

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
13 January 2011 (13.01.2011)

(10) International Publication Number
WO 2011/004175 A2

PCT

(51) International Patent Classification:
A61K 9/00 (2006.01)

(21) International Application Number:
PCT/GB2010/051027

(22) International Filing Date:
22 June 2010 (22.06.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0911951.2 9 July 2009 (09.07.2009) GB

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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, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, 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, SD, SL, SZ, TZ, UG,
ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, SE, SI, SK,
SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished
upon receipt of that report (Rule 48.2(g))

(54) Title: VISCOUS TOPICAL ANTIMICROBIAL COMPOSITIONS

(57) Abstract: Provided are antimicrobial compositions especially suited for application to the epidermis, e.g., hands, arms, legs, face, scalp as well as other body areas which preferably exhibits an acidic pH. The compositions exhibit at least 3 log kill efficacy, preferably at least 4 log kill efficacy at 60 seconds contact time of at least two, preferably at least three and most preferably at least four of microorganisms selected from the group consisting of: *S. aureus*, *E. coli*, *P. aeruginosa* and *E. hirae*, according to the protocols of prEN 12054. The compositions are largely aqueous and desirably exhibit a viscosity of at least 500 cPs at 25°C, and desirably exhibit a pH of 4.5-5.5. Methods for the manufacture of the topical antimicrobial compositions and methods for their use are also disclosed. The antimicrobial compositions also find utility in the treatment of inanimate hard surfaces and inanimate soft surfaces.



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VISCOUS TOPICAL ANTIMICROBIAL COMPOSITIONS

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The present invention relates to topical antimicrobial compositions for application to the epidermis, e.g., hands, arms, legs, face, scalp as well as other body areas.

Topical compositions, per se, are well-known in the cosmetic, dermatological as well as in the pharmaceutical fields. Most topical compositions are intended to provide at least one but generally provide multiple or more specific benefits after being applied to the human skin. For example, personal care compositions which are primarily intended to be soaps for general cleaning of the human skin such as hand soaps or body wash soaps are well known in the fields of cosmetics and personal care products. While providing a primary cleaning benefit, such personal care compositions frequently also provide ancillary benefits such as moisturizing and nourishing the skin. Such personal care compositions which provide a good general cleaning benefit are usually based on one or more anionic soaps or anionic surfactants which are recognized to provide good cleaning and good foaming. However, such compositions typically provide only limited antimicrobial benefits.

Also known to the art are topical compositions which are primarily directed to provide an antimicrobial benefit to the epidermis or other body part when applied thereto. Such typically take the form of lotions and are often largely comprised of an alcohol, usually ethanol with further constituents, e.g., thickeners. While often technically effective to provide an antimicrobial benefit, such compositions are also known to be prone to unduly dry the skin due to the evaporation of the alcohol which leaves the treated part of the epidermis with a chapped or dried feel. Further, such largely alcohol based topical compositions rarely provide a cleaning benefit. Additionally such largely alcohol based topical compositions may not have a high level of antimicrobial efficacy when applied to an epidermal surface for short contact times, such as may be modeled by test protocol and success requirements of the known-art protocol of prEN12054 -

Chemical Disinfectants and antiseptics – Quantitative suspension test for the evaluation of antimicrobial activity.

It is to these shortcomings in the art to which the current invention is directed.

In a first aspect of the invention there are provided topical antimicrobial compositions for application to the epidermis, e.g., hands, arms, legs, face, scalp as well as other body areas.

According to a second aspect of the invention there are provided topical antimicrobial compositions according to the first aspect of the invention which exhibits at least 3 log kill efficacy, preferably at least 4 log kill efficacy at 60 seconds contact time of at least two, preferably at least three and most preferably at least four of microorganisms selected from the group consisting of: *S. aureus*, *E. coli*, *P. aeruginosa* and *E.hirae*, according to the protocols of prEN12054.

According to a third aspect of the invention there are provided are provided topical antimicrobial compositions according to any of the first through third aspects of the invention which is further characterized in having a viscosity of at least 500 cPs at 25°C, preferably a viscosity of between 500 – 7500 at 25°C.

A fourth aspect of the invention relates to a viscous topical antimicrobial compositions according to any of the first through fourth aspects of the invention which are thickened by a ternary thickening system which comprises a benzophenone constituent, a oxyalkylenated constituent of at least 2000 mw, and a fatty alkanolamide constituent.

According to a fifth aspect of the invention there is provided a ternary thickening system which comprises a benzophenone constituent, a oxyalkylenated constituent, and a fatty alkanolamide constituent, which may be advantageously used to thicken an aqueous composition including but not limited to surface treatment compositions intended to be applied to inanimate surfaces, e.g., hard surfaces such as stone, ceramic, metal, glass, synthetic polymers and the like, or soft surfaces, e.g., fibers, fabrics, textiles, carpets, pads, and the like, or to animate surfaces, e.g., topical surfaces of humans or animals, e.g., skin, scalp and hair surfaces.

According to a sixth aspect of the invention there are provided compositions according to any of the first through fifth aspects of the invention characterized in that the

compositions exclude one or more cationic surfactants which provide an appreciable germicidal benefit.

According to further aspect of the invention is provided a method for the manufacture or production of improved topical antimicrobial composition as set forth
5 herein, as well as methods for using the improved topical antimicrobial composition, especially in order to provide an effective cleaning and/or antimicrobial benefit.

These and further aspects of the invention are provided as described within this specification.

Broadly stated, in a first aspect of the invention there are provided topical
10 antimicrobial compositions for application to the epidermis, e.g., hands, arms, legs, face, scalp as well as other body areas. The compositions exhibit a satisfactory degree of foaming and exhibit excellent antimicrobial efficacy to treated surfaces, particularly a body surface, e.g., epidermis, skin, scalp and hair. The topical antimicrobial compositions are excellently suited for animal use, including human use.

15 The topical antimicrobial compositions includes a surfactant constituent which include one or more further surfactants selected from anionic, nonionic, cationic, amphoteric and/or zwitterionic surfactants which may be present either individually or in mixtures or two or more such surfactants.

Anionic surfactants and/or salt forms thereof may form part of the inventive
20 compositions. Non-limiting examples of anionic surfactants include alcohol sulfates and sulfonates, alcohol phosphates and phosphonates, alkyl ester sulfates, alkyl diphenyl ether sulfonates, alkyl sulfates, alkyl ether sulfates, sulfate esters of an alkylphenoxy polyoxyethylene ethanol, alkyl monoglyceride sulfates, alkyl sulfonates, alkyl ether sulfates, alpha-olefin sulfonates, beta-alkoxy alkane sulfonates, alkyl ether sulfonates,
25 ethoxylated alkyl sulfonates, alkylaryl sulfonates, alkylaryl sulfates, alkyl monoglyceride sulfonates, alkyl carboxylates, alkyl ether carboxylates, alkyl alkoxy carboxylates having 1 to 5 moles of ethylene oxide, alkylpolyglycolethersulfates (containing up to 10 moles of ethylene oxide), sulfosuccinates, octoxynol or nonoxynol phosphates, taurates, fatty taurides, fatty acid amide polyoxyethylene sulfates, acyl glycerol sulfonates, fatty oleyl
30 glycerol sulfates, alkyl phenol ethylene oxide ether sulfates, paraffin sulfonates, alkyl phosphates, isethionates, N-acyl taurates, alkyl succinamates and sulfosuccinates,

alkylpolysaccharide sulfates, alkylpolyglucoside sulfates, alkyl polyethoxy carboxylates, and sarcosinates or mixtures thereof. Anionic soaps may also be used in the inventive compositions. Examples of the foregoing anionic surfactants are available under the following tradenames: Rhodapon®, Stepanol®, Hostapur®, Surfine®, Sandopan®, and Biosoft® tradenames.

Exemplary useful nonionic surfactants are those which include a hydrophobic base portion, such as a long chain alkyl group or an alkylated aryl group, and a hydrophilic chain portion comprising a sufficient number of ethoxy and/or propoxy moieties to render the nonionic surfactant at least partially soluble or dispersible in water.

By way of non-limiting example, such nonionic surfactants include ethoxylated alkylphenols, ethoxylated and propoxylated fatty alcohols, polyethylene glycol ethers of methyl glucose, polyethylene glycol ethers of sorbitol, ethylene oxidepropylene oxide block copolymers, ethoxylated esters of fatty ($C_6 - C_{24}$) acids, condensation products of ethylene oxide with long chain amines or amides, and mixtures thereof. Further useful nonionic surfactants include condensates of alkylene oxides, particularly ethylene oxide with sorbitan fatty acid esters, e.g., polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monopalmitate, and polyoxyethylene sorbitan trioleates. Still further useful nonionic surfactants include alkoxylated alkanolamides, e.g. $C_8 - C_{24}$ alkyl di($C_2 - C_3$ alkanol amide). Examples of the useful nonionic surfactants include materials are available under the Tomadol®, Neodol®, Rhodasurf®, Genapol®, Pluronic® and Alfonic® tradenames. Further useful nonionic surfactants include oxo-alcohol ethoxylates (ex. BASF) under the Lutensol® ON tradename, as well as polyoxyalkylene alkylethers (ex. KAO Group, Japan) available under the Emulgen® tradename.

A further useful nonionic surfactants include alkylmonoglycosides and alkylpolyglycosides are prepared generally by reacting a monosaccharide, or a compound hydrolyzable to a monosaccharide with an alcohol such as a fatty alcohol in an acid medium. Various glycoside and polyglycoside compounds including alkoxylated glycosides and processes for making them are disclosed in U.S. Pat. Nos. 2,974,134; 3,219,656; 3,598,865; 3,640,998; 3,707,535, 3,772,269; 3,839,318; 3,974,138; 4,223,129 and 4,528,106 the contents of which are incorporated by reference. Examples of useful alkylglycosides include, for example APG 325 CS Glycoside® which is described as

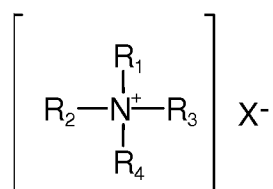
being a 50% C₉-C₁₁ alkyl polyglycoside, also commonly referred to as D-glucopyranoside, (ex. Henkel KGaA) and Glucopon® 625 CS which is described as being a 50% C₁₀-C₁₆ alkyl polyglycoside, also commonly referred to as a D-glucopyranoside, (ex. Henkel).

5 A preferred class of nonionic surfactants include amine oxide compounds including one or more of those which may be described in one or more of the following of the four general classes: (i) alkyl di (lower alkyl) amine oxides in which the alkyl group has about 6-24 carbon atoms, and can be straight or branched chain, saturated or unsaturated, and the lower alkyl groups include between 1 and 7 carbon atoms, e.g., octyl
10 dimethyl amine oxide, lauryl dimethyl amine oxide, myristyl dimethyl amine oxide, and those in which the alkyl group is a mixture of different amine oxides, such as dimethyl cocoamine oxide, dimethyl (hydrogenated tallow) amine oxide, and myristyl/palmityl dimethyl amine oxide; (ii) alkyl di (hydroxy lower alkyl) amine oxides in which the alkyl group has about 6-22 carbon atoms, and can be straight or branched chain, saturated or
15 unsaturated, e.g. bis-(2-hydroxyethyl) cocoamine oxide, bis-(2-hydroxyethyl) tallowamine oxide; and bis-(2-hydroxyethyl) stearylamine oxide; (iii) alkylamidopropyl di(lower alkyl) amine oxides in which the alkyl group has about 10-20 carbon atoms, and can be straight or branched chain, saturated or unsaturated, e.g., cocoamidopropyl dimethyl amine oxide and tallowamidopropyl dimethyl amine oxide; and (iv)
20 alkylmorpholine oxides in which the alkyl group has about 10-20 carbon atoms, and can be straight or branched chain, saturated or unsaturated.

 The topical antimicrobial compositions may include one or more amphoteric surfactants, specifically the following: derivatives of secondary and tertiary amines having aliphatic radicals that are straight chain or branched, and wherein one of the
25 aliphatic substituents contains from about 8 to 18 carbon atoms and at least one of the aliphatic substituents contains an anionic water-solubilizing group, e.g., a carboxy, sulfonate, or a sulfate group. Non-limiting examples of compounds falling within this description include: sodium 3-(dodecylamino)propionate, and sodium 3-(dodecylamino)propane-1-sulfonate. Further exemplary useful amphoteric surfactants
30 include sarcosinates and taurates, amide sulfosuccinates, and betaines including

phosphobetaines. Exemplary betaines include dodecyl dimethyl betaine, cetyl dimethyl betaine, and dodecyl amidopropyldimethyl betaine.

The surfactant constituent may also comprise one or more cationic surfactant constituents, especially preferably one cationic surfactants which provide an appreciable germicidal benefit. However in certain embodiments, the inventive compositions expressly exclude one or more cationic surfactant constituents. Non-limiting examples of preferred cationic surfactant compositions which may be included in the topical antimicrobial compositions are those which provide an appreciable germicidal benefit, and especially preferred are quaternary ammonium compounds and salts thereof, which may be characterized by the general structural formula:



where at least one of R_1 , R_2 , R_3 and R_4 is a alkyl, aryl or alkylaryl substituent of from 6 to 26 carbon atoms, and the entire cation portion of the molecule has a molecular weight of at least 165. The alkyl substituents may be long-chain alkyl, long-chain alkoxyaryl, long-chain alkylaryl, halogen-substituted long-chain alkylaryl, long-chain alkylphenoxyalkyl, arylalkyl, etc. The remaining substituents on the nitrogen atoms other than the abovementioned alkyl substituents are hydrocarbons usually containing no more than 12 carbon atoms. The substituents R_1 , R_2 , R_3 and R_4 may be straight-chained or may be branched, but are preferably straight-chained, and may include one or more amide, ether or ester linkages. The counterion X may be any salt-forming anion which permits water solubility or water miscibility of the quaternary ammonium complex. Preferred quaternary ammonium compounds which act as germicides according to the foregoing formula are those in which R_2 and R_3 are the same or different C_8 - C_{12} alkyl, or R_2 is C_{12} - C_{16} alkyl, C_{8-18} alkylethoxy, C_{8-18} alkylphenoethoxy and R_3 is benzyl, and X is a halide, for example chloride, bromide or iodide, or is a methosulfate anion. The alkyl groups recited in R_2 and R_3 may be straight-chained or branched, but are preferably substantially linear.

Particularly useful quaternary germicides include compositions which include a single quaternary compound, as well as mixtures of two or more different quaternary

compounds. Such useful quaternary compounds are available under the BARDAC®, BARQUAT®, HYAMINE®, LONZABAC®, and ONYXIDE® trademarks, which are more fully described in, for example, *McCutcheon's Functional Materials* (Vol. 2), North American Edition, 1998, as well as the respective product literature from the suppliers identified below. When one or more cationic surfactants which provide an appreciable germicidal benefit are present, they may be present as a co-antimicrobial agent, as the antimicrobial agent described hereinafter is necessarily present in order to provide the primary antimicrobial benefit. Further when one or more cationic surfactants which provide an appreciable germicidal benefit are present, preferably anionic surfactants and further optionally, amphoteric surfactants are omitted from the compositions of the invention. However, as noted previously, in certain preferred embodiments, cationic surfactants which provide an appreciable germicidal benefit are expressly excluded from the compositions of the invention, and thus, anionic surfactants as well as amphoteric surfactants may be used in such compositions.

Other surfactants, although not specifically disclosed herein but known to the art may also be used. Preferred surfactants are disclosed with reference to one of more of the following Examples. The surfactant constituent may be present in any effective amount, and are preferably present in amounts of from 0.01%wt. to 10%wt. based on the total weight of the composition of which they form a part.

The compositions of the invention necessarily include an antimicrobial agent constituent, which provides a primary antimicrobial benefit. The said antimicrobial agent constituent is/are one or more compounds other than cationic surfactants which provide an appreciable germicidal benefit, viz., cationic germicide, described above. The antimicrobial agent constituent desirably provides an effective antimicrobial benefit to a treated surface, other than a cationic germicide, preferably such that the composition of the invention exhibits at least 3 log kill efficacy, preferably at least 4 log kill efficacy at 60 seconds contact time of at least two, preferably at least three and most preferably at least four of microorganisms selected from the group consisting of: *S. aureus*, *E. coli*, *P. aeruginosa* and *E.hirae*, according to the protocols of prEN12054.

The antimicrobial agent constituent may include one or more of: pyrrithiones such as zinc pyrrithione, halohydantoin such as dimethyldimethylol hydantoin,

methylchloroisothiazolinone/methylisothiazolinone sodium sulfite, sodium bisulfite, imidazolidinyl urea, diazolidinyl urea, benzyl alcohol, 2-bromo-2-nitropropane-1,3-diol, formalin (formaldehyde), iodopropenyl butylcarbamate, chloroacetamide, methanamine, methyldibromonitrile glutaronitrile, glutaraldehyde, 5-bromo-5-nitro-1,3-dioxane, phenethyl alcohol, o-phenylphenol/sodium o-phenylphenol, sodium hydroxymethylglycinate, polymethoxy bicyclic oxazolidine, dimethoxane, thimersal dichlorobenzyl alcohol, captan, chlorphenenesin, dichlorophene, chlorbutanol, glyceryl laurate, halogenated diphenyl ethers such as 2,4,4-trichloro-2-hydroxy-diphenyl ether (Triclosan®) and 2,2-dihydroxy-5,5-dibromo-diphenyl ether, phenolic antimicrobial compounds such as mono- and poly-alkyl and aromatic halophenols, such as p-chlorophenol, methyl p-chlorophenol, 4-chloro-3,5-dimethyl phenol, 2,4-dichloro-3,5-dimethylphenol, 3,4,5,6-tetrabromo-2-methylphenol, 5-methyl-2-pentylphenol, 4-isopropyl-3-methylphenol, para-chloro-meta-xlenol, dichloro meta xlenol, chlorothymol, and 5-chloro-2-hydroxydiphenylmethane, resorcinol and its derivatives, bisphenolic compounds such as 2,2-methylene bis (4-chlorophenol) and bis (2-hydroxy-5-chlorobenzyl)sulphide, benzoic esters (parabens), halogenated carbanilides such as 3-trifluoromethyl-4,4'-dichlorocarbanilide (Triclocarban), 3-trifluoromethyl-4,4-dichlorocarbanilide and 3,3,4-trichlorocarbanilide.

The antimicrobial agent constituent may include one or more of: biguanides such as polyhexamethylene biguanide, p-chlorophenyl biguanide; 4-chlorobenzhydryl biguanide, 1,6-bis-(4-chlorobenzylbiguanido)-hexane (Fluorhexidine®), halogenated hexidine including, but not limited to, chlorhexidine (1,1'-hexamethylene-bis-5-(4-chlorophenyl biguanide) (Chlorohexidine®), as well as salts of any of the foregoing, e.g. polyhexamethylene biguanide hydrochloride.

The antimicrobial agent constituent may include one or more organic acids providing an antimicrobial benefit. Exemplary organic acids are those which generally include at least one carbon atom, and include at least one carboxyl group (--COOH) in its structure. Derivatives of said organic acids are also contemplated to be useful. Exemplary organic acid include linear aliphatic acids such as acetic acid; dicarboxylic acids, acidic amino acids, and hydroxy acids such as glycolic acid, lactic acid, hydroxyacrylic acid, alpha-hydroxybutyric acid, glyceric acid, malic acid, tartaric acid and citric acid, as well

as acid salts of these organic acids. Of these, glycolic acid, lactic acid and salicylic acid and/or derivatives thereof, e.g., salicylic acid derivatives such as esters of salicylic acid, such as ethylhexyl salicylate, dipropylene glycol salicylate, TEA salicylate, salicylic acid 2-ethylhexylester, salicylic acid 4-isopropyl benzylester, salicylic acid homomenthylester
5 are preferred.

The antimicrobial constituent may comprise a peroxygen compound which may be essentially any compound containing a dioxygen (O--O) bond. Dioxygen bonds, particularly bivalent O--O bonds, are readily cleavable, thereby allowing compounds containing them to act as powerful oxidizers. Non-limiting examples of classes of
10 peroxygen compounds include peracids, peracid salts, and peroxides such as hydrogen peroxide. The peroxygen can be any aliphatic or aromatic peracid (or peroxyacid) that is functional for disinfectant purposes in accordance with embodiments of the present invention. While any functional peroxyacid can be used, peroxyacids containing from 1 to 7 carbons are the most practical for use. These peroxyacids can include, but not be
15 limited to, peroxyformic acid, peroxyacetic acid, peroxyoxalic acid, peroxypropanoic acid, perlactic acid, peroxybutanoic acid, peroxy pentanoic acid, peroxyhexanoic acid, peroxyadipic acid, peroxycitric, and/or peroxybenzoic acid. Exemplary peracid salts include permanganates, perborates, perchlorates, peracetates, percarbonates, persulphates, and the like. Exemplary peroxide compounds include hydrogen peroxide, metal
20 peroxides and peroxyhydrates. The metal peroxides that can be used include, but are not limited to, sodium peroxide, magnesium peroxide, calcium peroxide, barium peroxide, and/or strontium peroxide. Other salts (for example sodium percarbonate) have hydrogen peroxide associated therewith are also considered to be a source of hydrogen peroxide, thereby producing hydrogen peroxide in situ.

The antimicrobial constituent may comprise one or more polyols in amounts which are effective in imparting a sanitizing or disinfecting benefit to surfaces upon which the compositions are applied. By way of non-limiting example, preferred are polyols containing from 2 to about 6 hydroxyl groups. Preferred polyols are water soluble. Specific albeit non-limiting examples of polyols include, but are not limited to,
30 ethylene glycol, propylene glycol, glycerol, diethylene glycol, triethylene glycol, dipropylene glycol, tripropylene glycol, hexylene glycol, butylene glycol and when

present, the polyols should be present in a sufficient concentration such the antimicrobial constituent of which they form at least a part, provides an effective sanitizing or disinfecting benefit to surfaces being treated with the compositions. Advantageously the one or more polyols comprise up to 100% of the antimicrobial constituent of the present invention.

It is to be noted that polyols are also known to be useful as humectants or emollients, thus wherein one or more polyols are present, such may also provide an ancillary skin conditioning function in addition to the primary function as an antimicrobial constituent. Further, when present, one or more polyols may also function as an organic solvent.

The antimicrobial constituents may also comprise one or more monohydric alcohols, especially C₁-C₄ monohydric alcohols and/or C₁-C₄ ketones wherein such are present in should be present in a sufficient concentration such the antimicrobial constituent of which they form at least a part, provides an effective sanitizing or disinfecting benefit to surfaces being treated with the compositions. Advantageously the one or more monohydric alcohols and/or ketones comprise up to 100% of the antimicrobial constituent of the present invention. Further, when present, the one or more alcohols or ketones may also function as an organic solvent.

The antimicrobial constituent may comprise a halogenated compound or species. By way of non-limiting example such include halogens, and especially I₂, as well as iodophors such as povidone-iodine, or any substance comprising iodine and a solubilizing agent that releases free iodine when in solution. While other halogen species are contemplated as being potentially useful as the antimicrobial constituent of the invention, I₂, as well as iodophors are preferred for use as being relatively safe from a toxicological perspective.

The antimicrobial agent constituent may comprise one or more of the foregoing compounds or materials which are described above, which may be present in any effective amount in order to provide a sanitizing or disinfecting benefit to surfaces upon which they have been applied, especially topical surfaces or other body surfaces as discussed herein. Advantageously, the antimicrobial agent constituent is preferably present in amounts of from 0.0001%wt. to 40%wt., preferably from 0.001%wt. to

25%wt., more preferably 0.001%wt. to 20%wt., and particularly preferably from 0.001%wt. to 10%wt. based on the total weight of the composition of which they form a part.

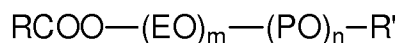
In a further aspect the inventive compositions include a ternary thickening system which comprises a benzophenone constituent, a oxyalkylenated constituent of at least 2000 mw, and a fatty alkanolamide constituent

Exemplary oxyalkylenated compound(s) which may be used in the composition of the invention may comprise ethylene oxide groups (oxyethylenated compounds), propylene oxide groups (oxypropylenated compounds) or both (oxyethylenated/oxypropylenated compounds). One or more oxyalkylenated compounds may be used, and the amount of oxyalkylenated compound in the composition of the invention may range, for example, on an active material weight basis, from 0.1% to 20% preferably from 0.25% to 10% by weight relative to the total weight of the composition of which it forms a part.

Suitable oxyalkylenated compounds include, in particular, polyethylene glycols, polyethylene glycol esters and/or polypropylene glycol esters, polyethylene glycol ethers and/or polypropylene glycol ethers, alkoxylated aryl derivatives and in particular ethoxylated aryl polyol derivatives, oxyalkylenated and in particular oxyethylenated triesters of glycerol and of fatty acids, ethoxyethylenated urethane derivatives modified with alkyl chains, and mixtures thereof.

Exemplary polyethylene glycols which may be used in the composition of the invention include ethylene oxide polycondensates having a number of ethylene oxide (EO) units of greater than 10. The ethylene oxide number may range, for example, from 10 to 50 000 and preferably from 14 to 10 000. Suitable examples of polyethylene glycols include polyethylene glycol comprising 7 000 EO (CTFA name: PEG-7M), polyethylene glycol comprising 75 EO (CTFA name: PEG-75), polyethylene glycol comprising 20,000 EO (CTFA name: PEG-20M) and polyethylene glycol comprising 150 EO (CTFA name: PEG-150).

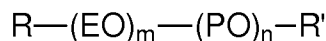
Also useful as oxyalkylenated compounds are polyethylene glycol esters and/or polypropylene glycol esters which are condensates of polyethylene glycol and/or polypropylene glycol with one or more fatty acids. These compounds have the formula:



in which m has a value of 0 to 300, n has a value of 0 to 300 the sum of m and n is 6 or greater, and R and R' represent, independently of each other, hydrogen or a saturated or unsaturated, linear or branched, hydroxylated or non-hydroxylated alkyl chain containing from 1 to 30 carbon atoms and preferably from 12 to 22 carbon atoms, or an aryl chain, with the proviso that R and R' are not simultaneously hydrogen.

Suitable, non-limiting examples of polyethylene glycol acid esters and/or polypropylene glycol acid esters include polyethylene glycol distearate (150 EO), the copolymer of polyethylene glycol ligand (30 EO) and of 12-hydroxystearic acid and polyethylene glycol stearate (40 EO), as well as such compounds based on polyoxyethylene/polyoxypropylene copolymers.

Further useful compounds include polyethylene glycol ethers and/or polypropylene glycol ethers are condensates of polyethylene glycol and/or polypropylene glycol with one or more fatty alcohols. These are compounds of formula:



in which m has a value of 0 to 300, n has a value of 0 to 300 the sum of m and n is 6 or greater, and R and R' represent, independently of each other, hydrogen or a saturated or unsaturated, linear or branched, hydroxylated or non-hydroxylated alkyl chain containing from 1 to 30 carbon atoms and preferably from 12 to 22 carbon atoms, or an aryl chain, with the proviso that R and R' are not simultaneously hydrogen. Suitable, albeit non-limiting examples of such polyethylene glycol ethers include, oxyethylenated (30 EO) cetyl alcohol, oxyethylenated (30 EO) behenyl alcohol, oxyethylenated (23 EO) lauryl alcohol, oxyethylenated (20 EO) isocetyl alcohol, and, oxyethylenated (100 EO) stearyl alcohol. Suitable non-limiting examples of polyethylene glycol/polypropylene glycol ethers include oxyethylenated (5 EO) oxypropylenated (5 PO) lauryl alcohol, and oxyethylenated (25 EO) oxypropylenated (25 PO) lauryl alcohol. Further suitable oxyalkylenated compounds include the ethoxylated alkyl or aryl derivatives of polyol include, for example, oxyethylenated derivatives of fatty acid esters or of fatty alcohol ethers and of a polyol such as glycerol, sorbitol, glucose or pentaerythritol. Non-limiting examples of such compounds include, oxyethylenated (78 EO) glyceryl cocoate, oxyethylenated (120 EO) methylglucose dioleate, oxyethylenated (10 EO) polyglyceryl

(2 mol of glycerol) laurate, and oxyethylenated (150 EO) pentaerythrityl tetrastearate. Still further suitable compounds include oxyalkylenated glyceryl triesters of fatty acids, for example, oxyethylenated (6 EO) caprylic/capric acid glycerides, and oxyethylenated (50 EO) olive oil.

5 A preferred oxyalkylenated compound of the topical compositions are polyethylene glycol diesters such as polyethylene glycol distearates ethoxylated with 50 - 350 units ethylene oxide. A preferred material is Stepan PEG 6000 DS, described to be a polyethylene glycol distearate ethoxylated with 150 units of ethylene oxide.

10 Other oxyalkylenated compounds falling within the above descriptions, although not specifically disclosed herein but known to the art may also be used. Preferred oxyalkylenated compounds are disclosed with reference to one of more of the following Examples. The oxyalkylenated compounds may be present as single compounds or as mixtures of two or more oxyalkylenated compounds.

15 The oxyalkylenated compound(s) may be present in any effective amount, and are preferably present in amounts of from 0.01%wt. to 10%wt. based on the total weight of the composition of which they form a part. Preferably however the oxyalkylenated compounds comprises 0.1 - 8%wt., preferably from 0.5 - 5%wt. based on the total weight of the topical antimicrobial compositions of which they form a part.

20 The oxyalkylenated compound(s) are one of the three constituents of a ternary thickening system.

25 A second constituent of the ternary thickening system of the invention is a fatty alkanolamides examples of which include but are not limited to: cocamide MEA, cocamide DEA, soyamide DEA, lauramide DEA, oleamide MIPA, stearamide MEA, myristamide MEA, lauramide MEA, capramide DEA, ricinoleamide DEA, myristamide DEA, stearamide DEA, oleylamide DEA, tallowamide DEA, lauramide MIPA, tallowamide MEA, isostearamide DEA, isostearamide MEA, and mixtures thereof.

30 The one or more fatty alkanolamides are present in amounts of up to about 10%wt., but are preferably included in amounts of from about 0.1 - 10%wt. based on the total weight of the topical composition of which they form a part. The one or more fatty alkanolamides are essential constituents of the present invention.

In addition to a thickening benefit, the fatty alkanolamide constituent may provide an ancillary foam boosting benefit as well.

The third constituent of the ternary thickening system of the invention are benzophenone compounds and/or derivatives thereof e.g., 2-hydroxy-4-methoxy
5 benzophenone, 2-hydroxy-4-methoxy-4'-methyl benzophenone, n-hexyl 2-(4-diethylamino-2-hydroxybenzoyl)benzoate and 2,2'-dihydroxy-4-methoxy benzophenone as well as those materials currently marketed under the UVINUL tradename by BASF.

The benzophenone compounds or benzophenone derivatives are present in amounts of up to about 10%wt., but are preferably included in amounts of from about 0.1
10 – 5%wt. based on the total weight of the topical composition of which they form a part. The benzophenone compounds or benzophenone derivatives are essential constituents of the present invention.

The present inventors have surprisingly found that many aqueous compositions may be thickened by combining a fatty alkanolamide, an oxyalkylenated compound and
15 a benzophenone compound or benzophenone derivative in order to provide a ternary thickening system which will boost the viscosity at least twice, preferably threefold and more preferably at least fourfold, even in the absence of conventional thickening constituents, e.g., clays, polyacrylate thickeners or polysaccharide based thickeners, as compared to aqueous compositions which exclude one of these three constituents.
20 Preferred respective weight ratios of the respective fatty alkanolamide, an oxyalkylenated compound and a benzophenone compound or benzophenone derivative are disclosed with reference to one or more of the Examples.

It is to be understood that the ternary thickening system advantageously present in the topical antimicrobial compositions described herein, or in other compositions, e.g.,
25 hard surface cleaning and/or disinfecting compositions according to further embodiments of the invention, and preferably this ternary thickening system is present in the absence of clays or clay thickeners, polyacrylate thickeners or polysaccharide based thickeners.

It is also to be understood that although the ternary thickening system viz., the fatty alkanolamide, an oxyalkylenated compound and a benzophenone compound or
30 benzophenone derivative is useful in the topical antimicrobial compositions described herein, the utility of the ternary thickening system is not limited to the topical

antimicrobial compositions described herein, but may find use in other aqueous based cleaning and/or disinfecting compositions which may include one or more surfactants including anionic, cationic, nonionic, amphoteric and zwitterionic surfactants, organic solvents and other constituents which are commonly used hard surface as well as soft surface treating compositions. Thus, the technical advantages of the ternary thickening system extends beyond the class of topical antimicrobial compositions described herein, and thus the principles of the invention, although discussed with reference to topical antimicrobial compositions apply mutatis mutandis to both hard surface treatment compositions and soft surface treatment compositions as well.

The preferred compositions are acidic in nature and the inventors have observed that good antimicrobial efficacy is provided when the inventive foaming topical compositions are also maintained in a specific acidic pH range, preferably of about 6 or less, preferably when the pH is maintained in the range of from about 2 – 6, more preferably when the pH is, in order of increasing preference, at least 2.2, 2.4, 2.5, 2.6, 2.8, 3, 3.2, 3.4, 3.5, 3.6, 3.8, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 and 5 while concurrently the pH is, in order of increasing preference is not more than 6, 5.9, 5.8, 5.6, 5.7 and 5.5. Particularly preferred pH values those in the range of from 4.5 – 5.5, and more preferably between 5 – 5.5 Further preferred pH values are disclosed with reference to one or more of the Example compositions.

The pH of the compositions may optionally be established or adjusted by the use of suitable amounts of an acid, e.g., one or more inorganic acids, mineral acids, but preferably by the use of one or more organic acids

These acids can be used singly or as a mixture of two or more individual acids. When present, they may be present in any effective amount in order to attain a desired acidic pH, advantageously they are present in an amount of from about 0 – 15%wt., more preferably from 0.001 – 10%wt., yet more preferably from 0.01 – 5%wt. based on the total weight of the compositions of which they form a part.

In certain preferred embodiments of the invention the sole acids present are one or more of: citric acid, and/or lactic acid to the exclusion of other acids. It is to be understood that the antimicrobial agent constituent includes an organic acid, e.g., as

lactic, salicylic, or glycolic acid, said antimicrobial agent constituent may also be used to adjust the composition to a desired acidic pH.

It is to be expressly understood that topical antimicrobial compositions may be formed without the necessity to add one or more acids, dependant upon the nature of the other constituents which may be present.

The compositions of the invention may include an organic solvents constituent which may include one or more organic solvents. The organic solvent constituent may include one or more alcohols, glycols, acetates, ether acetates and glycol ethers. When present the organic solvent constituent comprises from about 0.001 – 15%wt., more preferably from 0.1 – 10%wt., yet more preferably from 0.5 – 5%wt. based on the total weight of the compositions of which they form a part.

Preferred topical antimicrobial compositions of the invention are those which, according to a third aspect of the invention there are provided topical antimicrobial compositions according to the first or second aspects of the invention which exhibits at least 3 log kill efficacy, preferably at least 4 log kill efficacy and especially preferably at least 4 log kill efficacy at 60 seconds contact time of at least two, preferably at least three and most preferably at least four of microorganisms selected from the group consisting of: *S. aureus*, *E. coli*, *P. aeruginosa* and *E.hirae*, according to the protocols of prEN 12054. As is recognized in the art, this test “prEN12054 – Chemical Disinfection and Antiseptics – Products for Hygienic and Surgical Handrub and Handwash, Bactericidal Activity – Test Methods and Requirements (Phase 2, Step 1)” is one which is particularly difficult to pass with a plurality of the designated test organisms at short contact times. Thus the preferred embodiments of the topical antimicrobial compositions taught herein provide a significant advance over prior art compositions which fail to exhibit at least 3, preferably 4 and particularly preferably 5 log₁₀ kill efficacy, at 60 seconds contact time of at least three, preferably all four of microorganisms selected from the group consisting of: *S. aureus*, *E. coli*, *P. aeruginosa* and *E.hirae* according to prEN12054. Particularly preferred are compositions which exhibit least 4 log₁₀ kill efficacy at 60 seconds contact time, yet more preferably at least 5 log₁₀ reduction of *P. aeruginosa* according to the protocols of prEN12054.

Preferably topical antimicrobial compositions according the invention include those which may be further characterized in having a viscosity of at least 500 cPs at 25°C, preferably a viscosity of between 1000 – 8500 cPs, and especially a viscosity of between 2000 – 6000 cPs at 25°C.

5 The topical antimicrobial compositions of the invention may include one or more further optional constituents which may be used to impart one or more desired esthetic or technical benefits to the said compositions. In certain preferred embodiments of the invention, one or more of the following recited optional constituents may be considered as essential constituents according to a particular preferred embodiment. Such optional
10 constituents include additives and adjuvants which are conventional in the cosmetic, pharmaceutical or dermatological field, such as hydrophilic or lipophilic gelling agents, hydrophilic or lipophilic active agents, further thickeners, humectants, opacifiers, preservatives, antioxidants, solvents especially organic solvents, pH adjusting agents, pH buffers, chelating agents, fragrances, fragrances or other materials which provide an
15 aromatherapy benefit, fillers, preservatives, dyestuffs or colorants, and light stabilizers including UV absorbers. The total amounts of these various additives and adjuvants are those conventionally used in the field, and, for example, range from 0.001% to 25% of the total weight of the composition, however such may be included in any desired or effective amount.

20 The inventive compositions may optionally include further thickeners which are not found to deleteriously affect the favorable technical characteristics of the present invention, especially the antimicrobial characteristics. Coming into consideration are one or more of polyacrylate cross-polymer thickeners, polysaccharide polymers such as xanthan gum, guar gum, locust bean gum, tragacanth gum, or derivatives thereof,
25 naturally occurring or modified celluloses, polycarboxylate polymers, polyacrylamides, clays, and mixtures thereof, although such are preferably absent.

 The topical antimicrobial compositions may include one or more preservatives, such as those well known to the art and widely commercially available Kathon® CG/ICP (ex. Rohm and Haas Inc.), Proxel® (ex. Zeneca), Suttocide® A (ex. Sutton Laboratories)
30 which, when present the preservative is included in any amount found to be effective in retarding or inhibiting the growth of undesired microorganisms in the topical

antimicrobial compositions, particularly during storage for several months at room temperature. When present such are typically included in amounts of up to about 1.5%wt., preferably are present in amounts of from about 0.00001%wt. to about 0.5%wt., but usually are not needed and can be omitted.

5 The topical antimicrobial compositions may include one or more fillers in the form of powders. By way of non-limiting examples these powders include chalk, talc, kaolin, starch, smectite clays, chemically modified magnesium aluminum silicate, organically modified montmorillonite clay, hydrated aluminum silicate, fumed silica, aluminum starch octenyl succinate and mixtures thereof.

10 The topical antimicrobial compositions may also include a fragrance constituent, which may be based on natural and synthetic fragrances and most commonly are mixtures or blends of a plurality of such fragrances, optionally in conjunction with a carrier such as an organic solvent or a mixture of organic solvents in which the fragrances are dissolved, suspended or dispersed. When present a fragrance constituent may be
15 present in any effective amount such that it can be discerned by a consumer of the topical composition, however is advantageously present in amounts of up to about 1%wt., preferably are present in amounts of from about 0.00001%wt. to about 0.5%wt.

 The inventive topical antimicrobial compositions may include one or more colorants, e.g. dyes or pigments which are known to the art be useful in cosmetic or
20 topical compositions which may be used to impart a desired color or tint to the inventive compositions. When present, one or more such colorants are advantageously present in an amount of from about 0.001%wt. to about 0.1% by weight.

 The topical antimicrobial compositions may comprise one or more humectants, including polyhydric alcohols including polyalkylene glycols as well as alkylene polyols
25 and derivatives thereof, e.g., propylene glycol, dipropylene glycol, sorbitol, hydroxypropyl sorbitol, erythritol, threitol, pentaerythritol, xylitol, glucitol, mannitol, hexylene glycol, butylene glycol (e.g., 1,3-butylene glycol), hexane triol (e.g., 1,2,6-hexanetriol), glycerine, ethoxylated glycerine and propoxylated glycerine. Further useful humectants include sodium 2-pyrrolidone-5-carboxylate, aloe vera in any of its
30 variety of forms (e.g., aloe vera gel); hyaluronic acid and derivatives thereof (e.g., salt derivatives such as sodium hyaluronate); lactamide monoethanolamine; acetamide

monoethanolamine; urea; and, panthenol. When present, one or more humectants may be included in effective art recognized amounts, e.g. from about 0.01 to about 5%wt.

Topical antimicrobial compositions of the invention may include one or more constituents, particularly may include one or more essential oils which are selected to provide a so-called "aromatherapy benefit" to the user. Such essential oils are frequently extracted from naturally occurring botanical sources such as flowers, stems, leaves, roots and barks of aromatic plants. While essential oils may be used singly, it is also common to utilize blends of essential oils in order to provide a conjunctive aroma benefit, and possibly a therapeutic benefit as well. Similarly to fragrance compositions which may also include one or more essential oils, frequently, due to their potency, essential oils are often supplied dispersed in a liquid carrier such as in one or more organic solvents in which the essential oils are dissolved or dispersed. Preferred essential oils providing an aromatherapy benefit include one or more selected from chamomile oil, lavandin oil, lavender oil, grapefruit oil, lemon oil, lime oil, mandarin orange oil, orange flower oil and orange oil. When present, these one or more essential oils providing an aromatherapy benefit are present in an amount about 0.00001 wt. % to about 1 wt. %, based on the total weight of the composition. It is to be understood that these one or more essential oils providing an aromatherapy benefit may be used with or without the optional fragrant constituent recited previously and may be used wholly or partially in place of said fragrant constituent.

The topical antimicrobial compositions may include one or more antioxidant constituents. Examples of antioxidants include but are not limited to, water-soluble antioxidants such as sulfhydryl compounds and their derivatives, lipoic acid and dihydrolipoic acid, resveratrol, lactoferrin, glutathione, and ascorbic acid and ascorbic acid derivatives (e.g., ascorbyl palmitate and ascorbyl polypeptide), as well as oil-soluble antioxidants including butylated hydroxytoluene, retinoids, tocopherols e.g., tocopherol acetate, tocotrienols, and ubiquinone, extracts containing flavonoids and isoflavonoids and their derivatives, extracts containing resveratrol and the like. Examples of such natural extracts include grape seed, green tea, pine bark, propolis, and the like. When present the total amount of such antioxidants are present in art-recognized amounts but typically are not present in excess of 5%wt.

Optionally the topical antimicrobial compositions may include one or more vitamins, non-limiting examples which include vitamin A, any of the B vitamins, vitamin C, such as L-ascorbic acid, vitamin D, such as ergocalciferol and cholecalciferol; vitamin E, such as one or more tocopherols, e.g., alpha-tocopherol, beta-tocopherol, Such
5 vitamins, when present, may be included in effective amounts, advantageously from 0.0001 – 2%wt.

The topical antimicrobial compositions of the invention may include one or more light stabilizers as well as UV absorbers. Any cosmetically acceptable material or compound which provides protection for one or more of the constituents in the inventive
10 compositions from photolytic degradation or photo-oxidative degradation may be used, and when present may be included in art-recognized amounts, and advantageously are present in amounts up to about 5%wt.

Exemplary light stabilizers as well as UV absorbers include: triazines including s-triazine, triazine derivatives, sulphonic acid derivatives of benzophenones, cinnamic acid
15 and cinnamic acid amides, and sulfonated benzimidazoles, compounds or derivatives of compounds based on benzylidenecamphor,

The inventive compositions may comprise one or more buffers and/or pH adjusting agents In order to adjust the pH of the inventive compositions. By way of non-limiting example pH adjusting agents include phosphorus containing compounds,
20 monovalent and polyvalent salts such as of silicates, carbonates, and borates, certain acids and bases, tartrates and certain acetates. Further exemplary pH adjusting agents include mineral acids, basic compositions, and organic acids, which are typically required in only minor amounts. By way of further non-limiting example pH buffering compositions include the alkali metal phosphates, polyphosphates, pyrophosphates,
25 triphosphates, tetraphosphates, silicates, metasilicates, polysilicates, carbonates, hydroxides, and mixtures of the same. When present, the buffers/pH adjusting agent are present in an amount effective in order to maintain the pH of the inventive composition within a desired or a target pH range. Advantageously they may be included in generally minor amounts such as from 0.001 - 2.5 %wt. Exemplary and preferred pH buffers and
30 pH adjusting agents are described with reference to one or more of the following Examples.

The inventive topical antimicrobial compositions may include one or more chelating agents. Exemplary useful chelating agents include those known to the art, including by way of non-limiting example; aminopolycarboxylic acids and salts thereof wherein the amino nitrogen has attached thereto two or more substituent groups. When
5 present they are typically included in the present inventive composition in amounts from 0.01 - 1%wt.

As is noted above, the compositions according to the invention are largely aqueous in nature. Water is added to order to provide to 100% by weight of the compositions of the invention. The water may be tap water, but is preferably distilled
10 and is most preferably deionized water or "soft" water. Water forms a major proportion of the inventive compositions and is necessarily present in amounts of at least 50%wt., and in order of increasing preference comprises at least: 60%, 65%, 70%, 75%, and 80%wt. of the composition of which it forms a part.

In a further aspect, the present invention also contemplates a method for
15 providing a cleaning and/or providing an antimicrobial benefit to skin or other topical surface which method contemplates the topical application of the aqueous topical antimicrobial compositions as described herein in a cleaning and/or antimicrobially effective amount. Preferably according to the foregoing method, a antimicrobial benefit is provided to the skin or other topical surface to which the composition has been applied.

20 While the topical antimicrobial compositions disclosed herein find a primary use in application to the skin to provide a cleaning and/or antimicrobial benefit thereto and is contemplated as being provided in a dispenser for use in such a treatment, it is to be understood that this is not to be understood as a limiting definition and that other forms and other uses of the present inventive composition, such as face lotion, milky lotion,
25 cream, face cleansing cream, massage materials, liquid toilet soap, as well as in hair care products such as shampoo, rinse or other hair or scalp treatment are expressly contemplated as being within the scope of the present invention. The topical antimicrobial compositions of the invention can be formulated as a lotion, a cream or a gel, which may be transparent, translucent or opaque. In certain preferred embodiments
30 the topical antimicrobial compositions is provided as a translucent or transparent, preferably a transparent composition.

The composition can be packaged in a suitable container to suit its viscosity and intended use by the consumer. For example, a lotion or cream can be packaged in a bottle, or can be packaged with a propellant in a propellant-driven aerosol device or a may be packaged in a container fitted with a manually operable pump. The inventive
5 composition can be provided and stored in a non-deformable bottle but more preferably is provided in a squeezable container, such as a tube or deformable bottle which provides for easy dispensing of the composition by the consumer. Thus a further aspect of the invention provides a closed container containing the inventive composition as described herein.

10 It is to be further expressly understood that topical application of the topical antimicrobial compositions disclosed herein may be applied to the skin on any part of the body, including the skin on the face, neck, chest, back, arms, axilla, hands, legs, and scalp. The topical antimicrobial compositions disclosed herein may also be used on the hair.

15 It is contemplated that in use, the consumer dispenses a quantity of the topical antimicrobial composition described herein and applied it to the skin or any other part of the body which has preferably been wetted with water (e.g, rinsed) prior to application of the said composition. The topical antimicrobial compositions may be rubbed into the applied skin or other part of the body by the consumer to generate a lather or foam, and
20 thereafter it is expected that the treated area is rinsed by the consumer under a stream of running water, e.g, in a shower or by immersion into water, e.g, a bath. Thereafter the skin or other parts of the body of the consumer is permitted to air dry or the use of one or more towels to absorb excess moisture is also contemplated. Thus, a further aspect of the invention is directed to the use of the topical antimicrobial compositions as described
25 herein.

Claims:

1. Topical antimicrobial compositions for application to the epidermis, e.g., hands,
5 arms, legs, face, scalp as well as other body areas which are characterized in comprising an antimicrobial agent constituent and a ternary thickening system which comprises a benzophenone constituent, a oxyalkylenated constituent, and a fatty alkanolamide constituent.
- 10 2. Topical antimicrobial compositions according to claim 1, further characterized in that said composition exhibits an acidic pH which exhibits at least 3 log kill efficacy, preferably at least 4 log kill efficacy at 60 seconds contact time of at least two, preferably at least three and most preferably at least four of microorganisms selected from the group consisting of: *S. aureus*, *E. coli*, *P. aeruginosa* and *E.hirae*, according to the protocols of
15 prEN12054.
3. Topical antimicrobial compositions according to any preceding claim, further characterized in exhibiting a viscosity of at least 500 cPs at 25°C, preferably a viscosity of between 500 – 7500 cPs at 25°C.
20
4. Topical antimicrobial compositions according to any preceding claim, wherein the said composition excludes cationic surfactants which provide an appreciable germicidal benefit.
- 25 5. Aqueous hard surface treatment compositions including a ternary thickening system which comprises: a benzophenone constituent, a oxyalkylenated constituent, and a fatty alkanolamide constituent
6. Aqueous soft surface treatment compositions including a ternary thickening
30 system which comprises: a benzophenone constituent, a oxyalkylenated constituent, and a fatty alkanolamide constituent

7. Method for the manufacture or production of a topical antimicrobial composition according to any of claims 1 – 4.

5 8. An improved method for the treatment of the skin or other body surface including the hair which method comprises the step of:

applying a cleaning and/or antimicrobially effective amount of the topical antimicrobial composition according to any of claims 1 - 4 to provide an effective cleaning and/or antimicrobial benefit to the skin, body surface or hair to which the topical
10 antimicrobial composition has been applied.