



- (51) **International Patent Classification:**
A01P 1/00 (2006.01) *A61Q 19/00* (2006.01)
- (21) **International Application Number:**
PCT/US2016/067439
- (22) **International Filing Date:**
19 December 2016 (19.12.2016)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
62/270,692 22 December 2015 (22.12.2015) US
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(81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report (Art. 21(3))

(54) **Title:** METHODS FOR SPORE REMOVAL

(57) **Abstract:** Disclosed herein are methods for removing spores from skin, the method including dispensing an effective amount of a composition into or onto an article, wherein the composition includes water and from 0.15 wt% to 4 wt% anionic thickener; contacting a skin surface with the composition; mechanically acting on the skin surface for at least one (1) second while the skin surface is in the presence of the composition; and removing at least a portion of the composition from the surface of the skin, wherein removing the composition also removes spores from the skin surface.



METHODS FOR SPORE REMOVAL

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application No. 62/270,692,
5 filed December 22, 2015, the disclosure of which is incorporated by reference in its entirety
herein.

FIELD

The present disclosure relates to methods of removing spores from skin.

BACKGROUND

10 There is a great deal of interest and urgency in preventing the spread of *C. difficile*,
particularly in medical settings such as hospitals. Patients in a hospital setting often times
develop *C. difficile* infections during or shortly after a course of antibiotics. While it is
relatively easy to kill the vegetative form of *C. difficile*, the spore form of *C. difficile*, can be
15 very difficult to kill. New technologies are therefore needed to address the problem of
preventing the spread of *C. difficile*, between patients, health care workers, and the
environment.

SUMMARY

20 Disclosed herein are methods for removing spores from skin, the method including
dispensing an effective amount of a composition into or onto an article, wherein the
composition includes water and from 0.1 wt% to 4 wt% anionic thickener; contacting a skin
surface with the composition; mechanically acting on the skin surface for at least one (1)
second while the skin surface is in the presence of the composition; and removing at least a
25 portion of the composition from the surface of the skin, wherein removing the composition also
removes spores from the skin surface.

Also disclosed are methods for removing spores from skin, the method including
dispensing an effective amount of a composition into a container, wherein the composition
includes water and from 0.5 wt% to 4 wt% anionic thickener; contacting a skin surface with the
30 composition in the container; mechanically acting on the skin surface for at least one (1) second
while the skin surface is in the presence of the composition; and removing at least a portion of
the composition from the surface of the skin.

Also disclosed are methods for removing spores from skin, the method including
obtaining a spore removing article, the spore removing article being capable of carrying an
35 effective amount of a composition, wherein the composition includes water and from 0.5 wt%
to 4 wt% anionic thickener; contacting a skin surface with the spore removing article and the

composition; mechanically acting on the skin surface for at least one (1) second with the spore removing article; and removing the spore removing article from the surface of the skin.

The above summary of the present disclosure is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The description that follows
5 more particularly exemplifies illustrative embodiments. In several places throughout the application, guidance is provided through lists of examples, which examples can be used in various combinations. In each instance, the recited list serves only as a representative group and should not be interpreted as an exclusive list.

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DETAILED DESCRIPTION

In the following description of illustrative embodiments, reference is made to the accompanying figures which form a part hereof, and in which are shown, by way of illustration, specific embodiments. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the present disclosure.

15

All scientific and technical terms used herein have meanings commonly used in the art unless otherwise specified. The definitions provided herein are to facilitate understanding of certain terms used frequently herein and are not meant to limit the scope of the present disclosure.

20

As used in this specification and the appended claims, “top” and “bottom” (or other terms like “upper” and “lower”) are utilized strictly for relative descriptions and do not imply any overall orientation of the article in which the described element is located.

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” encompass embodiments having plural referents, unless the content clearly dictates otherwise.

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As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise. The term “and/or” means one or all of the listed elements or a combination of any two or more of the listed elements.

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As used herein, “have”, “having”, “include”, “including”, “comprise”, “comprising” or the like are used in their open ended sense, and generally mean “including, but not limited to”. It will be understood that “consisting essentially of”, “consisting of”, and the like are subsumed in “comprising” and the like. For example, a conductive trace that “comprises” silver may be a conductive trace that “consists of” silver or that “consists essentially of” silver.

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As used herein, “consisting essentially of,” as it relates to a composition, apparatus, system, method or the like, means that the components of the composition, apparatus, system, method or the like are limited to the enumerated components and any other components that do

not materially affect the basic and novel characteristic(s) of the composition, apparatus, system, method or the like.

The words “preferred” and “preferably” refer to embodiments that may afford certain benefits, under certain circumstances. However, other embodiments may also be preferred,
5 under the same or other circumstances. Furthermore, the recitation of one or more preferred embodiments does not imply that other embodiments are not useful, and is not intended to exclude other embodiments from the scope of the disclosure, including the claims.

Also herein, the recitations of numerical ranges by endpoints include all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, etc. or 10 or less
10 includes 10, 9.4, 7.6, 5, 4.3, 2.9, 1.62, 0.3, etc.). Where a range of values is “up to” a particular value, that value is included within the range.

Use of “first,” “second,” etc. in the description above and the claims that follow is not intended to necessarily indicate that the enumerated number of objects are present. For example, a “second” substrate is merely intended to differentiate from another infusion device
15 (such as a “first” substrate). Use of “first,” “second,” etc. in the description above and the claims that follow is also not necessarily intended to indicate that one comes earlier in time than the other.

Patients with *Clostridium difficile* infection (CDI) shed spores through fecal contamination, resulting in contamination of their skin, clothing, bedding, and environmental
20 surfaces. It has been shown that contamination of multiple skin sites, including the chest, abdomen, arm, and hand, was common among patients with CDI and could easily be transferred to gloved hands. In addition, skin contamination often persisted after resolution of diarrhea. These data suggest that the skin of CDI patients may be an important source of transmission.

It has been shown that bathing with chlorhexidine gluconate is an effective way of reducing microbial burden on skin with pathogens such as vancomycin-resistant *Enterococcus* (VRE) and methicillin-resistant *Staphylococcus aureus*. However, it is known that bathing a patient with chlorhexidine gluconate wipe or a soap would not be useful for removal of spores.
25

Bathing becomes even more important when patients with CDI are not very mobile. In these cases, it is important to be able to remove or kill spores while the patient is in bed. Soaps that are commonly used in the market include soaps that are antimicrobial and non-antimicrobial. A non-antimicrobial soap like IVORY, for example, can be reasonably effective in removing spores; however, bacteria cannot be killed as with a non-antimicrobial soap. Chlorhexidine wipes (containing 2% chlorhexidine gluconate (CHG)) sold by Sage Corporation
30 (Cary, IL) are being used in hospitals for daily patient bathing since they offer an effective way of killing vegetative bacteria. In some cases, a health care worker can use dilute bleach baths
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or wipes that have dilute bleach to clean the patient as hypochlorous acid has been shown to kill spores effectively. These solutions of dilute bleach need to be in wet contact with the skin of the patient for a few minutes to get an effective kill. Such exposure can be a concern however, because toxicity can build upon repeated use. Commonly owned United States Provisional
5 Patent Application Serial No. 62/187,372, filed July 1, 2015 discloses the use of skin-friendly alcohol containing solutions.

It is therefore important to develop compositions and methods that are safe for repeated use on the skin; reduce spores to a level equivalent to that of the CDC recommended protocol (soap, water and paper towel); can be used on patients at their bed side; and may optionally
10 have the ability to kill vegetative bacteria.

Disclosed herein are methods for removing spores that include steps of dispensing a composition, mechanically acting on a skin surface, and removing at least a portion of the composition from the surface of the skin. Compositions disclosed herein, e.g., compositions that can be utilized in disclosed methods can include water and an anionic thickener. In some
15 embodiments, useful compositions can also include an optional antimicrobial. For example, some illustrative compositions can include water, anionic thickener, and a cationic antimicrobial, a nonionic antimicrobial, or some combination thereof.

Water utilized in disclosed compositions can be deionized water, sterilized water, or both deionized and sterilized water for example. Compositions for use in disclosed methods can include various amounts of water. In some embodiments, compositions for use in disclosed
20 methods can include not less than 35 wt% water. In some embodiments, compositions for use in disclosed methods can include not less than 40 wt% water. In some embodiments, compositions for use in disclosed methods can include not less than 41 wt% water. In some embodiments, compositions for use in disclosed methods can include not greater than 99.5%
25 water. In some embodiments, compositions for use in disclosed methods can include not greater than 95% water. In some embodiments, compositions for use in disclosed methods can include not greater than 90% water.

Disclosed compositions also include an anionic thickener (“an anionic thickener” or “anionic thickener” may also refer to more than one type of anionic thickener). Anionic
30 thickeners that can be utilized in disclosed compositions and methods can include, but are not limited to, natural polysaccharides, synthetic carbomers, or combinations thereof. Particular natural anionic thickeners that can be used can include gums or pectin for example. Specific anionic thickeners that can be used can include xanthan gum, carrageenan, alginic acid, pectin and carboxymethyl cellulose sodium salt, glycosaminoglycans such as chondroitin sulfate,
35 heparin, similar compounds, and combinations thereof. Mixtures of more than one anionic

thickener can also be utilized in compositions, as such use of “an anionic thickener” can imply one or more than one specific anionic thickener.

Arabinoxylans, beta-glucans, chitin, galactomannans like guar gum, locus bean gum etc., glucomannans, agar, cellulose and the like that are neutral may be detrimental to spore removal.

The “polyanion characteristics” differed from gum to gum, e.g., the number of anionic groups on the polymer (acid equivalent weight) and the proportion in the salt and acid forms. The polyanionic characteristics of the compound may influence the viscosity of the solution which could have an indirect effect on spore removal. The viscosity of the gum increases as it is changed from the acid to the salt form, e.g., as the pH is increased. In the salt form, the polysaccharide can assume a more extended configuration. The anionic groups could include a carboxylate, sulfate, sulfonate or a phosphate. Specific anionic gums could include xanthan gum, alginic acid, sodium alginate, ammonium alginate, propyleneglycol alginate, iota-, kappa-, or lambda-carrageenan, gum ghatti, karaya gum, tragacanth gum, gum arabic, pectin, alkoxycelluloses, carboxymethyl guar or carboxymethyl locust bean gum. Anionic polyelectrolytes that are anionic polymers could also be utilized, with a linear or branched structure, with anionic groups distributed along the polymeric chain, optionally present also in the chain end groups.

In compositions where a natural polysaccharide is utilized, it can be described by its equivalent weight, defined as molecular weight/number of anionic groups present in the polysaccharide. In some embodiments, useful polysaccharides can have an equivalent weight of not less 70, in some embodiments not less 150, in some embodiments not less than 200, or in some embodiments not less than 250.

The anionic charges of the anionic thickener may result from the incorporation of an anionic monomer into the polymer, for example. Non-limiting examples of suitable anionic monomers can include: acrylic acid, methacrylic acid, 3-(sulfopropyl)-acrylate potassium salt, 3-(sulfopropyl)-methacrylate potassium salt, 2-acrylamido-2-methylpropanesulfonic acid, crotonic acid, sodium vinyl sulfonate, acrylamidoglycolic acid, 2-acrylamido-2-methylbutanoic acid, 2-acrylamido-2-methylpropanephosphonic acid, sodium vinyl phosphonate, allyl phosphonic acid and salts thereof. Illustrative examples can include polymers of CARBOPOL, AMPHOMER® polymeric resin, BALANCE® CR (acrylates copolymer), FLEXAN® 130 (sodium polystyrene sulfonate) polymers, and RESYN® 28–2930 (vinyl acrylate/crotonates/vinyl deodeconate copolymer) resin. The equivalent weight of useful anionic polyelectrolytes may be not greater than 10,000, in some embodiments not greater than 3,000, and in some embodiments not greater than 1,500.

Compositions that include thickeners other than anionic, for example cationic or non-ionic may not aid in spore removal and may in fact be detrimental to spore removal. Given that spores have a mild negative charge, it is surprising that a thickener with a negative charge would be more effective in spore removal than would a thickener with a positive charge or no charge. One would not expect the addition of an anionic thickener with or without low levels of cationic or nonionic antimicrobials to assist in spore removal.

Disclosed compositions and compositions for use in disclosed methods can include an anionic thickener at various levels. In some embodiments, compositions include not greater than 5 wt% anionic thickener. In some embodiments, compositions include not greater than 4 wt% anionic thickener. In some embodiments, compositions include not greater than 2 wt% anionic thickener. In some embodiments, compositions include not less than 0.05 wt% anionic thickener. In some embodiments, compositions include not less than 0.1 wt% anionic thickener. In some embodiments, compositions include not less than 0.15 wt% anionic thickener. In some embodiments, compositions include not less than 0.5 wt% anionic thickener. Thickeners that have lower viscosities may be able to be used at higher levels than those with higher viscosities, for example.

In some embodiments, disclosed compositions can also include an optional antimicrobial component(s). The optional antimicrobials can be either cationic or nonionic.

Cationic antimicrobials ("cationic antimicrobial" or "a cationic antimicrobial" may also refer to more than one type of cationic antimicrobial) that can be utilized in disclosed compositions and methods can include cationic quaternary ammonium salts for example. Cationic quaternary ammonium salts can include, but are not limited to cetyl pyridinium chloride, cetrimonium bromide (CTAB), behentrimonium chloride, benzothonium chloride, bis-biguanides include chlorhexidine salts and polymeric guanides such as polyhexamethylenbiguanide (PHMB), benzethonium chloride, chlorhexidine salts such as chlorhexidine gluconate (CHG), octenidine salts such as octenidine dihydrochloride, and stearylalkonium chloride. Mixtures of more than one cationic antimicrobial can also be utilized in compositions, as such use of "a cationic antimicrobial" can imply one or more than one specific cationic antimicrobial. In some embodiments, a composition can include PHMB, CHG, or a combination thereof.

Nonionic antimicrobials ("nonionic antimicrobial" or "a nonionic antimicrobial" may also refer to more than one type of nonionic antimicrobial) that can optionally be utilized in disclosed compositions and methods can include triclosan, PCMX and the like. In some embodiments, compositions include not greater than 4 wt% nonionic antimicrobial if the composition includes a nonionic antimicrobial. In some embodiments compositions, if the

composition includes a nonionic antimicrobial, includes not less than 0.5 wt% nonionic antimicrobial.

Cationic antimicrobials are generally utilized to kill bacteria, but are generally not known to kill spores. CDC and WHO guidelines recommend hand washing with soap, water and paper towel for CDI rooms. The type of soap is not specified by the guidelines, but hospitals are increasingly using antimicrobial soaps instead of regular soaps in wards, ICUs, peri-operative spaces, physicians' lounges, etc. Some antimicrobial soaps can have high concentrations of cationic antimicrobials, for example up to about 2%. The inventors of the instant compositions and methods unexpectedly found that the addition of cationic antimicrobials, in such concentrations can detrimentally affect spore removal.

Disclosed compositions and compositions for use in disclosed methods that include a cationic antimicrobial generally do not include high concentrations of cationic antimicrobial. Disclosed compositions and compositions for use in disclosed methods that optionally include cationic antimicrobial can include them at preservative levels, for example. In some embodiments, compositions include not greater than 0.5 wt% cationic antimicrobial if the composition includes a cationic antimicrobial. In some embodiments, compositions include not greater than 0.3 wt% cationic antimicrobial if the composition includes a cationic antimicrobial. In some embodiments compositions, if the composition includes a cationic antimicrobial, includes not less than 0.02 wt% cationic antimicrobial. In some embodiments compositions, if the composition includes a cationic antimicrobial, includes not less than 0.04 wt% cationic antimicrobial. Disclosed compositions and methods utilizing disclosed compositions that include optional cationic antimicrobial do not see any detrimental effect to spore removal from the cationic antimicrobial, presumably because of the relatively low levels present.

Mixtures of cationic antimicrobials with nonionic antimicrobials can also be utilized in compositions. In some embodiments, disclosed compositions for use in disclosed methods can be characterized by the total amount, if any of antimicrobial (cationic, nonionic, or the combination thereof) present. In some embodiments, a composition for use in disclosed methods can include, if present, not greater than 4 wt% total antimicrobial. In some embodiments, a composition for use in disclosed methods can include, if present, not less than 0.04 wt% total antimicrobial.

Disclosed compositions and compositions for use in disclosed methods may also include other components. Illustrative examples of other components that may optionally be included in compositions can include alcohols, surfactants, humectants, emulsifiers, skin conditioning agents and abrasives or polishing agents.

Disclosed compositions and compositions for use in disclosed methods can optionally include an alcohol ("an alcohol" or "alcohol" may also refer to more than one type of alcohol).

Any kind of alcohol can optionally be utilized in disclosed compositions and methods. In some embodiments, a lower hydrocarbon chain alcohol such as a C₂-C₅ alcohol can be utilized. In some embodiments the alcohol can be chosen from ethanol and isopropanol, and in some embodiments ethanol. Ethanol may be useful because it may provide a broad spectrum and quick kill of microbes and an odor acceptable to consumers such as doctors, nurses and clinicians. Propyl alcohol (1-propanol) may also be used. A blend of two or more lower alcohols may also be utilized. The lower alcohols may be denatured, such as for example, denatured ethanol including SDA-3C (commercially available from Eastman Chemical, Kingsport, TN). Co-solvents may be further included in the composition with the lower alcohol. Considering likely applications contemplated, suitable co-solvents can include for example acetone, hydrocarbons such as isooctane, glycols, ketones, ethers, and short chain esters.

In disclosed compositions and compositions for use in disclosed methods, alcohol, if included can be included in various amounts. In some embodiments, if disclosed compositions include an alcohol, the composition can include not greater than 50 wt% of an alcohol, not greater than 40 wt% of an alcohol, or not greater than 20 wt% of an alcohol. In some embodiments, if disclosed compositions include an alcohol, the composition can include not less than 2 wt% of an alcohol, or not less than 5 wt% of an alcohol.

Disclosed compositions and compositions for use in disclosed methods can optionally include a surfactant ("a surfactant" or "surfactant" may also refer to more than one type of surfactant). Any kind of surfactant can optionally be utilized in disclosed compositions and methods. In some embodiments, disclosed compositions can be in the form of a soap. In some embodiments, soap like compositions can include a surfactant as a base, in some embodiments an aqueous one. Surfactant bases can function to dissolve the ampholyte(s) in the aqueous medium, for example. Suitable surfactants can include, but are not limited to, amphoteric surfactants, nonionic surfactants, zwitterionic surfactants, or any combination thereof.

Illustrative amphoteric or zwitterionic surfactants can include aliphatic secondary or tertiary amine derivatives, specifically those in which the aliphatic radical is a linear or branched chain containing 8 to 18 carbon atoms and containing at least one water-solubilizing anionic group (for example carboxylate, sulfonate, sulfate, phosphate or phosphonate); carboxybetaines; (C8-C20) alkylbetaines; sulfobetaines; (C8-C20); alkylamido (C1-C6) alkylbetaines; and (C8-C20) alkylamido (C1-C6) alkylsulfobetaines. Useful amphoteric or zwitterionic surfactants could also include amidobetaines and amidosulfobetaines for example. Useful zwitterionic surfactants can include the derivatives of aliphatic quaternary ammonium, phosphonium, and sulfonium compounds, specifically those in which the aliphatic radicals are straight or branched, and wherein one of the aliphatic substituents contains from about 8 to 18

carbon atoms and one contains an anionic group, e.g., carboxy, sulfonate, sulfate, phosphate or phosphonate.

Illustrative non-ionic surfactants can include condensates of sorbitan monostearate with ethylene oxide, condensates of ethylene oxide with propylene oxide, and condensates of propylene glycol (available under the tradename PLURONICS®). Other examples of water-soluble non-ionic surfactants useful herein can include condensation products of ethylene oxide with various other compounds which are reactive therewith and have long hydrophobic chains (e.g. C12-C20 aliphatic chains), such condensation products (ethoxamers) may contain hydrophilic polyoxyethylene moieties, such as condensation products of polyethylene oxide with fatty acids, fatty alcohols, fatty amides, or polyhydric alcohols (e.g. sorbitan monostearate). Specific examples include decyl glucosides, polysorbates, EO/PO block copolymers such as PLURONICS®.

In disclosed compositions and compositions for use in disclosed methods, surfactant, if included can be included in various amounts. In some embodiments, if disclosed compositions include a surfactant, the composition can include not greater than 5 wt% of a surfactant, or not greater than 3 wt% of a surfactant. In some embodiments, if disclosed compositions include a surfactant, the composition can include not less than 0.5 wt% of a surfactant, or not less than 0.1 wt% of a surfactant.

Disclosed compositions and compositions for use in disclosed methods can optionally include a humectant ("a humectant" may also refer to more than one type of humectant). Any kind of humectant can optionally be utilized in disclosed compositions and methods. Suitable humectants may include for example glycerin, propylene glycol, sorbitol, polypropylene glycol, polyethylene glycol, and combinations thereof. Various amounts of humectants could be utilized in disclosed compositions.

Disclosed compositions and compositions for use in disclosed methods can optionally include a skin conditioning agent ("a skin conditioning agent" may also refer to more than one type of skin conditioning agent). Any kind of skin conditioning agent can optionally be utilized in disclosed compositions and methods. Suitable skin conditioning agents such as glycerides, sorbitol, castor oil, allantoin, lanolin and its derivatives, cetyl alcohol and cationic polymers could be utilized for example. Various amounts of skin conditioning agents could be utilized in disclosed compositions.

Disclosed compositions and compositions for use in disclosed methods can optionally include an abrasive or exfoliating material ("abrasive or polishing material" may also refer to more than one type of abrasive and/or polishing material). In some embodiments abrasive or polishing materials could include water insoluble abrasives such as phosphates, carbonates, silicates, hydrated silica, hydrated alumina, bentonite, as well as polymeric beads such a poly

methacrylate (PMMA), polystyrene, and polyolefin beads and particulates and the like as well as mixtures thereof. In some cases, other mild exfoliating agents could optionally be used in disclosed compositions for mechanically removing spores. Illustrative exfoliating agents could include arrowroot powder or walnut powder for example. Various amounts of abrasive or polishing material could be utilized in disclosed compositions.

In some embodiments, the pH of the composition can be controlled and/or modified. In some embodiments useful compositions or compositions useful in disclosed methods can have a pH of not less than 3, or in some embodiments not less than 5 for example. In some embodiments useful compositions or compositions useful in disclosed methods can have a pH of not greater than 10, or in some embodiment not greater than 9 for example.

In some embodiments, the temperature of the composition can be controlled and/or modified. In some embodiment useful compositions or compositions useful in disclosed methods can have a temperature that is not less than room temperature (about 25° C), or in some embodiments higher than room temperature. In some embodiments, useful compositions or compositions useful in disclosed methods can have a temperature that is not so high that it is not tolerated by skin (for example not greater than 40 °C, or more specifically not greater than 38 °C). In some embodiments methods that will be disclosed heretofore can include steps of heating a composition or heating an article which a composition (either heated or not) has been dispensed into or onto.

Disclosed methods include a step of dispensing a composition. The composition can be dispensed into or onto an article. Dispensing can be accomplished via pouring, spraying, bringing the article into the composition (e.g., dipping), or submerging the article in the composition, for example. As indicated, the composition can be dispensed into or onto an article.

In embodiments where the composition is dispensed into an article, illustrative articles can include for example basins, bowls, and tubs. Such methods can be useful in instances where the skin from which the spores are to be removed is to be brought into contact with the composition in the article, for example. More specifically, this can be useful if some part of, or all of the patient is going to be immersed in the composition in the article. For example, the patient could be going to bathe in the article (e.g., a tub). Another example could include a basin where some part of a patient, for example one or more hands are to be immersed in the composition in the basin. This can also be useful if a secondary article is going to be immersed in the composition in the article and then that secondary article is going to be brought into contact with the skin.

The amount of the composition dispensed into an article, or an effective amount, can depend at least in part on how the skin from which the spores are to be removed is to be

brought into contact with the composition in the article, the particular skin to be cleaned, the type of mechanical action (discussed below), whether or not there is a secondary article, or combinations thereof.

5 In some embodiments where the composition is to be dispensed into an article, not less than 5 milliliters (mL) of composition can be dispensed into an article, not less than 10 mL of composition, not less than 20 mL of composition, or not less than 50 mL of composition. Relevant upper amounts of composition would depend at least in part on the particular article (e.g., its maximum volume), the volume to be immersed (if immersion is relevant) in the article, and combinations thereof.

10 In some embodiments where the composition is to be dispensed into an article, the amount dispensed, or an effective amount can also depend, at least in part, on the surface area of skin from which spores are to be removed. In some embodiments, not less than 1 mL/10 cm² of skin surface from which spores are to be removed can be dispensed into the article, and in some embodiments not less than 1 mL/50 cm² of skin surface from which spores are to be removed can be dispensed into the article.

The composition can also be dispensed onto an article. In embodiments where the composition is dispensed onto an article, illustrative articles can include for example wipes, sponges, cloths, loofahs, brushes, pads, or fibrous mats for example. It should be understood that dispensing a composition into an article can imply bringing the composition to the article, 20 bringing the article to the composition, or any combination thereof. Such methods can be useful in instances where the skin from which the spores are to be removed is to be brought into contact with an article that is associated with the composition, for example. More specifically, this can be useful for wiping affected skin of a patient with the article to which the composition has been dispensed, to remove spores from the skin of the patient.

25 The amount of the composition dispensed onto an article, or an effective amount, can depend at least in part on the particular skin to be cleaned, the total surface area of skin to be cleaned, the type of mechanical action (discussed below), the particular type of article (e.g., the amount the article can absorb, hold, etc.) or combinations thereof.

In some embodiments where the composition is to be dispensed onto an article, not less 30 than 30 mL of composition can be dispensed onto an article, not less than 40 mL of composition, not less than 50 mL of composition, or not less than 20 mL of composition. Relevant upper amounts of composition would depend at least in part on the particular article (e.g., its surface area, the material thereof, its porosity, etc.), a desired level of “wetness” of the article, and combinations thereof.

35 In some embodiments where the composition is to be dispensed onto an article, the amount dispensed, or an effective amount can also depend, at least in part, on the surface area

of skin from which spores are to be removed. In some embodiments, not less than 1 mL/10 cm² of skin surface from which spores are to be removed can be dispensed onto the article, and in some embodiments not less than 5 mL/10 cm² of skin surface from which spores are to be removed can be dispensed onto the article.

5 In some embodiments where the composition is to be dispensed onto an article, an effective amount is one which provides a sufficient amount of composition in contact with the skin surface from which spores are to be removed. In some embodiments, an effective amount can be described with respect to the amount of the composition necessary to saturate the article. An article is “saturated” when the article is contacted with more composition than the article
10 can hold and reasonable pressure is applied to the article to remove the excess. In articles that are easily wet, “saturation” can be determined substantially immediately after incorporation. In articles that are more hydrophobic, it may be necessary to expose the article to the composition for a longer period of time. A reasonable amount of pressure can be that applied with an average hand squeezing motion until no further solution is seen dripping from the wipe. The
15 amount of composition retained in the article after pressure has been applied can be referred to as the saturation amount.

In some embodiments, an effective amount of composition that can be dispensed onto an article can be an amount that renders the wipe as wet as possible so that the saturation amount is bypassed. In some embodiments, it may not be desirable to go below the saturation
20 level, or not less than 5% below the saturation amount. In some embodiments, an effective amount of composition that can be dispensed onto an article can be not greater than 40% above the saturation amount of the article. In some embodiments, an effective amount can be not greater than 20% above the saturation amount of the article, in some embodiments not greater than 15% above the saturation amount, and in some embodiments not greater than 5% above
25 the saturation amount. In some embodiments, an effective amount of a composition can be one that makes the article as wet as possible while maintaining a useful article.

For the purposes of illustration only, a 4 inch x 6 inch SONTARA® 8005, 100% PET (DuPont) wipe has a saturation amount of 3.5 g liquid, so illustrative effective amounts for such an article could include not greater than 4.9 g of liquid, not greater than 4.2 g liquid, not greater
30 than 4.0 g liquid, not greater than 3.7 g liquid, and not less than 3.3 g liquid.

In some embodiments, a different first step (as opposed to the first step discussed above, dispensing a composition into or onto an article) can be utilized. For example, in some embodiments, a first step can include obtaining a spore removing article. A spore removing article is an article that is capable of carrying an effective amount of a composition distributed
35 throughout the material of the article.

The step of obtaining a spore removing article can be accomplished by contacting a carrier with a composition, such as those compositions described above. This step can be carried out as discussed above with respect to dispensing the composition onto an article, which in this case is the carrier. The carrier can be a wipe, or a sponge for example. Also as
5 discussed above, the carrier can be dipped into the composition, the composition can be sprayed onto the carrier, the composition can be applied to the composition, or any combination thereof.

The step of obtaining a spore removing article can also alternatively be accomplished by obtaining a carrier pre-moistened with the composition. For example, one or more spore
10 removing articles can be packaged together in any type of air tight or re-sealable packaging, for example a foil pack, a plastic container, or any combination thereof.

Disclosed methods also include steps of contacting the skin from which the spores are to be removed with the composition. Details regarding this step can vary based at least in part on whether the composition was dispensed into an article or onto an article, the type of article,
15 the skin to be contacted, or combinations thereof. In some embodiments where the composition is dispensed into an article, this step can be accomplished by immersing the skin from which the spores are to be removed in the composition in the article (e.g., immersing the skin in a tub or basin). In some embodiments where the composition is dispensed onto an article, this step can be accomplished by contacting the article with the skin or vice versa (e.g.,
20 contacting a composition containing wipe with the skin). The skin surface can be any portion of a patient's skin that has spores thereon, is thought to have spores thereon, may have spores thereon, or any combination thereof.

Disclosed methods also include a step of mechanically acting on the skin surface or subjecting the skin to mechanical action. The mechanical action can occur while the skin
25 surface is in the presence of the composition, or while the skin is in contact with some portion of the composition. Virtually any type of mechanical action could be utilized in disclosed methods. Illustrative types of mechanical action can include, for example, rubbing the skin (for example rubbing the skin with the article onto which the composition was dispensed, rubbing the skin with an article not treated with the composition, rubbing the skin with some
30 other portion of the skin, or any combination thereof), wiping the skin (e.g., moving the article onto which the composition was dispensed, moving an article not treated with the composition, moving additional skin over the skin from which the spores are to be removed, or any combination thereof). In some embodiments, mechanical action can include rubbing, wiping, scouring, sliding, scraping, or exfoliating (for example) the surface with the article onto which
35 the composition was dispensed or a different article. In some embodiments, mechanical action can include moving a first surface contacted with the composition across or over a second

surface contacted with the composition. A specific example of such an embodiment can include rubbing two hands contacted with the composition together.

The step of subjecting the surface to mechanical action can occur for any amount of time. In some embodiments, the surface can be subjected to mechanical action for not less than 1 second, not less than 5 seconds, not less than 10 seconds, or not less than 20 seconds. In some embodiments, the surface can be subjected to mechanical action for not greater than 2 minutes, or not greater than 1 minute, for example.

The steps of contacting the skin with a composition and subjecting the skin in contact with the composition to mechanical action can occur with at least some overlap. For example, in some embodiments, while at least some of the composition is being contacted with the skin, mechanical action can begin. Specifically, for example, while a hand, or hands, is being dipped into the composition (or even soaked in the composition), the hands can be rubbed together. Either (or both) of the steps of contacting the skin with the composition or subjecting the skin to mechanical action can be repeated more than once in some embodiments.

In some embodiments, the step of subjecting the skin to mechanical action can be described by the force of the mechanical action. In some embodiments, the mechanical action on the skin have a force of not less than 20 N.

Disclosed methods also include a step of removing at least a portion of the composition from the skin. Removing this portion of the composition also removes at least some spores from the skin. In some embodiments, this step is accomplished without an excess of water, for example without rinsing under running water or without rinsing in additional water (e.g., water in a basin).

The step of removing a portion of the composition from the skin can leave some portion of the composition on the skin surface. In some embodiments, not greater than 3 mL of composition remains on the skin surface, or in some embodiments not greater than 1 mL of composition remains on the skin surface. In some embodiments, the composition does not substantially evaporate from the skin surface, but has to be removed via some other action.

Disclosed compositions and methods can be utilized on skin of patients, health care workers, other individuals, or any combination thereof. Disclosed methods can be utilized with various compositions, including those disclosed herein.

Illustrative disclosed embodiments are provided below.

Some illustrative embodiments can include methods for removing spores from skin, the methods comprising: dispensing an effective amount of a composition into or onto an article, wherein the composition comprises: water; and from 0.15 wt% to 4 wt% anionic thickener; contacting a skin surface with the composition; mechanically acting on the skin surface for at least one (1) second while the skin surface is in the presence of the composition; and removing

at least a portion of the composition from the surface of the skin, wherein removing the composition also removes spores from the skin surface.

Such methods wherein the composition comprises from about 0.5 wt% to about 4 wt% anionic thickener. Such methods, wherein the anionic thickener is selected from natural
5 polysaccharides, synthetic carbomers, or combinations thereof. Such methods, wherein the anionic thickener is a gum, a pectin, or a combination thereof. Such methods, wherein the anionic thickener is xanthan, caregeenan, alginic acid, or some combination thereof. Such a method, wherein the composition is dispensed into an article. Such methods, wherein the article is a basin, bowl, or tub. Such methods, wherein at least about 5 mL of composition is dispensed
10 into the article. Such methods, wherein at least about 10 mL of composition is dispensed into the article. Such methods, wherein at least about 20 mL of composition is dispensed into the article. Such methods, wherein at least about 50 mL of composition is dispensed into the article. Such methods, wherein at least about 1 mL/ 10 cm² of the skin surface to be cleaned is dispensed into the article. Such methods, wherein at least about 1 mL/50 cm² of the skin surface
15 to be cleaned is dispensed into the article. Such methods, wherein the composition is dispensed onto an article. Such methods, wherein the article is a wipe, a sponge, or a fibrous mat. Such methods, wherein at least about 1 mL/cm² to 10 mL/cm² of the skin surface to be cleaned is dispensed onto the article. Such methods, wherein at least about 3 mL/cm² to 10 mL/cm² of the skin surface to be cleaned is dispensed onto the article. Such methods, wherein the effective
20 amount of composition is not more than about 40% of a saturation amount of the article. Such methods, wherein the effective amount of composition is not more than about 20% of a saturation amount of the article. Such methods, wherein the effective amount of composition is not more than about 15% of a saturation amount of the article. Such methods, wherein the effective amount of composition is not less than about 20% of a saturation amount of the
25 article. Such methods, wherein the effective amount of composition is not less than about 15% of a saturation amount of the article. Such methods, wherein the mechanical action lasts for at least about 5 seconds. Such methods, wherein the mechanical action lasts for at least about 15 seconds. Such methods, wherein the mechanical action lasts for at least about 30 seconds. Such methods, wherein mechanically acting on the skin has a force of at least about 20 N. Such
30 methods, wherein mechanically acting comprises rubbing, wiping, scrubbing, pulsing, sliding or some combination thereof. Such methods, wherein the step of removing is accomplished without an excess of water. Such methods, wherein the step of removing leaves less than 3 mL of composition on the surface. Such methods, wherein the step of removing leaves less than 1 mL of composition on the surface. Such methods, wherein the composition further comprises a
35 lower hydrocarbon chain alcohol. Such methods, wherein the lower chain alcohol is a C₂ to C₅ alcohol, or mixture thereof. Such methods, wherein the composition comprises from about 2 to

about 20 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition comprises from about 5 to about 20 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition comprises not greater than about 50 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition further comprises a
5 surfactant. Such methods, wherein the composition comprises not greater than about 5 wt% surfactant. Such methods, wherein the composition further comprises a cationic antimicrobial. Such methods, wherein the composition comprises from about 0.04 wt% to about 0.3 wt% cationic antimicrobial. Such methods, wherein the cationic antimicrobial is PHMB, CHG, or some combination thereof. Such methods, wherein the composition further comprises a
10 nonionic antimicrobial. Such methods, wherein the composition comprises not less than 0.5% nonionic antimicrobial. Such methods, wherein the composition further comprises humectants, emulsifiers, or combinations thereof.

Additional illustrative embodiments can include methods comprising: dispensing an effective amount of a composition into a container, wherein the composition comprises: water;
15 and from 0.15 wt% to 4 wt% anionic thickener; contacting a skin surface with the composition in the container; mechanically acting on the skin surface for at least one (1) second while the skin surface is in the presence of the composition; and removing at least a portion of the composition from the surface of the skin.

Such methods, wherein the composition comprises from about 0.5 wt% to about 4 wt%
20 anionic thickener. Such methods, wherein the anionic thickener is selected from natural polysaccharides, synthetic carbomers, or combinations thereof. Such methods, wherein the anionic thickener is a gum, a pectin, or a combination thereof. Such methods, wherein the anionic thickener is xanthan, caregeenan, alginic acid, or some combination thereof. Such methods, wherein the article is a basin, bowl, or tub. Such methods, wherein at least about 5
25 mL of composition is dispensed into the article. Such methods, wherein at least about 10 mL of composition is dispensed into the article. Such methods, wherein at least about 20 mL of composition is dispensed into the article. Such methods, wherein at least about 50 mL of composition is dispensed into the article. Such methods, wherein at least about 1 mL/ 10 cm² of the skin surface to be cleaned is dispensed into the article. Such methods, wherein at least about
30 1 mL/50 cm² of the skin surface to be cleaned is dispensed into the article. Such methods, wherein the mechanical action lasts for at least about 5 seconds. Such methods, wherein the mechanical action lasts for at least about 15 seconds. Such methods, wherein the mechanical action lasts for at least about 30 seconds. Such methods, wherein mechanically acting on the skin has a force of at least about 20 N. Such methods, wherein mechanically acting comprises
35 rubbing, wiping, scrubbing, pulsing, sliding or some combination thereof. Such methods, wherein the step of removing is accomplished without an excess of water. Such methods,

wherein the step of removing leaves less than 3 mL of composition on the surface. Such methods, wherein the step of removing leaves less than 1 mL of composition on the surface. Such methods, wherein the composition further comprises a lower hydrocarbon chain alcohol. Such methods, wherein the lower chain alcohol is a C₂ to C₅ alcohol, or mixture thereof. Such methods, wherein the composition comprises from about 2 to about 20 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition comprises from about 5 to about 20 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition comprises not greater than about 50 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition further comprises a surfactant. Such methods, wherein the composition comprises not greater than about 5 wt% surfactant. Such methods, wherein the composition further comprises a cationic antimicrobial. Such methods, wherein the composition comprises from about 0.04 wt% to about 0.3 wt% cationic antimicrobial. Such methods, wherein the cationic antimicrobial is PHMB, CHG, or some combination thereof. Such methods, wherein the composition further comprises a nonionic antimicrobial. Such methods, wherein the composition comprises not less than 0.5% nonionic antimicrobial. Such methods, wherein the composition further comprises humectants, emulsifiers, or combinations thereof.

Additional illustrative embodiments can include methods comprising: obtaining a spore removing article, the spore removing article being capable of carrying an effective amount of a composition, wherein the composition comprises: water; and from 0.15 wt% to 4 wt% anionic thickener; contacting a skin surface with the spore removing article and the composition; mechanically acting on the skin surface for at least one (1) second with the spore removing article; and removing the spore removing article from the surface of the skin.

Such methods, wherein the step of obtaining a spore removing article comprises contacting a carrier with the composition. Such methods, wherein the carrier is a wipe, a sponge, or a fibrous mat. Such methods, wherein the step of contacting the carrier with the composition comprises dipping the carrier in the composition, spraying the composition onto the carrier, or some combination thereof. Such methods, wherein the step of obtaining a spore removing article comprises obtaining a carrier pre-moistened with the composition. Such methods, wherein the step of obtaining a spore removing article comprises obtaining the spore removing article from a package comprising a plurality of spore removing articles. Such methods, wherein the package comprises a foil pack, a plastic container, or some combination thereof. Such methods, wherein the spore removing article is capable of carrying at least about 5 mL of composition. Such methods, wherein the spore removing article absorbs the composition, holds the composition, or some combination thereof. Such methods, wherein the amount of composition in contact with the skin surface during the contacting step is at least

about 5 mL. Such methods, wherein the amount of composition in contact with the skin surface during the contacting step is at least about 10 mL. Such methods, wherein the amount of composition in contact with the skin surface during the contacting step is not greater than about 50 mL. Such methods, wherein the amount of composition in contact with the skin surface during the contacting step is at least about 1 mL/ 10 cm² of the skin surface to be cleaned. Such methods, wherein the composition comprises from about 0.5 wt% to about 4 wt% anionic thickener. Such methods, wherein the anionic thickener is selected from natural polysaccharides, synthetic carbomers, or combinations thereof. Such methods, wherein the anionic thickener is a gum, a pectin, or a combination thereof. Such methods, wherein the anionic thickener is xanthan, caregeenan, alginic acid, or some combination thereof. Such methods, wherein the mechanical action lasts for at least about 5 seconds. Such methods, wherein the mechanical action lasts for at least about 15 seconds. Such methods, wherein the mechanical action lasts for at least about 30 seconds. Such methods, wherein mechanically acting on the skin has a force of at least about 20 N. Such methods, wherein mechanically acting comprises rubbing, wiping, scrubbing, pulsing, sliding or some combination thereof. Such methods, wherein the step of removing is accomplished without an excess of water. Such methods, wherein the step of removing leaves less than 3 mL of composition on the surface. Such methods, wherein the step of removing leaves less than 1 mL of composition on the surface. Such methods, wherein the composition further comprises a lower hydrocarbon chain alcohol. Such methods, wherein the lower chain alcohol is a C₂ to C₅ alcohol, or mixture thereof. Such methods, wherein the composition comprises from about 2 to about 20 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition comprises from about 5 to about 20 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition comprises not greater than about 50 wt% of the lower hydrocarbon chain alcohol. Such methods, wherein the composition further comprises a surfactant. Such methods, wherein the composition comprises not greater than about 5 wt% surfactant. Such methods, wherein the composition further comprises a cationic antimicrobial. Such methods, wherein the composition comprises from about 0.04 wt% to about 0.3 wt% cationic antimicrobial. Such methods, wherein the composition further comprises a nonionic antimicrobial. Such methods, wherein the composition comprises not less than 0.5% nonionic antimicrobial. Such methods, wherein the cationic antimicrobial is PHMB, CHG, or some combination thereof. Such methods, wherein the composition further comprises humectants, emulsifiers, or combinations thereof.

EXAMPLES

Objects and advantages are further illustrated by the following examples, but the particular materials and amounts thereof recited in these examples, as well as other conditions and details, should not be construed to unduly limit this disclosure.

5 Table 1 describes the list of reagents utilized herein.

Table 1

Trade Name	Company	Chemical
CHG (20%Solids In Water)	Xxtrium Laboratories, Chicago, IL	Chlorhexidine gluconate
Cosmocil CQ (20% Solids In Water)	Arch Chemicals, Norwalk, CT	Polyhexamethylene biguanide hydrochloride (PHMB)
Tween 20	Alfa Aesar, Ward Hill, MA	Polysorbate 20
Glycerol Anhydrous Pure	EMD Chemicals, Gibbstown, NJ	glycerol
Carrageenan (type II)	Aldrich Chemical Company, Inc., Milwaukee, WI	t-carrageenan
Keltrol CG-F	CP Kelco, Atlanta, GA	xanthan gum
Alginic Acid	Sigma Chemical Company, St. Louis, MO	alginate
1,000 N Hydrochloric Acid	J.T. Baker, Mallinckrodt Baker Inc., Phillipsburg, NJ	HCl
1,000 N Sodium Hydroxide	VWR International, West Chester, PA	NaOH
Premium Kandiyohi Purified Water	Chippewa Falls, WI PKD 4/13/11 0104	H ₂ O
Potassium dihydrogen phosphate	Sigma-Aldrich Corp., St. Louis, MO	KH ₂ PO ₄
Sodium hydrogen phosphate	Sigma-Aldrich Corp., St. Louis, MO	Na ₂ HPO ₄
Triton X-100	Sigma-Aldrich Corp., St. Louis, MO	4-(,1,3,3-Tetramethylbutyl)phenyl-polyethylene glycol
Carbopol Ultrez 10	Lubrizol Advanced Materials, Cleveland, Ohio	Poly(acrylic acid)
Jaguar Excel (Guar gum)	Solvay S.A., Brussels, Belgium	2-hydroxy-3-(trimethylammonium)propyl ether chloride
Ethanol	Columbus Chemical Industries, Columbus, WI	CH ₃ CH ₂ OH

Table 2

Trade Name	Company	Active Ingredient	Inactive Ingredients
Bacti stat AE	Ecolab, St. Paul, MN	0.3% Triclosan	water, potassium cocoate, SD alcohol 40-B, glycerin, cocamidopropyl PG-dimonium chloride phosphate, potassium stearate, tetrasodium EDTA, hydroxyethylcellulose, fragrance, cocamine oxide, methylparaben, tocopheryl acetate, citric acid, isopropyl alcohol, propylparaben, aloe barbadensis leaf juice, FDC blue 1, FDC yellow 5
Endure 200	Ecolab, St. Paul, MN	1% Triclosan	water, potassium cocoate, propylene glycol, glycerin, potassium stearate, tetrasodium EDTA, hydroxyethylcellulose, boric acid, cocamine oxide, fragrance, isopropyl alcohol, aloe barbadensis leaf juice, FD&C green #3, FD&C blue #1, FD&C yellow #5
Endure 400	Ecolab, St. Paul, MN	4% chlorhexidine gluconate	cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, hydroxyethylcellulose, isopropyl alcohol, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water *contains one or more of these ingredients
Endure 420	Ecolab, St. Paul, MN	2% chlorhexidine gluconate	cocamide DEA, cocamine oxide, fragrance, gluconic acid*, gluconolactone*, hydroxyethylcellulose, isopropyl alcohol, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water *contains one or more of these ingredients
Medi-Scrub	Ecolab, St. Paul, MN	0.6% PCMX	water, potassium cocoate, glycol stearate, potassium stearate, propylene glycol, glycerin, hydroxyethylcellulose, tetrasodium EDTA, isopropyl alcohol, cocamide DEA, boric acid, cocamine oxide, fragrance, PEG-75 lanolin, methylparaben, propylparaben, aloe barbadensis leaf juice, D&C red 33
Sage 2% chlorhexidine gluconate cloths	Sage Products, Cary, IL	2% chlorhexidine gluconate	aloe vera, dimethicone, fragrance, glucono-delta-lactone, glycerin, Igepal, polysorbate 20, propylene glycol, water
Comfort Bath Cleansing Washcloths	Sage Products, Cary, IL	none	water, methylpropanediol, glycerin, tetrasodium glutamate diacetate, decyl glucoside, phenoxyethanol, polysorbate 20, citric acid, benzoic acid, dehydroacetic acid, ethylhexylglycerin, simethicone, tocopheryl acetate, aloe barbadensis leaf, fragrance

TENA Ultra Washcloths	SCA Hygiene Products, Stockholm, Sweden	none	water, mineral oil, chamomilla recutita flower extract, aloe barbadensis leaf extract, tocopheryl acetate, fragrance, dimethicone PEG-7 cocoate, isopropyl myristate, glyceryl stearate citrate, sodium hydroxymethylglycinate, PEG-4 laurate, iodopropynyl butylcarbamate, citric acid, disodium EDTA
Dey-Engley Neutralizing Broth	Sigma-Aldrich Corp. St. Louis, MO	none	casein enzymic hydrolysate, yeast extract, dextrose, sodium thiosulphate, sodium thioglycollate, sodium bisulphite, lecithin, polysorbate 80, bromo cresol purple

Example 1: Preparation of formulations

All of the formulations that were tested for their ability to remove spores from Vitro Skin were constructed in the same fashion.

5 First the correct amount of cationic antimicrobial was added to a known amount of water and the resultant solution was mixed. Next, the relevant amount of thickener was weighed out and added to the aqueous solution while mixing at 5000 rpm for two minutes. Then, the surfactant was added. The solution was mixed again for two minutes at 5000 rpm. Finally the pH was adjusted accordingly with either NaOH or HCl.

10

Example 2: General description of in-vitro experiment designed to evaluate ability of test formulations to remove spores from skin like surfaces

The in-vitro method was designed to evaluate the removal of microbes from skin using a synthetic skin material from the cosmetic industry, Vitro-skin from IMS inc, Portland

15 METhis method enables rapid screening of formulations for their propensity to promote release of microbes from skin and may be predictive of in-vivo activity.

Materials

The following materials were utilized. *C.sporogenes* spores ATCC 3584 ~1.0x10⁸ CFU/ml; Triton - X 100 sampling buffer (pH 7.4) Filter Sterilized: 0.4g KH₂PO₄, 10.1 g Na₂HPO₄, 1 g Triton -X 100, and 1L dH₂O; D/E neutralizing broth; Fingers from disposable polyethylene gloves (VWR 32915-268); Sterile dH₂O (WFI quality water); 3M AC Petrifilm; and 5ml Falcon tubes; 1.5ml EPI Centrifuge tubes; Petri Dishes; Vitro-Skin IMS Inc.; and double-sided tape.

20

25 The method included the following. Punched-out specified number of Vitro-Skin samples using the 3/4" punch. Attached punch-out Vitro-Skin samples to a Petri-dish or any other sterile flat surface using double-sided tape. Contaminated the Vitro-Skin samples accordingly with 10µl of spores/spore prep (~1x10⁶CFU/Sample). Used the pipette tip to spread spores over the surface and used a new pipette tip for each sample. Allowed the

samples to dry (~40 minutes). Placed three samples directly into separate finger bags containing 3ml of triton-x 100 sampling solution or D/E neutralizing broth if one of the samples going to be tested contains antimicrobials. Used the “Finger bag collection method “below for each of the three recovery controls.

5 The Finger bag collection method was carried out as follows. First, a finger bag was cut from disposable gloves.

For the controls: Filled the finger bag with 3ml of sampling solution. Placed contaminated Vitro-Skin sample into the finger bag containing sampling solution. Massaged finger bag for 1 minute using thumb and index finger. Removed aliquot of fluid from the finger bag and place into an appropriately labeled 1.5ml centrifuge tube.

For the tested samples: Placed contaminated Vitro-Skin sample into a finger bag containing 3ml of appropriate test solution. Massage in finger bag for 20 seconds. Removed the Vitro-Skin sample from the finger bag and place into a new finger bag containing 3ml of sampling solution (Triton x-100 glove juice buffer or D/E neutralizing broth). Collected sample by using the finger bag collection method noted above. Repeat “Placed contaminated vitro-skin sample...” to “Collected sample...” for each of the test solutions.

For best statistical data each test solution was repeated 3 times. Heat treated appropriately labeled 1.5ml centrifuge tubes containing aliquots of solution for 20 min at 80C. Serially diluted samples in butterfield’s buffer and plate 10^{-1} to 10^{-4} dilution on AC Petrifilm. Heat shocked, diluted, and plated spore stock day of experiment. Incubated Petrifilm in an anaerobic chamber at 37C for 20-24 hours. Counted plates and analyzed data.

Example 3: Effect of pH on spore removal using either CHG or PHMB as part of the formulation

25 Various cationic antimicrobials were prepared in water at the concentrations specified in Tables 3a and 3b below.

Table 3a

Ex. 3a	PHMB	CHG	Tween 20	Glycerol	Carra-geenan	Keltrol CG-F	Algenic Acid	Water	Avg log10 Reduction	St Dev	pH
3a-1	0	0	0	0	0	0	0	100	0.88	0.08	6.5
3a-2	0	0	3	5	0	0	0	92	0.95	0.10	6.5
3a-3	0	0	3	5	0	0.5	0	91.5	1.42	0.35	6.5
3a-4	0.04	0	3	5	0	0.5	0	91.46	1.23	0.31	6.5
3a-5	0	0	3	5	0.5	0	0	91.5	1.39	0.44	5
3a-6	0	0	3	5	0.5	0	0	91.5	1.66	0.11	6
3a-7	0	0	3	5	0.5	0	0	91.5	0.87	0.20	7
3a-8	0	0	3	5	0.5	0	0	91.5	1.62	0.08	8
3a-9	0	0.1	3	5	0.5	0	0	91.4	1.99	0.15	5

3a-10	0	0.1	3	5	0.5	0	0	91.4	2.02	0.06	6
3a-11	0	0.1	3	5	0.5	0	0	91.4	2.03	0.04	7
3a-12	0	0.1	3	5	0.5	0	0	91.4	1.80	0.15	8
3a-13	0	0	3	5	0	0	0.5	91.5	1.81	0.06	5
3a-14	0	0	3	5	0	0	0.5	91.5	1.94	0.03	6
3a-15	0	0	3	5	0	0	0.5	91.5	1.80	0.08	7
3a-16	0	0	3	5	0	0	0.5	91.5	1.95	0.09	8
3a-17	0	0.1	3	5	0	0	0.5	91.4	1.94	0.05	5
3a-18	0	0.1	3	5	0	0	0.5	91.4	1.89	0.03	6
3a-19	0	0.1	3	5	0	0	0.5	91.4	1.83	0.06	7
3a-20	0	0.1	3	5	0	0	0.5	91.4	1.92	0.10	8
Recovery Control									0.11	0.11	
Input Control									0.00	0.05	

Table 3b

Ex. 3b	PHMB	Tween 20	Glycerol	Carra-geenan	Keltrol CG-F	Alginate Acid	Water	Avg log10 Reduction	St Dev	pH
3b-1	0	0	0	0	0	0	100	0.37	0.17	6.5
3b-2	0	3	5	0	0	0	92	0.26	0.26	6.5
3b-3	0	3	5	0	0.5	0	91.5	1.10	0.06	6.5
3b-4	0.04	3	5	0	0.5	0	91.46	1.08	0.13	6.5
3b-5	0	3	5	0.5	0	0	91.5	0.92	0.57	5
3b-6	0	3	5	0.5	0	0	91.5	1.49	0.27	6
3b-7	0	3	5	0.5	0	0	91.5	1.23	0.30	7
3b-8	0	3	5	0.5	0	0	91.5	1.16	0.29	8
3b-9	0.04	3	5	0.5	0	0	91.46	1.92	0.16	5
3b-10	0.04	3	5	0.5	0	0	91.46	1.96	0.31	6
3b-11	0.04	3	5	0.5	0	0	91.46	2.25	0.11	7
3b-12	0.04	3	5	0.5	0	0	91.46	1.92	0.23	8
3b-13	0	3	5	0	0	0.5	91.5	1.71	0.20	5
3b-14	0	3	5	0	0	0.5	91.5	1.80	0.13	6
3b-15	0	3	5	0	0	0.5	91.5	1.84	0.24	7
3b-16	0	3	5	0	0	0.5	91.5	1.79	0.06	8
3b-17	0.04	3	5	0	0	0.5	91.46	2.02	0.12	5
3b-18	0.04	3	5	0	0	0.5	91.46	1.88	0.10	6
3b-19	0.04	3	5	0	0	0.5	91.46	1.85	0.07	7
3b-20	0.04	3	5	0	0	0.5	91.46	1.94	0.12	8
Recovery Control								0.06	0.05	
Input Control								0.00	0.05	

Example 4: Effect of competitor soaps on spore removal performance.

Competitor products such as Ecolab Bacti stat AE (0.3% Triclosan), Ecolab Endure 200 (1% Triclosan), Ecolab Endure 400 (4% chlorhexidine gluconate), Ecolab Endure 420 (2% chlorhexidine gluconate), and Ecolab Medi-scrub (0.6% PCMX), were evaluated against disclosed compositions. Compositions tested are shown in Table 4a and Table 4b shows spore removal results. While CHG by itself showed poor spore removal, the combination of xanthan gum and CHG in the formulation resulted in spore removal equivalent to that of water.

Table 4a

Ex. 4	PHMB	CHG	Tween 20	Glycerol	Xanthan Gum	Water
4-1	0	0	0	0	0	100
4-2	0.2	0	3	5	0.5	91.3
4-3	0	0.2	3	5	0.5	91.3

Table 4b

	Average Log10 Reduction	Standard Deviation
4-1	0.78	0.15
4-2	1.42	0.12
4-3	1.46	0.13
Bacti-Stat AE	0.33	0.19
Endure 200	0.60	0.13
Endure 400	0.27	0.10
Medi-Scrub	0.07	0.08
Endure 420	0.20	0.07
Input Control	0.00	0.08

As seen above, Xanthan gum with either PHMB or CHG has higher log reduction for spore removal as compared to competitor products.

Example 5: Effect of charge of thickener and viscosity

The compositions shown in Table 4, which all included PHMB, were made and spore removal performance thereof were tested.

Table 5

Ex. 5	PHMB	Tween 20	Glycerol	Carra-geenan	Keltrol CG-F	Alginate Acid	Jaguar Excel (quat guar)	Water	Avg Log10 Reduction	St dev
5-1	0	3	5	0	0	0	0.5	91.5	0.94	0.03
5-2	0.05	3	5	0	0	0	0.5	91.45	0.74	0.17
5-3	2	3	5	0	0	0	0.5	89.5	1.04	0.13
5-4	0	3	5	0	0	0	1	91	0.26	0.08

5-5	0.05	3	5	0	0	0	1	90.95	0.36	0.27
5-6	2	3	5	0	0	0	1	89	0.39	0.08
5-7	0	3	5	0	0.5	0	0	91.5	1.22	0.13
5-8	0.05	3	5	0	0.5	0	0	91.45	1.34	0.09
5-9	0	3	5	0	1	0	0	91	0.93	0.31
5-10	0.05	3	5	0	1	0	0	90.95	0.56	0.15
5-11	0	3	5	0.5	0	0	0	91.5	1.49	0.14
5-12	0.05	3	5	0.5	0	0	0	91.45	1.96	0.09
5-13	0	3	5	1	0	0	0	91	0.59	0.31
5-14	0.05	3	5	1	0	0	0	90.95	1.40	0.10
5-15	0	3	5	0	0	0.5	0	91.5	1.54	0.15
5-16	0.05	3	5	0	0	0.5	0	91.45	1.92	0.07
5-17	0	3	5	0	0	1	0	91	1.60	0.33
5-18	0.05	3	5	0	0	1	0	90.95	1.51	0.11
5-19	0.05	3	5	0	0	0	0	91.95	0.95	0.51
5-20	2	3	5	0	0	0	0	90	1.49	0.16
5-21	0	0	0	0	0	0	0	100	0.73	0.20
5-22	0	3	5	0	0	0	0	92	1.04	0.50
5-23	0.04	3	5	0	0.5	0	0	91.46	1.64	0.18
Recovery Control									0.21	0.07
Input Control									0.00	0.01

As seen from Table 5, the quat guar by itself at 1% with and without PHMB had poor spore removal performance. The anionic thickeners like xanthan gum, alginic acid and carrageenan increased spore removal.

5

Example 6: Effect of charge of thickener and viscosity

The compositions shown in Table 5, which all included CHG, were made and spore removal performance thereof were tested.

Table 6

Ex 6	CHG	PHMB	Tween 20	Glycerol	Carrageenan	Keltrol CG-F	Alginic Acid	Jaguar Excel (quat guar)	Water	Avg log ₁₀ Reduction	St dev
6-1	0	0	3	5	0	0	0	0.5	91.5	0.65	0.07
6-2	1	0	3	5	0	0	0	0.5	90.5	0.34	0.44
6-3	2	0	3	5	0	0	0	0.5	89.5	0.49	0.35
6-4	0	0	3	5	0	0	0	1	91	0.00	0.06
6-5	1	0	3	5	0	0	0	1	90	0.01	0.06
6-6	2	0	3	5	0	0	0	1	89	0.02	0.18
6-7	0	0	3	5	0	0.5	0	0	91.5	1.10	0.12

6-8	0.225	0	3	5	0	0.5	0	0	91.275	0.60	0.21
6-9	0	0	3	5	0	1	0	0	91	0.77	0.09
6-10	0.225	0	3	5	0	1	0	0	90.775	0.18	0.13
6-11	0	0	3	5	0.5	0	0	0	91.5	1.39	0.14
6-12	0.2	0	3	5	0.5	0	0	0	91.3	1.88	0.06
6-13	0	0	3	5	1	0	0	0	91	0.61	0.04
6-14	0.2	0	3	5	1	0	0	0	90.8	1.65	0.06
6-15	0	0	3	5	0	0	0.5	0	91.5	1.25	0.09
6-16	0.2	0	3	5	0	0	0.5	0	91.3	1.94	0.32
6-17	0	0	3	5	0	0	1	0	91	1.52	0.15
6-18	0.2	0	3	5	0	0	1	0	90.8	1.60	0.09
6-19	0	0	0	0	0	0	0	0	100	0.46	0.16
6-20	0	0	3	5	0	0	0	0	92	0.46	0.17
6-21	0	0.04	3	5	0	0.5	0	0	91.46	0.99	0.20
6-22	1	0	0	0	0	0	0	0	99	0.08	0.08
6-23	0.225	0	0	0	0	0	0	0	99.775	0.07	0.08
6-24	0.2	0	0	0	0	0	0	0	99.8	0.14	0.06
6-25	2	0	0	0	0	0	0	0	98	0.60	0.10
Recovery Control										0.00	0.05
Input Control										0.00	0.11

Quat guar at 1% with or without CHG results in poor spore removal performance.

Anionic thickeners such as xanthan gum, carrageenan as well as alginic acid used with CHG result in high spore removal.

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Example 7: Effect of Carbopol in formulation for removal of spores

Table 7a

Ex 7a	Carbopol (Ultrez 10)	Algenic Acid	PHMB	Tween 20	Glycerol	Ethanol	Water	Avg Log10 Reduction	St dev
7a-1	0.15	0	0.05	3	5	5	86.8	2.42	0.14
7a-2	0.15	0	0.05	3	5	10	81.8	2.15	0.06
7a-3	0.15	0	0.05	3	5	20	71.8	1.92	0.14
7a-4	0.15	0	0.05	3	5	50	41.8	1.45	0.23
7a-5	0.15	0	0	3	5	5	86.85	1.82	0.12
7a-6	0.15	0	0	3	5	10	81.85	1.74	0.06
7a-7	0.15	0	0	3	5	20	71.85	1.49	0.09
7a-8	0.15	0	0	3	5	50	41.85	1.07	0.07
7a-9	0	0	0	0	0	5	95	1.04	0.15
7a-10	0	0	0	0	0	10	90	0.99	0.23
7a-11	0	0	0	0	0	20	80	0.92	0.08

7a-12	0	0	0	0	0	35	65	0.86	0.13
7a-13	0.15	0	0.05	3	0	0	96.8	1.73	0.13
7a-14	0.15	0	0	3	5	0	91.85	1.57	0.04
7a-15	0	0	0.05	0	0	0	99.95	1.11	0.20
7a-16	0	1	0	3	5	0	91	0.92	0.22
7a-17	0	1	0.05	3	5	0	90.95	1.22	0.18
7a-18	0	0	0	0	0	0	100	0.67	0.13
Input Control								-0.02	0.03
Recovery Control								0.00	0.03

Table 7b

Ex7b	Carbopol (Ultraz 10)	Alginic Acid	PHMB	Tween 20	Glycerol	Ethanol	Water	Avg Log10 Reduction	St dev
7b-1	0.15	0	0.05	3	5	5	86.8	2.10	0.03
7b-2	0.15	0	0	3	5	5	86.85	2.14	0.14
7b-3	0	1	0.05	3	5	0	90.95	1.86	0.06
7b-4	0	1	0	3	5	0	91	1.26	0.38
7b-5	0	0	0	0	0	5	95	0.68	0.07
7b-6	0	0	0	0	0	0	100	0.57	0.06
7b-7	0	0	0	3	5	5	87	1.34	0.06
7b-8	0	0	0	3	5	0	92	1.19	0.20
Input Control								-0.05	0.03
Recovery Control								0.00	0.03

Thus, embodiments of methods for spore removal are disclosed. The implementations described above and other implementations are within the scope of the following claims. One skilled in the art will appreciate that the present disclosure can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation.

CLAIMS:

1. A method for removing spores from skin, the method comprising:
dispensing an effective amount of a composition into or onto an article, wherein the
5 composition comprises:
water; and
from 0.15 wt% to 4 wt% anionic thickener;
contacting a skin surface with the composition;
mechanically acting on the skin surface for at least one (1) second while the skin
10 surface is in the presence of the composition; and
removing at least a portion of the composition from the surface of the skin, wherein
removing the composition also removes spores from the skin surface.
2. The method according to claim 1, wherein the composition comprises from about
15 0.5 wt% to about 4 wt% anionic thickener.
3. The method according to claim 1, wherein the anionic thickener is a gum, a
pectin, or a combination thereof.
- 20 4. The method according to claim 1, wherein the anionic thickener is xanthan,
carrageenan, alginic acid, or some combination thereof.
5. The method according to claim 1, wherein the composition further comprises from
about 2 to about 20 wt% of a C₂ to C⁵ alcohol, or mixture thereof.
25
6. The method according to claim 1, wherein the composition further comprises not
greater than about 5 wt% of a surfactant.
7. The method according to claim 1, wherein the composition further comprises from
30 about 0.04 wt% to about 0.3 wt% of a cationic antimicrobial.
8. The method according to claim 1, wherein the composition further comprises not
less than 0.5% nonionic antimicrobial.
- 35 9. The method according to claim 1, wherein the composition further comprises
humectants, emulsifiers, or combinations thereof.

10. A method comprising:
dispensing an effective amount of a composition into a container, wherein the composition comprises:
5 water; and
 from 0.15 wt% to 4 wt% anionic thickener;
contacting a skin surface with the composition in the container;
mechanically acting on the skin surface for at least one (1) second while the skin surface is in the presence of the composition; and
10 removing at least a portion of the composition from the surface of the skin.
11. The method according to claim 10, wherein at least about 5 mL of composition is dispensed into the container.
- 15 12. The method according to claim 10, wherein at least about 1 mL/ 10 cm² of the skin surface to be cleaned is dispensed into the container.
13. The method according to claim 10, wherein the step of removing is accomplished without an excess of water.
20
14. The method according to claim 10, wherein the step of removing leaves less than 3 mL of composition on the surface.
15. A method comprising:
25 obtaining a spore removing article, the spore removing article being capable of carrying an effective amount of a composition, wherein the composition comprises:
 water; and
 from 0.15 wt% to 4 wt% anionic thickener;
contacting a skin surface with the spore removing article and the composition;
30 mechanically acting on the skin surface for at least one (1) second with the spore removing article; and
 removing the spore removing article from the surface of the skin.
16. The method according to claim 15, wherein the carrier is a wipe, a sponge, or a
35 fibrous mat.

17. The method according to 15, wherein the step of obtaining a spore removing article comprises obtaining a carrier pre-moistened with the composition.

5 18. The method according to claim 15, wherein the step of obtaining a spore removing article comprises obtaining the spore removing article from a package comprising a plurality of spore removing articles.

19. The method according to claim 15, wherein the spore removing article is capable of carrying at least about 5 mL of composition.

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20. The method according to claim 15, wherein the amount of composition in contact with the skin surface during the contacting step is at least about 1 mL/ 10 cm² of the skin surface to be cleaned.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/67439

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01P 1/00; A61Q 19/00 (2017.01)

CPC - A61L 2300/404; C11D 17/049; A61Q 19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A01P 1/00; A61Q 19/00 (2017.01)

CPC: A61L 2300/404; C11D 17/049; A61Q 19/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 510/130

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Google Scholar, Google Patents, PatBase

Keywords used: kill, remove, spores, disinfect, antimicrobial, pectin, arabic, xanthan, gum, water, aqueous, skin, topical, wipe, towel, sponge, contact, clean

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 2011/0182958 A1 (Omidbakhsh) 28 July 2011 (28.07.2011); entire document, but especially: para [0014], para [0026], para [0031], para [0041], para [0044], para [0046], para [0056]- para [0062], para [0070], para [0077], table 4 solution 11	1-7, 9-20 ----- 8
Y	US 2011/0182959 A1 (Cahill et al.) 28 July 2011 (28.07.2011); para [0002], para [0030]- para [0033], para [0083], para [0090], para [0092], para [0098], para [0143]	8
A	US 2006/0198876 A1 (Tichy et al.) 07 September 2006 (07.09.2006); entire document	1-20
A	US 2006/0204467 A1 (Littau et al.) 14 September 2006 (14.09.2006); entire document	1-20

☐ Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search

03 February 2017

Date of mailing of the international search report

27 MAR 2017

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