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(54) **NONWOVEN MATERIALS CONTAINING CHLORHEXIDINE ACETATE AND TRICLOSAN**

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(57) **ABSTRACT**

This invention provides medical articles having antimicrobial efficacy and good barrier properties. In particular, the medical articles comprise a nonwoven material and a coating comprising chlorhexidine acetate and triclosan.

NONWOVEN MATERIALS CONTAINING CHLORHEXIDINE ACETATE AND TRICLOSAN

FIELD OF THE INVENTION

[0001] The present invention is directed to medical articles having antimicrobial efficacy and good barrier properties.

BACKGROUND OF THE INVENTION

[0002] In the United States, hospital-acquired infections, also known as nosocomial infections, cause or contribute to almost 100,000 deaths each year. Disposable medical articles, such as gowns, drapes, shoe covers, wraps, and caps are regularly used to minimize the transmission of such infections. These articles are often worn or used for a short period of time, for example less than ten minutes.

[0003] Many of these articles are made with nonwoven materials or fabrics, such as spunbond/meltblown/spunbond (SMS) laminates of polypropylene fibers and can form barriers against microbes and/or fluids. The ability to block the penetration of fluids, such as bodily fluids, is important in a medical environment. Some medical articles, such as medical gowns, are classified into levels of barrier performance based on the AAMI/ANSI PB70 standard, which is a standard developed by the Association for the Advancement of Medical Instrumentation and approved by the American National Standards Institute. In the AAMI/ANSI PB70 standard, the key test for measuring the barrier performance of a material is the Water Resistance: Hydrostatic Pressure Test, AATCC Test Method 127, which was established by the American Association of Textile Chemists and Colorists. The hydrostatic pressure test measures the resistance of a material to the penetration of water under increasing pressure. There are four levels of barrier performance according to the AAMI/ANSI PB70 standard. Materials having an AAMI Level 1 classification pass a spray impact test and are effective for impact penetration. Examples of materials typically having an AAMI Level 1 classification include basic cover gowns and isolation gowns. Materials having an AAMI Level 2 classification require a hydrostatic pressure of at least 20 cmH_2O for water to penetrate through the material. Examples of materials typically having an AAMI Level 2 classification include articles that offer basic protection and are often used when the amount of exposure to fluids is relatively small and for a short period of time. Materials having an AAMI Level 3 classification require a hydrostatic pressure of at least 50 cmH_2O for water to penetrate through the material. Examples of materials typically having an AAMI Level 3 classification include articles that offer increased barrier protection and are often used when the amount of fluid exposure is moderate. Materials having an AAMI Level 4 classification are impervious to water passing through. Surgical drapes and gowns often have an AAMI Level 4 classification.

[0004] Some nonwoven materials are coated with an antimicrobial material to kill microbes that contact the surface of the articles. Antimicrobial activity is measured by determining the log reduction of infectious bacterial counts after exposure to an antimicrobial substance. For example, a 3-log reduction refers to a 99.9% reduction, and a 4-log reduction refers to a 99.99% reduction. While the use of antimicrobial coatings on nonwoven materials may be beneficial in reducing the amount of microbes present on the surface, the coating can sometimes compromise the barrier properties of nonwoven materials, thereby increasing the possibility for fluids to penetrate.

[0005] There is a need in the art for nonwoven materials which have effective barrier properties and which demonstrate fast-acting antimicrobial activity. Preferably, the medical articles are able to kill a high number of microbes, such as a 3 or 4 log reduction (99.9% to 99.99%), within a short period of time, such as under 10 minutes. Such a material would help reduce the transmission of hospital-acquired infections, as the "quick kill" of microbes could break the chain of infection from one surface to another.

[0006] U.S. Pat. No. 6,146,651 relates to nonwoven fabrics treated with a biocidal composition including a halogenated phenolic biocide; a water-soluble, film-forming polymer; and at least one surfactant.

[0007] U.S. Pat. No. 6,626,873 and U.S. Pat. No. 5,772,640 relate to polymeric medical articles comprising chlorhexidine and salts thereof and triclosan. U.S. Pat. No. 6,626,873 and U.S. Pat. No. 5,772,640 refer to medical articles such as catheters, wound drainage tubes, arterial grafts, soft tissue patches, gloves, shunts, stents, tracheal catheters, wound dressings, sutures, guide wires, and prosthetic devices.

[0008] U.S. Pat. No. 6,503,952 relates to antimicrobial compositions comprising an antimicrobial such as chlorhexidine free base, chlorhexidine salt, polyhexamethylene biguanide, and alexidine; a quarternary ammonium compound; and a chlorinated phenol compound.

[0009] U.S. Patent Application Publication No. 2011/0150958 relates to antiseptic cleaning agents containing chlorhexidine acetate, a solvent such as alcohol and/or water, and a second biocidal agent such as triclosan.

[0010] All references cited herein are incorporated by reference in their entirety.

SUMMARY OF THE INVENTION

[0011] The present invention is directed to articles comprising a material, such as a nonwoven material, and a coating comprising chlorhexidine acetate and triclosan. The articles are preferably medical articles such as gowns, shoe covers, drapes, wraps and caps.

[0012] A coating having a combination of chlorhexidine acetate and triclosan on a material, such as a nonwoven material, has been found to provide effective, fast-acting antimicrobial activity, while minimally affecting the barrier properties of the material.

DETAILED DESCRIPTION OF THE INVENTION

[0013] The present invention is directed to articles comprising a material, such as a nonwoven material, and a coating comprising chlorhexidine acetate and triclosan. The articles may be medical articles, such as gowns, shoe covers, drapes, wraps, caps, facial masks, lab coats, or any other article that may be used to prevent the transmission of fluids and/or microbes.

[0014] In some embodiments, the material may comprise any fabric or materials, including nonwoven materials or fabrics. Nonwoven fabrics refer to a single web, or an assembly or laminate of multiple webs, formed of individual randomly laid fibers, for example using a spunlaid, thermobonded, spunbonded, meltblown or bonded carded web process. A laminate of nonwoven fabrics, such as a spunbond/meltblown/spunbond (SMS) laminate of polypropylene

fibers, is an example of one conventional fabric that could be used in the surgical field. Another example is a spunbond/film/spunbond (SFS) laminate. In some embodiments, spunlace (hydroentangled) materials may be used. In some embodiments, the material is about 1 to about 1000 grams per square meter, preferably 10 to 100 grams per square meter, more preferably 20 to 50 grams per square meter (gsm).

[0015] Chlorhexidine acetate, also known as chlorhexidine diacetate, is an antimicrobial agent. Chlorhexidine acetate, as well as chlorhexidine free base and other salts of chlorhexidine, such as chlorhexidine gluconate, are effective on gram-positive and gram-negative bacteria and have been found to have both bactericidal and bacteriostatic activity. Surprisingly, chlorhexidine acetate in particular, in combination with triclosan, has been found to provide effective antimicrobial activity while minimizing the impact on the barrier properties of a material.

[0016] Triclosan, also known as 5-chloro-2-(2,4-dichlorophenoxy)phenol and 2,4,4'-trichloro-2'-hydroxy diphenyl ether, is an antimicrobial agent with both antibacterial and antifungal activity.

[0017] The combination of chlorhexidine acetate and triclosan has been found to provide an effective antimicrobial coating on materials, such as nonwoven materials. The combination has been found to provide a synergistic effect, providing a high log reduction of bacteria while minimally affecting the barrier properties (fluid permeability) of the materials. In particular, the combination of chlorhexidine acetate and triclosan has been found to provide effective antimicrobial activity while keeping the material's resistance to fluid penetration, measured using the hydrostatic pressure test, at acceptable levels, compared to each agent alone and compared to other combinations such as chlorhexidine free base and triclosan and chlorhexidine gluconate and triclosan.

[0018] In some embodiments, the chlorhexidine acetate and triclosan are present in a chlorhexidine acetate:triclosan ratio, preferably about 25:1 to about 1:25, more preferably about 10:1 to about 1:10, even more preferably about 5:1 to about 1:5, and most preferably about 3:1 to about 1:3. In some embodiments, the total amount (dry weight) of the chlorhexidine acetate and triclosan is about 0.1% to about 70%, preferably 0.25% to 50%, more preferably about 0.35% to 20%, and most preferably about 0.50% to 10%, of the weight of the coated fabric.

[0019] The chlorhexidine acetate and triclosan may be applied to the materials separately or together. For example, in some embodiments, the chlorhexidine acetate may be applied first, and then the triclosan may be applied. In some embodiments, the chlorhexidine acetate and triclosan are combined into one formulation first, and then the combination formulation is applied to the materials. In some embodiments, a liquid formulation comprising the antimicrobials is prepared and applied to the material. The liquid formulation may comprise one or more solvents, such as an alcohol and/or water. Examples of solvents include, but are not limited to water, ethanol, hexanol, acetone, isopropanol, benzyl alcohol, propylene glycol, glycerol, and polyethylene glycol. In some preferred embodiments, the liquid formulation comprises the chlorhexidine acetate and triclosan in water and alcohol solutions; preferred alcohols include ethanol, hexanol, or octanol. One example of a liquid formulation comprises chlorhexidine acetate (at 0.3% w/w, 0.6% w/w, or 0.75% w/w), triclosan (0.60% w/w), and ethanol (70% w/w).

[0020] The coating of chlorhexidine acetate and triclosan may be applied to the materials in any way. Preferably, a coating solution containing the chlorhexidine acetate and triclosan is sprayed or kiss gravure coated onto a material, such as a nonwoven material. The coating may be applied directly to the fibers before bonding. In preferred embodiments, the coating is applied after the nonwoven web is formed and bonded. Other additives, including but not limited to antistats and coating aids to lower the solution surface tension, may be added to the coating solution. In other embodiments, the fabric may be dip-coated or may be coated using a dip and squeeze padding process, using a formulation of chlorhexidine acetate and triclosan.

[0021] After the application of the coating, the coated material may be dried, by air drying or by using dryers. For example, air-impingement and flotation dryers may be used. The coated material may also be dried by pulling a heated gas, such as air, through the material while pinning the material to a porous surface such as a drum or belt.

[0022] In some embodiments, the articles of the present invention have an antimicrobial efficacy of at least a 2 log reduction of bacteria, preferably at least a 3 log reduction, and more preferably at least a 4 log reduction. In some embodiments, the antimicrobial effect is achieved in less than about 60 minutes, preferably less than about 30 minutes, more preferably less that about 10 minutes, and most preferably less than about 5 minutes.

[0023] In some embodiments, the articles of the present invention, which comprise coated materials, have similar barrier properties compared to the same materials in uncoated form. For example, in some embodiments, applying chlorhexidine acetate and triclosan to an SMS nonwoven fabric may decrease the hydrostatic pressure resistance value of the SMS nonwoven fabric (in uncoated form) by no more than about 50%, preferably by no more than about 40%, more preferably by no more than about 30%, and more preferably by no more than about 0 to 10%.

[0024] In some embodiments, the hydrostatic pressure of the coated materials (as measured by, for example, the Water Resistance: Hydrostatic Pressure Test, AATCC Test Method 127) is preferably at least 20 cmH_2O and more preferably at least 30 cmH_2O. In some embodiments, for example, when the coated material is used for surgical gowns, the hydrostatic pressure of the coated materials may be preferably at least 50 cmH_2O.

EXAMPLE

[0025] An experiment was conducted to compare the effect of the combination of chlorhexidine acetate (CHA) and triclosan, to: (1) each of chlorhexidine free base (CH), chlorhexidine acetate, chlorhexidine gluconate (CHG), polyhexamethylene biguanide (PHMB), and triclosan alone, (2) each of the combinations of CH and triclosan, CHG and triclosan, and PHMB and triclosan. The following coating formulations were prepared with deionized water and sprayed onto 8×8 inch fabric swatches of a 34 gsm spunbond/meltblown/spunbond (SMS) nonwoven material using disposable atomizing hand sprayers.

[0026] Formulation A: CHA (0.6% w/w), triclosan (0.60% w/w), and ethanol (70%)

[0027] Formulation B: CHA (0.3% w/w), triclosan (0.60% w/w), and ethanol (70%)

[0028] Formulation C: CHA (0.75% w/w), triclosan (0.60% w/w), and ethanol (70%)

[0029] Formulation D: control with no coating

[0030] Formulation E: ethanol (70%)

[0031] Formulation F: CH (0.30% w/w) and ethanol (70%)

[0032] Formulation G: CH (0.60% w/w) and ethanol (70%)

[0033] Formulation H: CH (1.20% w/w) and ethanol (70%)

[0034] Formulation I: CHA (0.30% w/w) and ethanol (70%)

[0035] Formulation J: CHA (0.30% w/w) and ethanol (70%)

[0036] Formulation K: CHG (1.0% w/w) and hexanol (0.6%)

[0037] Formulation L: CHG (1.0% w/w) and hexanol (0.6%)

[0038] Formulation M: PHMB (1.0% w/w) and ethanol (70%)

[0039] Formulation N: PHMB (1.0% w/w) and hexanol (0.6%)

[0040] Formulation O: Triclosan (0.3% w/w) and ethanol (70%)

[0041] Formulation P: Triclosan (0.6% w/w) and ethanol (70%)

[0042] Formulation Q: CH (0.30% w/w), Triclosan (0.6% w/w) and ethanol (70%)

[0043] Formulation R: CH (0.60% w/w), Triclosan (0.6% w/w) and ethanol (70%)

[0044] Formulation S: CHG (0.35% w/w), Triclosan (0.6% w/w) and ethanol (70%)

[0045] Formulation T: PHMB (0.15% w/w), Triclosan (0.6% w/w) and ethanol (70%)

[0046] Formulation U: PHMB (0.45% w/w), Triclosan (0.6% w/w) and ethanol (70%)

[0047] Formulation V: PHMB (0.75% w/w), Triclosan (0.6% w/w) and ethanol (70%)

[0048] The formulations were sprayed onto the fabric swatches until the swatches were uniformly saturated. The saturation point was determined visually as the coating formulation wetted the fabric swatches, causing them to become translucent when fully saturated. The swatches were then placed horizontally on a wire rack and air dried in a fume hood. In some cases, the samples were placed in an oven for drying.

[0049] The samples were tested for antimicrobial efficacy using AATCC Test Method 100, using gram negative *E. coli* ATCC #11229 and gram positive *S. aureus,* MRSA, ATCC #43300. The log reductions of *E. coli* and MRSA were determined after five minutes. The barrier properties of the samples were also tested using the Water Resistance: Hydrostatic Pressure Test, AATCC Test Method 127. Two hydrostatic pressure readings were taken and the values were averaged. The results are listed in the table below.

[0050] The results show that the combination of chlorhexidine acetate and triclosan on the SMS nonwoven material demonstrated high log reductions of both *E. coli* and MRSA, which shows effective antimicrobial activity. In addition, the barrier properties of the coated SMS nonwoven material, measured by the hydrostatic pressure test, were maintained at a high value. In contrast, samples coated with the individual antimicrobial agents alone or with other combinations of antimicrobials demonstrated good antimicrobial activity but poor barrier properties, good barrier properties but poor antimicrobial activity, or both poor antimicrobial activity and poor barrier properties. For example, for samples coated with just triclosan, the barrier properties of the fabric were high, but the antimicrobial activity was very low. For samples coated with just chlorhexidine free base, the antimicrobial efficacy was high, but the barrier properties were poor. In addition, samples coated with just chlorhexidine acetate demonstrated poor barrier properties and poor antimicrobial activity against MRSA.

TABLE

	AM Treatment	AM#1	AM#2	AM#1 %	AM#2 %	Total AM Wt %	Wt % AM on Fabric	*E. coli* Log R	MRSA Log R	Hydrostatic pressure (cm)
A	CHA + Triclosan	CHA	Triclosan	0.60	0.60	1.20	3.93	4.40	5.85	31.6
B	CHA + Triclosan	CHA	Triclosan	0.30	0.60	0.90	1.80	4.00	3.85	44.1
C	CHA + Triclosan	CHA	Triclosan	0.75	0.60	1.35	5.04	4.46	3.43	30.0
D	Blank	Blank				0.00	0.00	0.01	0.00	62.9
E	Blank	Blank				0.00	−0.50	0.00	0.01	42.8
F	CH	CH		0.30		0.30	1.37	4.41	0.42	3.8
G	CH	CH		0.60		0.60	2.60	4.33	2.04	4.1
H	CH	CH		1.20		1.20	4.89	4.41	4.18	3.0
I	CHA	CHA		0.60		0.60	2.76	2.03	1.13	4.9
J	CHA	CHA		0.30		0.30	1.43	3.80	1.08	6.1
K	CHG	CHG		1.00		1.00	4.73	3.92	1.10	5.0
L	CHG	CHG		1.00		1.00	4.73	4.08	0.20	5.0
M	PHMB	PHMB		1.00		1.00	4.25	0.86	1.25	11.0
N	PHMB	PHMB		1.00		1.00	4.61	0.81	0.94	22.3
O	Triclosan	Triclosan		0.00	0.60	0.60	1.38	0.06	0.32	53.0
P	Triclosan	Triclosan		0.00	0.30	0.30	0.25	0.00	0.14	50.8
Q	CH + Triclosan	CH	Triclosan	0.30	0.60	0.90	3.41	4.43	1.98	18.6
R	CH + Triclosan	CH	Triclosan	0.60	0.60	1.20	4.85	3.58	1.31	16.3
S	CHG + Triclosan	CHG	Triclosan	0.35	0.60	0.95	2.81	4.14	4.32	7.1
T	PHMB + Triclosan	PHMB	Triclosan	0.15	0.60	0.75	2.17	3.50	2.08	12.8

TABLE-continued

	AM Treatment	AM#1	AM#2	AM#1 %	AM#2 %	Total AM Wt %	Wt % AM on Fabric	*E. coli* Log R	MRSA Log R	Hydrostatic pressure (cm)
U	PHMB + Triclosan	PHMB	Triclosan	0.45	0.60	1.05	3.44	3.13	2.90	6.9
V	PHMB + Triclosan	PHMB	Triclosan	0.75	0.60	1.35	4.62	3.95	3.48	6.6

What is claimed:

1. An article comprising a nonwoven material and a coating comprising chlorhexidine acetate and triclosan.

2. The article of claim **1**, wherein the nonwoven material comprises spunbond meltblown spunbond polypropylene.

3. The article of claim **1**, wherein the coating comprises chlorhexidine acetate and triclosan in a ratio of about 25:1 to about 1:25.

4. The article of claim **1**, wherein the coating comprises chlorhexidine acetate and triclosan in a ratio of about 5:1 to about 1:5.

5. The article of claim **1**, wherein the coating comprises chlorhexidine acetate and triclosan in a ratio of about 3:1 to about 1:3.

6. The article of claim **1**, wherein the article is a medical article selected from the group consisting of: gowns, shoe covers, drapes, wraps, caps, lab coats and face masks.

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