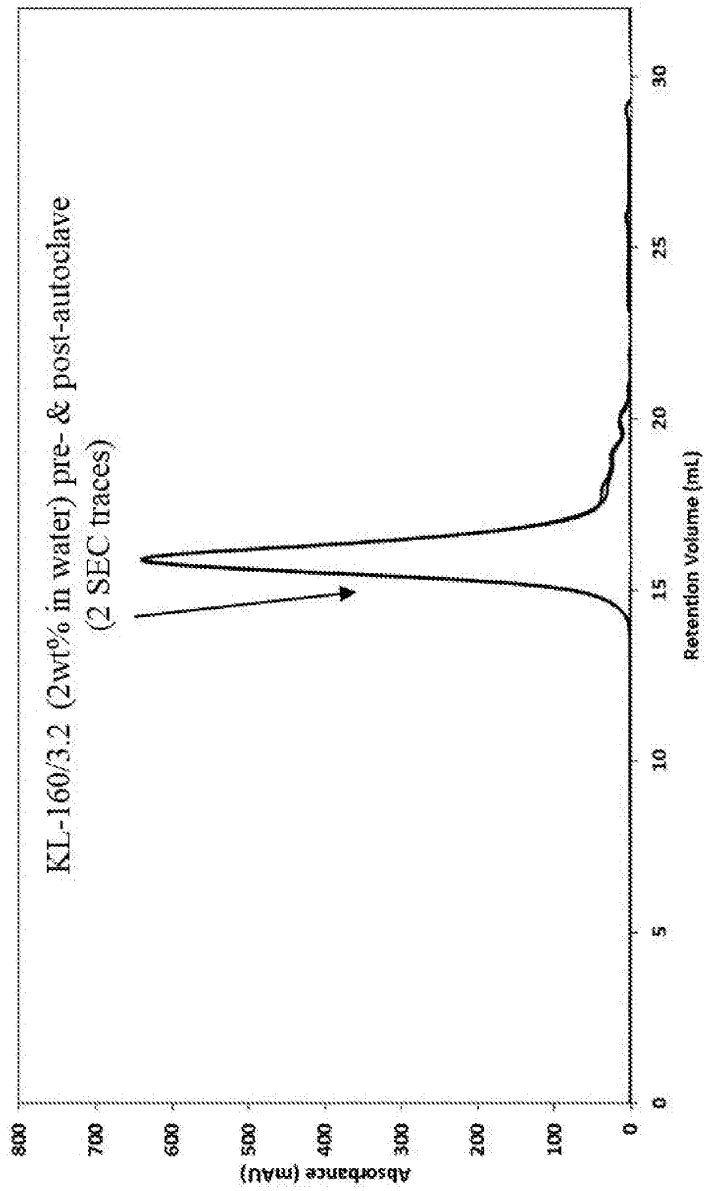

KL-160/3.2 (2wt% in water) pre- & post-autoclave
(2 SEC traces)
Absorbance (mAU)
0
100
200
300
400
500
600
700
800
Retention Volume (mL)
0
5
10
15
20
25
30

FIG. 44

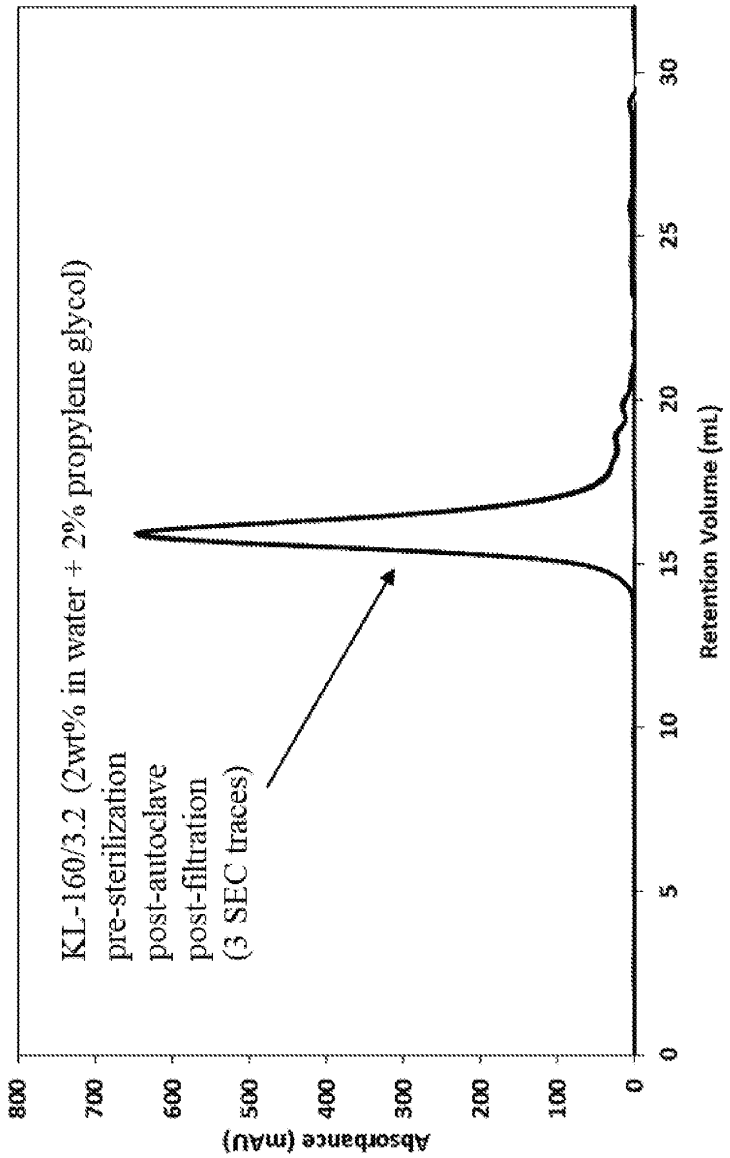

KL-160/3.2 (2wt% in water + 2% propylene glycol)
pre-sterilization
post-autoclave
post-filtration
(3 SEC traces)
Absorbance (mAU)
800
700
600
500
400
300
200
100
0
0
5
10
15
20
25
30
Retention Volume (mL)

FIG. 45

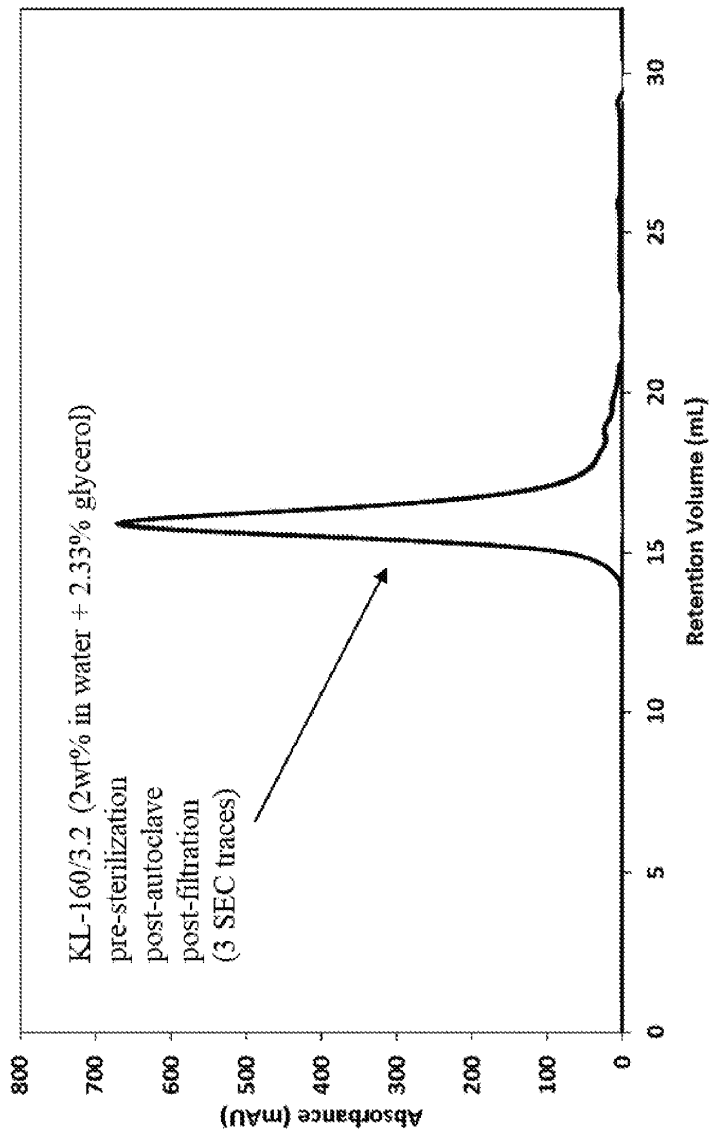

KL-160/3.2 (2wt% in water + 2.33% glycerol)
pre-sterilization
post-autoclave
post-filtration
(3 SEC traces)
Absorbance (mAU)
Retention Volume (mL)
0
100
200
300
400
500
600
700
800
0
5
10
15
20
25
30

FIG. 46

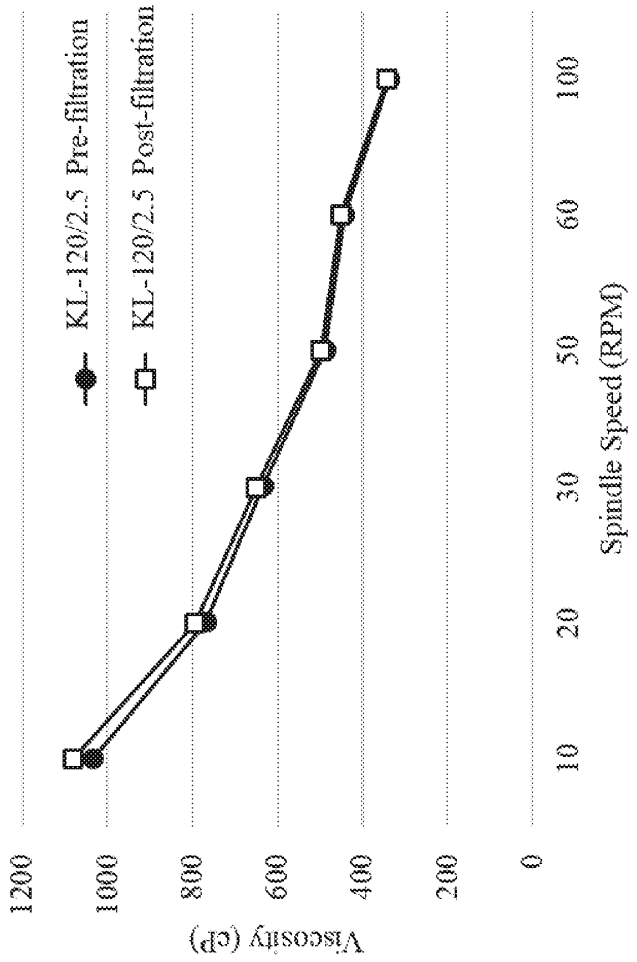

KL-120/2.5 Pre-filtration
KL-120/2.5 Post-filtration
Viscosity (cP)
1200
1000
800
600
400
200
0
10
20
30
50
60
100
Spindle Speed (RPM)

FIG. 47

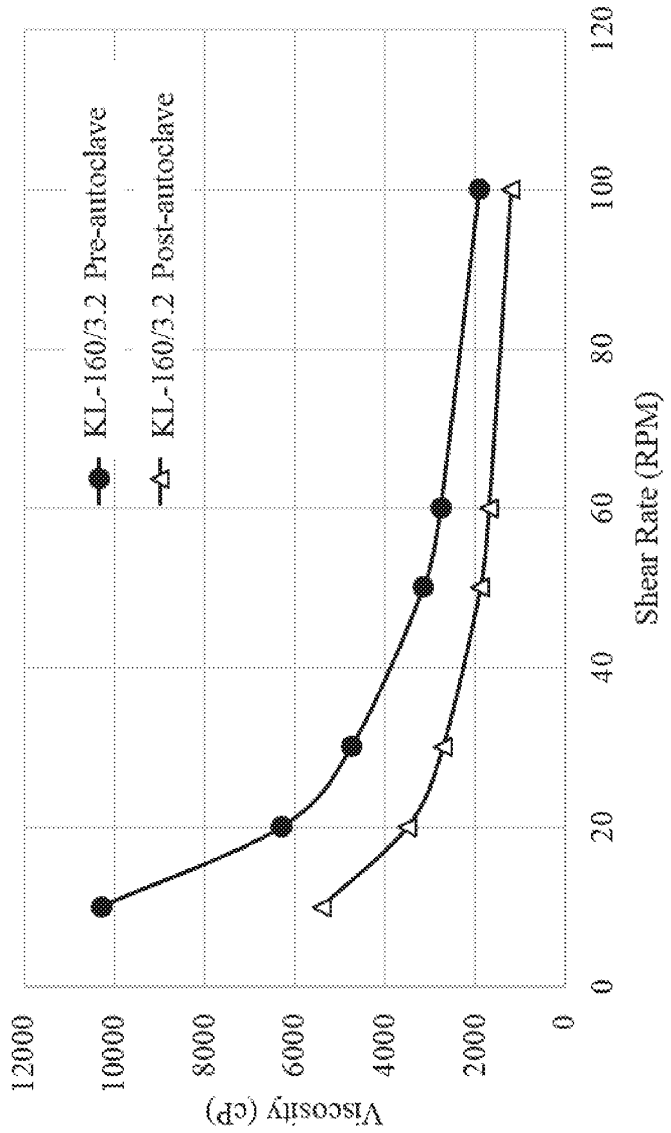

KL-160/3.2 Pre-autoclave
KL-160/3.2 Post-autoclave
Viscosity (cP)
12000
10000
8000
6000
4000
2000
0
0
20
40
60
80
100
120
Shear Rate (RPM)

FIG. 48

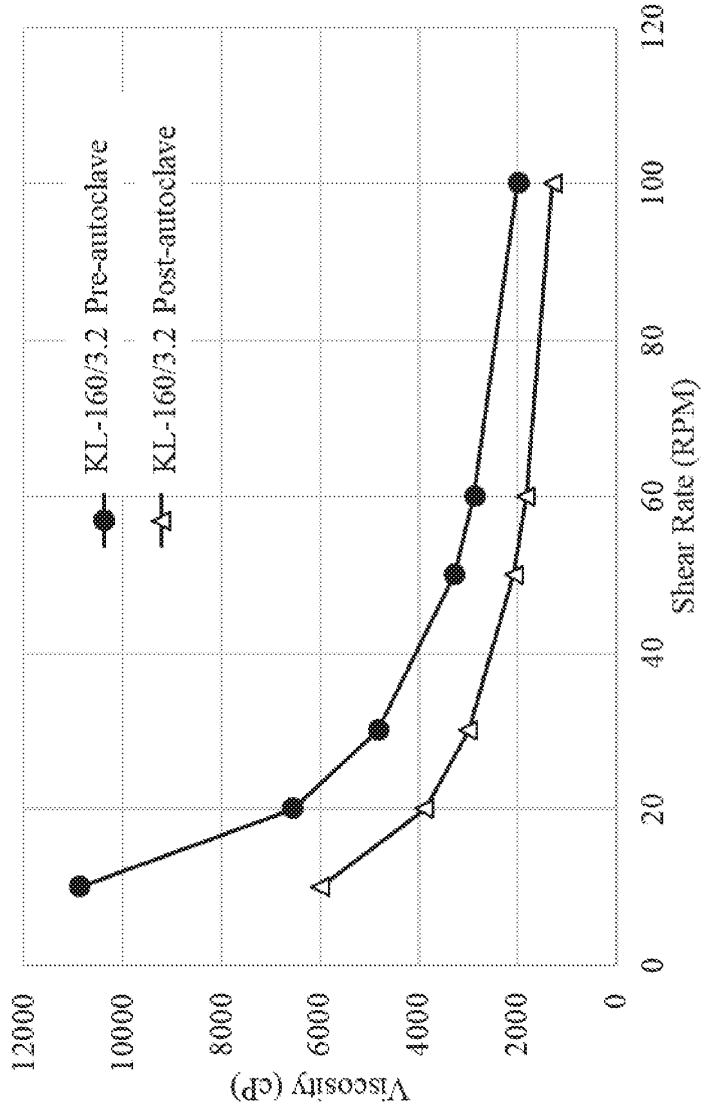

KL-160/3.2 Pre-autoclave
KL-160/3.2 Post-autoclave
Viscosity (cP)
12000
10000
8000
6000
4000
2000
0
0
20
40
60
80
100
120
Shear Rate (RPM)

FIG. 49

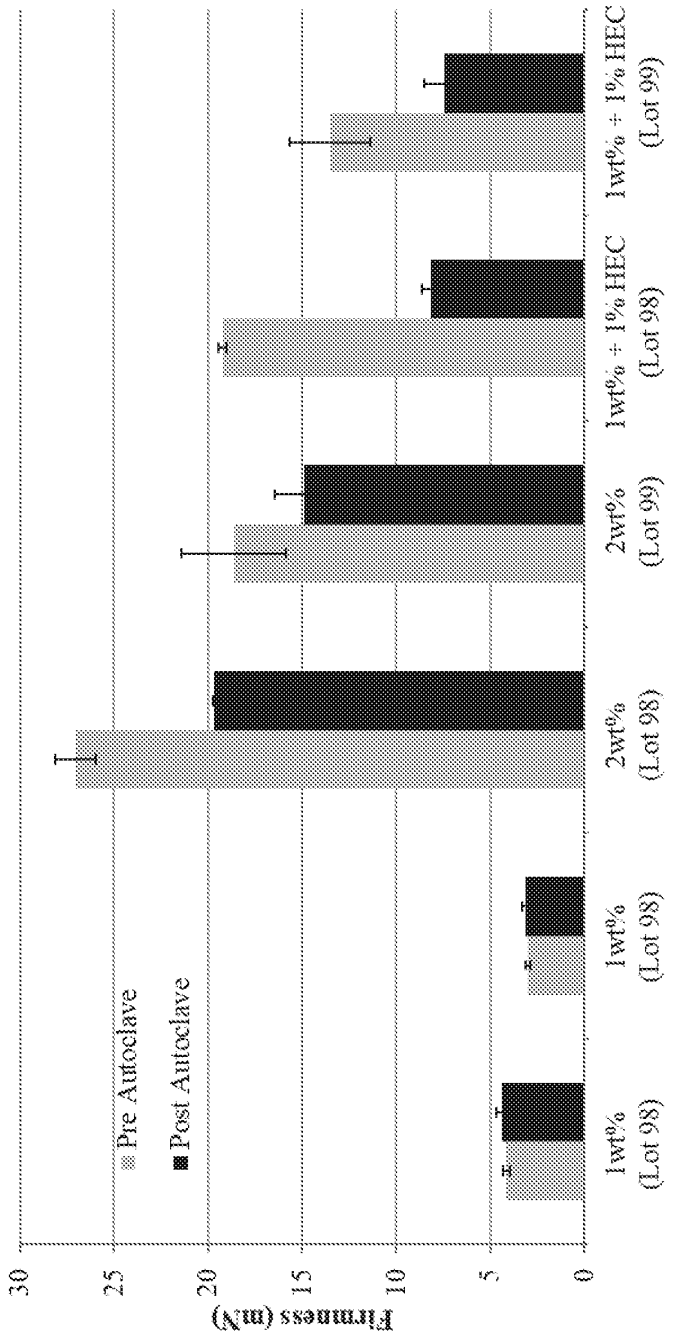

Firmness (mN)
30
25
20
15
10
5
0
Pre Autoclave
Post Autoclave
1wt% (Lot 98)
1wt% (Lot 98)
2wt% (Lot 98)
2wt% (Lot 99)
1wt% + 1% HEC (Lot 98)
1wt% + 1% HEC (Lot 99)
KL-140/2.5

FIG. 50

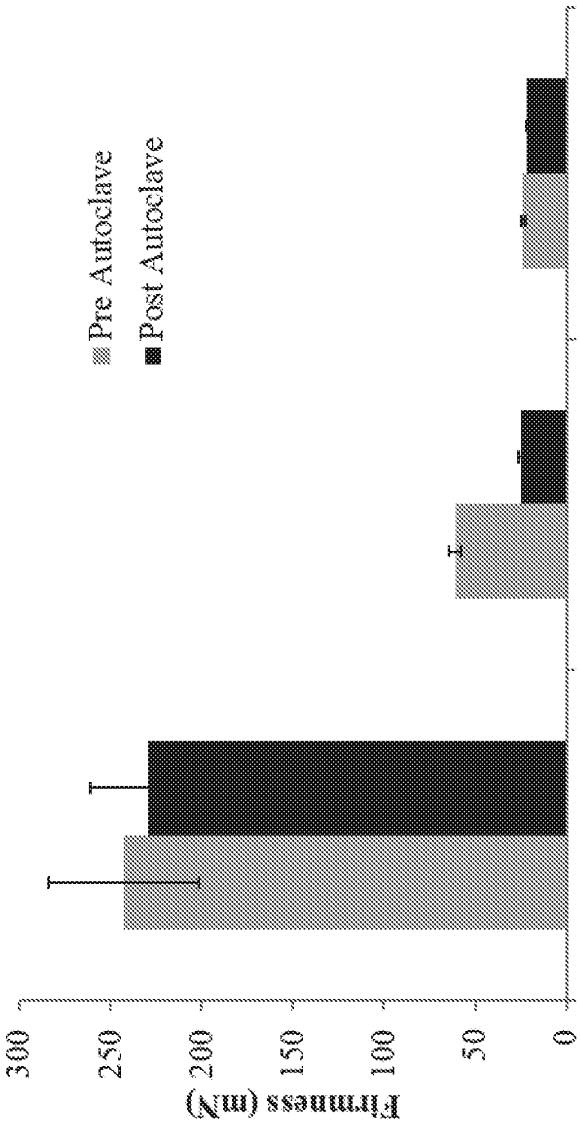

Pre Autoclave
Post Autoclave
Firmness (mN)
300
250
200
150
100
50
0
1wt% KL-140/2.5 + 1% HPC
1wt% KL-140/2.5 + 1% HPMC
1wt% KL-140/2.5 + 1% MC

FIG. 51

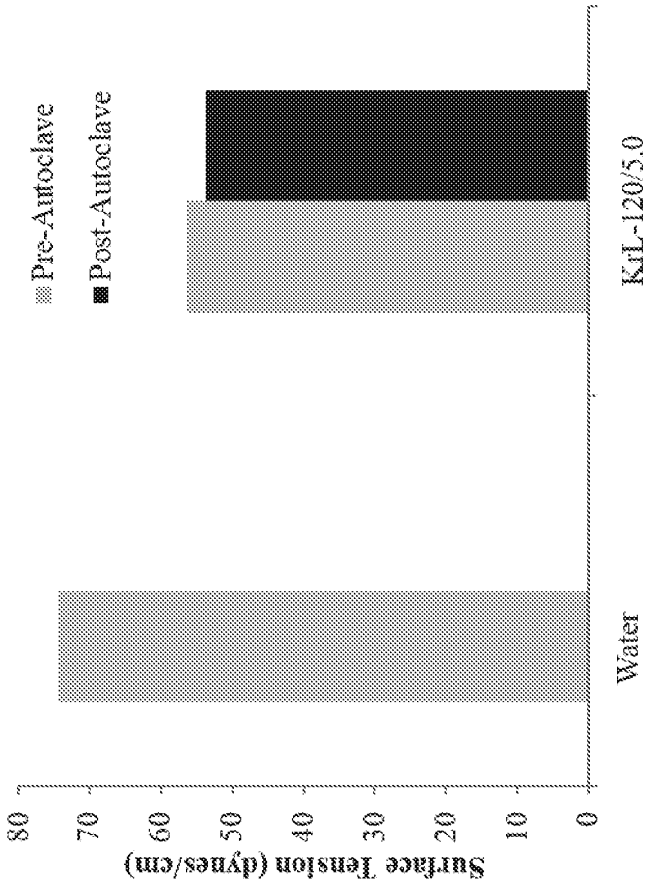

Pre-Autoclave
Post-Autoclave
Surface Tension (dynes/cm)
80
70
60
50
40
30
20
10
0
Water
KrL-120/5.0

FIG. 52

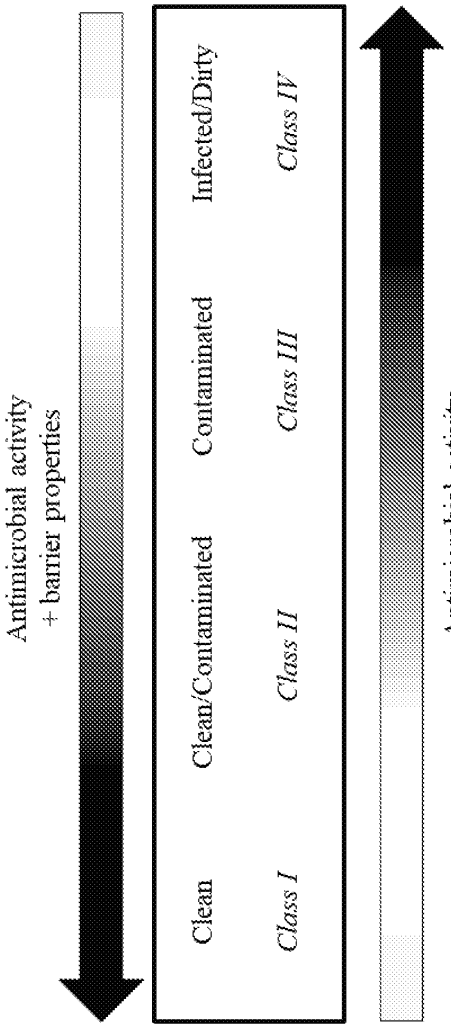
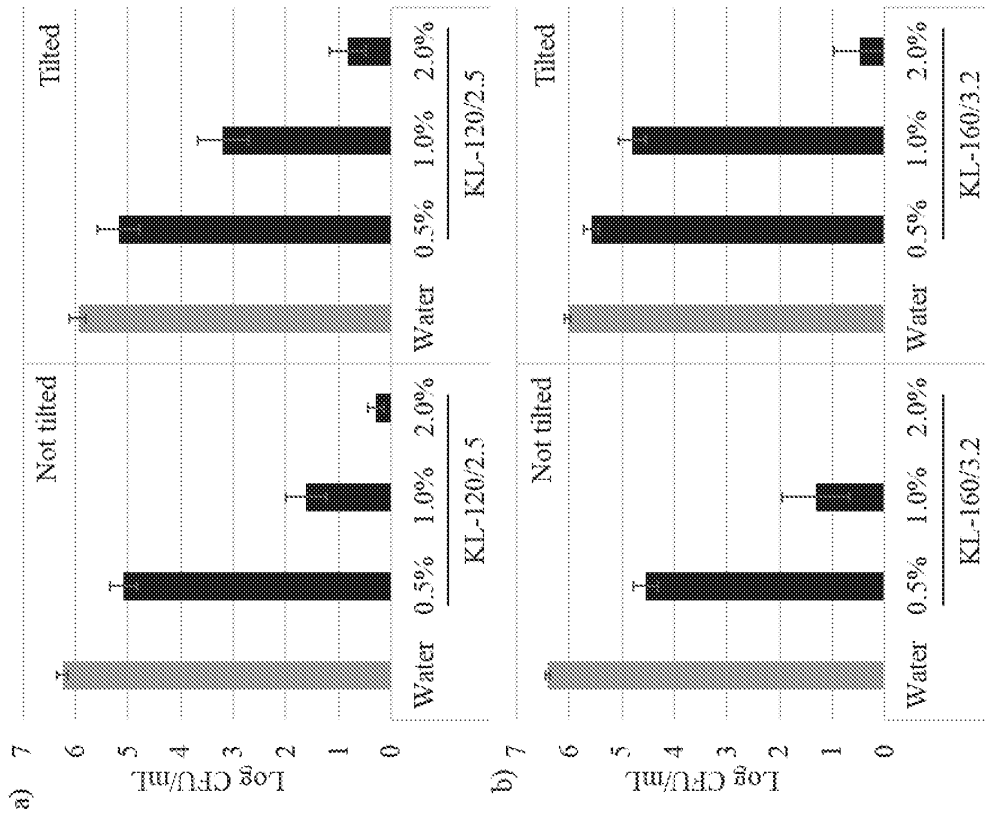
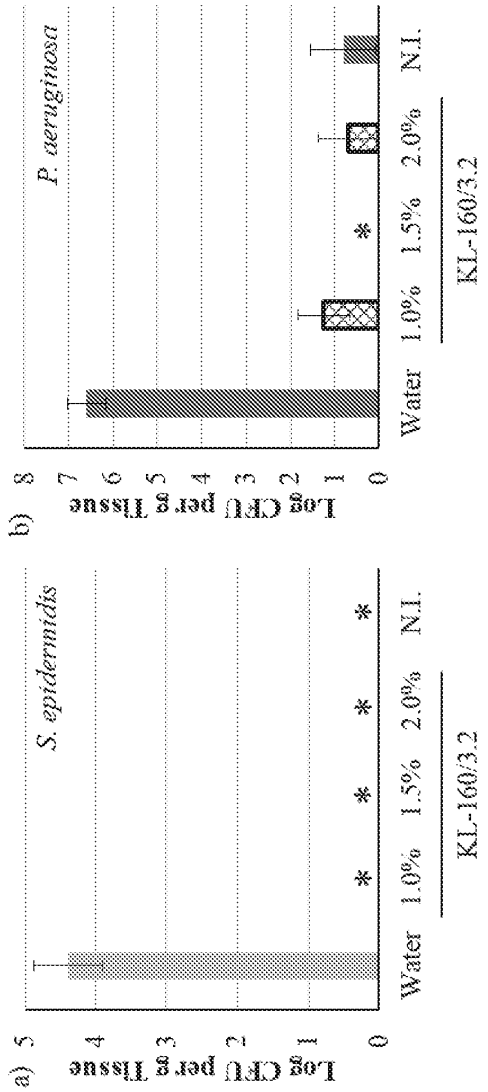

Antimicrobial activity
+ barrier properties
Clean
Class I
Clean/Contaminated
Class II
Contaminated
Class III
Infected/Dirty
Class IV
Antimicrobial activity
+ surfactant properties

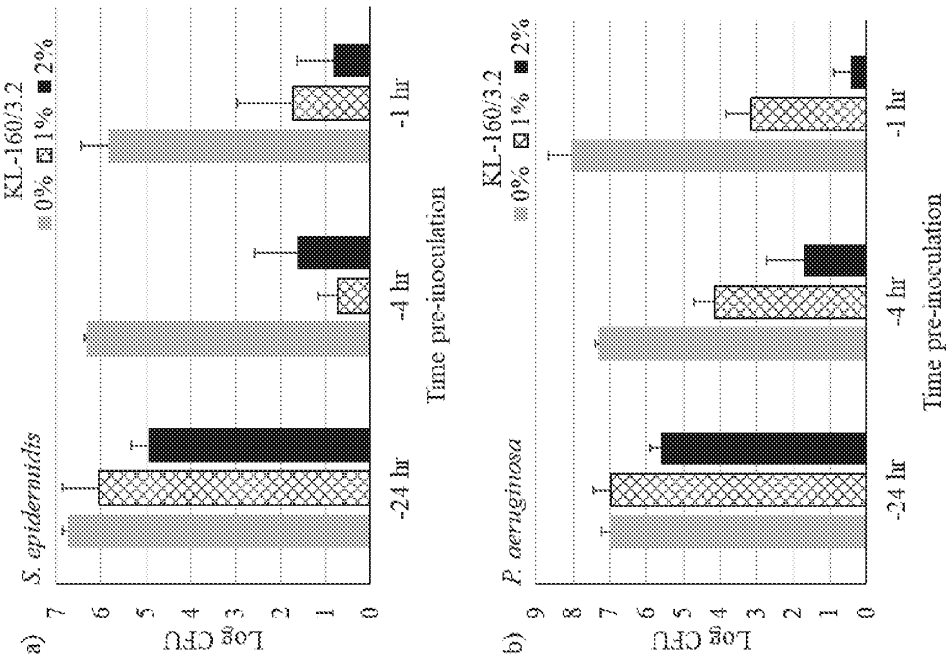
FIG. 53


a)
Not tilted
Tilted
Log CFU/mL
0
1
2
3
4
5
6
7
Water
0.5%
1.0%
2.0%
KL-120/2.5
b)
Not tilted
Tilted
Log CFU/mL
Water
0.5%
1.0%
2.0%
KL-160/3.2

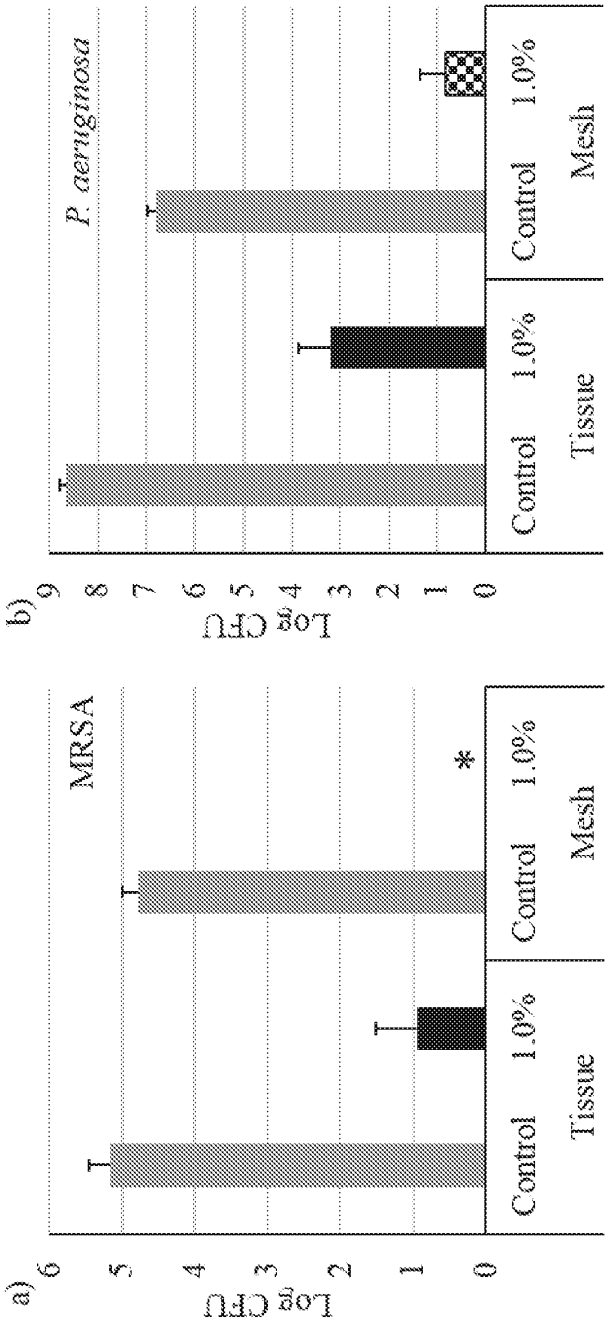
FIGS. 54A-B


a)
S. epidermidis
Log CFU per g Tissue
0
1
2
3
4
5
Water
1.0%
1.5%
2.0%
N.I.
KL-160/3.2
*
b)
P. aeruginosa
Log CFU per g Tissue
0
1
2
3
4
5
6
7
8
Water
1.0%
1.5%
2.0%
N.I.
KL-160/3.2
*

FIGS. 55A-B


a)
S. epidermidis
KL-160/3.2
0% 1% 2%
Log CFU
Time pre-inoculation
-24 hr
-4 hr
-1 hr
b)
P. aeruginosa
KL-160/3.2
0% 1% 2%
Log CFU
Time pre-inoculation
-24 hr
-4 hr
-1 hr

FIGS. 56A-B


a)
MRSA
Log CFU
0
1
2
3
4
5
6
*
Control
1.0%
Control
1.0%
Tissue
Mesh
b)
P. aeruginosa
Log CFU
0
1
2
3
4
5
6
7
8
9
Control
1.0%
Control
1.0%
Tissue
Mesh

FIGS. 57A-B

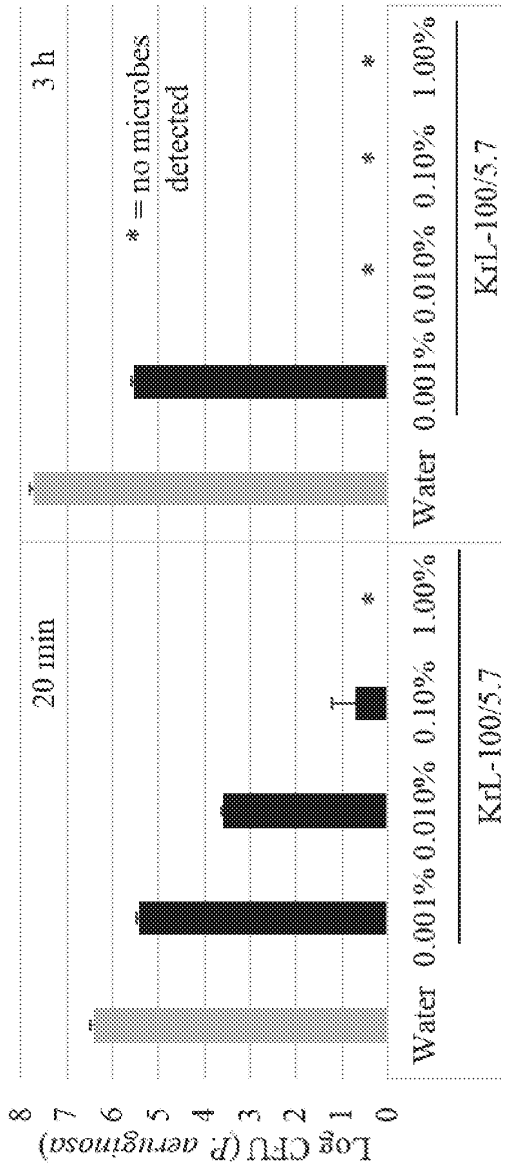

Log CFU (P. aeruginosa)
0
1
2
3
4
5
6
7
8
20 min
3 h
* = no microbes detected
*
*
*
*
Water
0.001%
0.010%
0.10%
1.00%
KrL-100/5.7
Water
0.001%
0.010%
0.10%
1.00%
KrL-100/5.7

FIG. 58

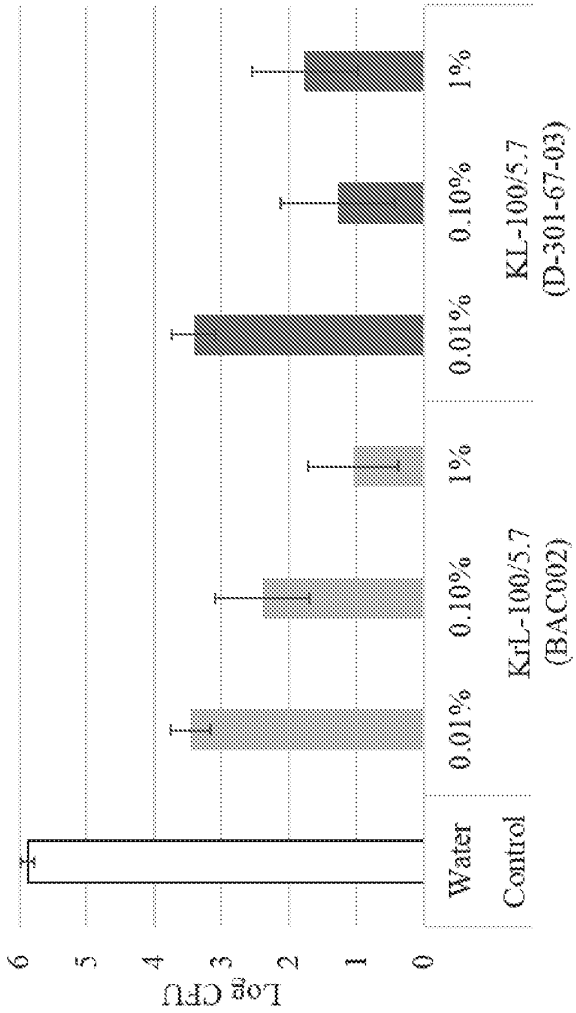

Log CFU
6
5
4
3
2
1
0
Water
Control
0.01%
0.10%
1%
KrL-100/5.7
(BAC002)
0.01%
0.10%
1%
KL-100/5.7
(D-301-67-03)

FIG. 59

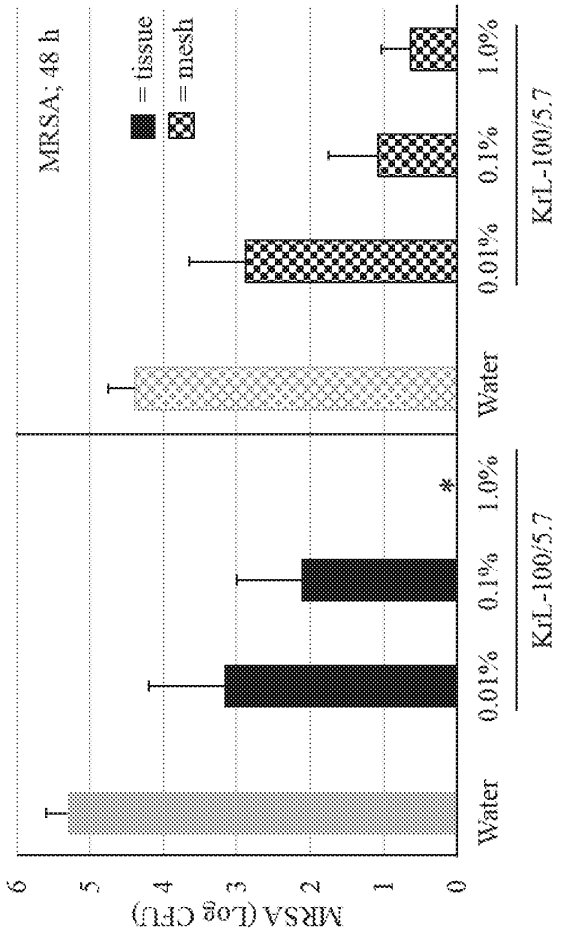

MRSA; 48 h
= tissue
= mesh
MRSA (Log CFU)
0
1
2
3
4
5
6
*
Water
0.01%
0.1%
1.0%
KrL-100/5.7
Water
0.01%
0.1%
1.0%
KrL-100/5.7

FIG. 60

a)

b)

Microbe	Biopsy	Test article	Inflammation Score										Mean	SEM
MRSA	Tissue	Water	2	3	2	2	3	1	3	2	1	2	2.1	0.2
		KrL-100/5.7 (1%)	1	3	1	1	1	1					1.4	0.4
	Mesh	Water	3	3	3	3	2	1	3	3	1	3	2.5	0.3
		KrL-100/5.7 (1%)	1	1	1	2	2						1.4	0.2

0=none 1=little 2=some 3=much = Photo

FIGS. 61A-B

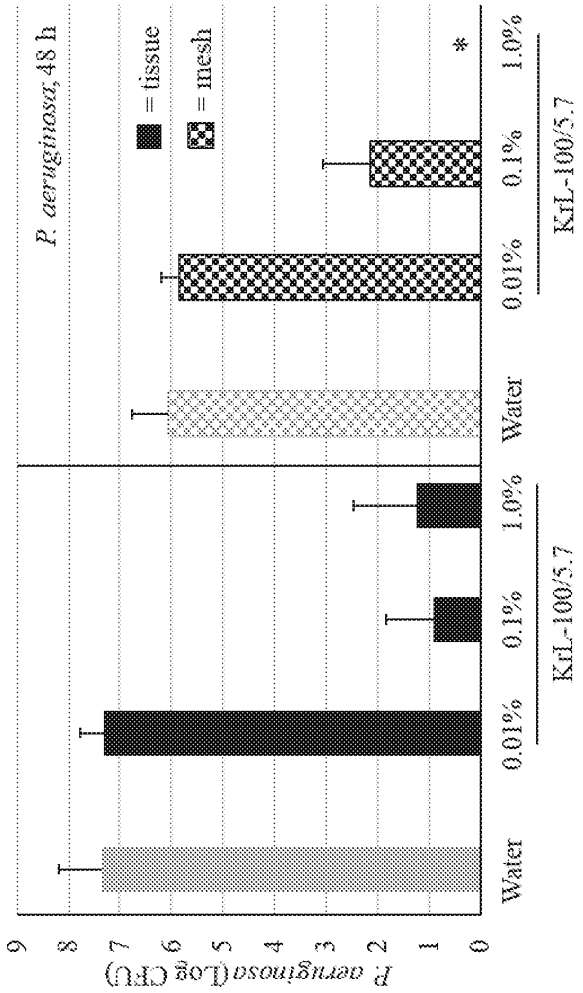
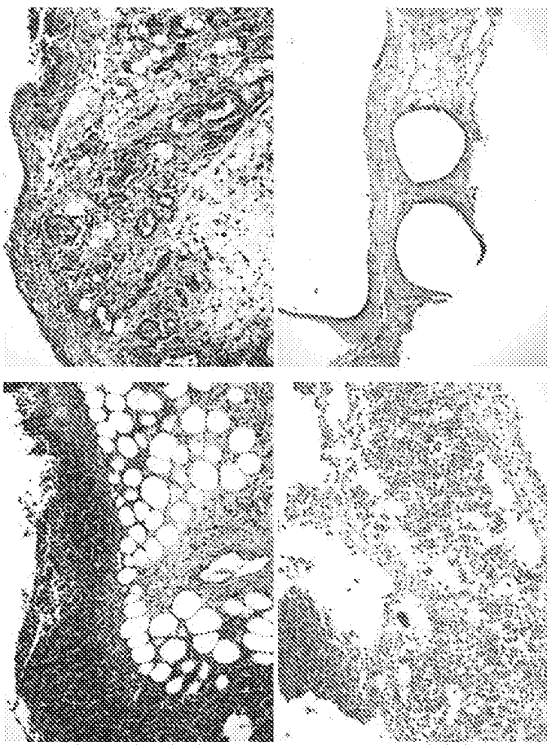

P. aeruginosa, 48 h
= tissue
= mesh
P. aeruginosa (Log CFU)
9
8
7
6
5
4
3
2
1
0
*
Water
0.01%
0.1%
1.0%
KrL-100/5.7
Water
0.01%
0.1%
1.0%
KrL-100/5.7

FIG. 62

a)



b)

Microbe	Biopsy	Sample	Inflammation Score										Mean	SEM
P. aeruginosa	Tissue	Water	3	1	3	2	3	3	3	3	3	1	2.6	0.3
		KrL-100/5.7 (1%)	2	1	2	2	1						1.6	0.2
	Mesh	Water	2	-	3	3	1	2	-	3	3	1	2.25	0.3
		KrL-100/5.7 (1%)	1	1	2	2	1						1.4	0.2

0=none 1=little 2=some 3=much = Photo

FIGS. 63A-B