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(71) Applicant: NANO GLOBAL [US/US]; 1705 Guadalupe Street, 4th Floor, Austin, Texas 78701 (US).

(72) Inventors: SCHEVE, Christine; c/o Nano Global, 1705 Guadalupe Street, 4th Floor, Austin, Texas 78701 (US). PETERSON, William, III; c/o Nano Global, 1705 Guadalupe Street, 4th Floor, Austin, Texas 78701 (US). PAPP, Zoltan; c/o Nano Global, 1705 Guadalupe Street, 4th Floor, Austin, Texas 78701 (US). SMID, Stephen; c/o Nano Global, 1705 Guadalupe Street, 4th Floor, Austin, Texas 78701 (US).

(74) Agent: RIVERA, Emmanuel, A.; Forefront IP Lawgroup of Christie & Rivera, 13492 Research Blvd, Austin, Texas 78750 (US).

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- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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- with international search report (Art. 21(3))
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(54) Title: ALKYL DIMETHYL ORGANOSILANE QUATERNARIES IN PERSISTENT SYSTEMS AND METHODS

(57) Abstract: The technology described herein includes methods and uses for quaternary ammonium, specifically an organosilane quaternary ammonium or quat, and particularly AMOSILQ™ quat to provide persistent disinfectant and anti-microbial protection. Uses include skin (derma) and medical applications.



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ALKYL DIMETHYL ORGANOSILANE QUATERNARIES IN PERSISTENT SYSTEMS AND METHODS

RELATED APPLICATIONS

- 5 [0001] This application claims the benefit of priority of U.S. Provisional Patent Application Serial No. 62/540,038 filed August 1, 2017, incorporated herein by reference.

BACKGROUND

[0002] Benzyl ammonium quaternary chlorides (BAC) are effective antimicrobial compounds. Current BAC formulations been found to be most effective as antimicrobial
10 agents as mixtures of various alkyl dimethyl chain lengths. Other well-known quaternary ammonium compounds or “quats” are known to have disinfectant properties and are used in various settings. Quat-based disinfectants and sanitizers may be used on skin and hard non-porous surfaces to kill and prevent the spread of infectious agents including bacteria, viruses, fungus, algae, and the like. Quat-based disinfectants may be used in healthcare,
15 hospitality, schools, agriculture, as well as various other locations and settings where killing and reducing the spread of infectious agents is desired.

[0003] Many skin and surface disinfectants are capable of disinfecting or treating immediately; however, the effectiveness is short lived and at times immediately goes away after application. Therefore, skin and surface treatments, along with disinfected surfaces
20 that keep a persistent or long-term state of effectiveness are desirable.

DETAILED DESCRIPTION

[0004] Described herein are uses, systems and methods for the use of a quaternary ammonium or “quat”, and in particular, octadecyldimethyl (3-trihydroxypropyl) ammonium chloride, or the trademarked AMOSILQ™ “quat”.

5 **[0005]** The AMOSILQ™ “quat” may be applied or be used in various forms such as the following described implementations. For example:

[0006] USE FOR SKIN AND SURFACES

○ ALCOHOL AND ORGANOSILANE COMBO ON SKIN:

- 10 ▪ Increased binding, homogeneity (minimal to no domain formation once dry) and antimicrobial efficacy of self-assembled organosilane quaternary based polymeric barrier on skin due to the presence of varying percentages of ethanol and isopropyl alcohol. Example formulation ranges includes up to 70% alcohol in solution, and organosilane quaternary of up to 10% in solution, based on
- 15 solubility in given formulation and amount required for desired antimicrobial efficacy. Formulation is also based on ranges within both hand and surface applications.
- 20 ▪ Better binding and be more effective as an antimicrobial in the presence of ethanol and or isopropyl alcohol. This combined effect could result in higher/broader spectrum of kill rates both in solution and once the organosilane quaternary binds to the surface. Once dried, the organosilane quaternary compound forms an organized antimicrobial layer capable of weakening/destroying the cell
- 25 membrane of the target organism. Alcohol works to denature all proteins once the membrane has been compromised. Together, the overall antimicrobial efficacy can be enhanced. Alcohol also increases the stability and drying time of the self-assembled polymeric nano-barriers formed, thus enhancing binding, antimicrobial efficacy and decreasing domain formation on the
- 30 surface.

- 5
 - Amylum
 - Balsam peru
 - Benzethonium chloride
 - Benzocaine
 - Bicarbonate of soda
 - Bismuth subnitrate
 - Boric acid
 - Calamine
 - Calcium carbonate
- 10
 - Camphor
 - Casein
 - Cod liver oil
 - Cysteine hydrochloride
 - Dibucaine
- 15
 - Dipiperidon hydrochlorid
 - Glycerin
 - Hexachlorophene
 - 8-hydroxyquinoline
 - Iron oxide
- 20
 - Lanolin
 - Menthol
 - Methapyrilene
 - Methionine
 - Methylbenzethonium chloride
- 25
 - Oil of eucalyptus
 - Oil of lavender
 - Oil of peppermint
 - Oil of white thyme
 - Panthenol
- 30
 - Para-chloromercuriphenol
 - Petrolatum
 - Phenol
 - Pramoxine hydrochloride
 - Salicylic acid

- Silicone
 - Sorbitan monosterate
 - Talc
 - Tetracaine
 - 5 ▪ Vitamin A
 - Vitamin A palmitate
 - Vitamin D
 - Vitamin D2
 - Vitamin E
 - 10 ▪ White petrolatum
 - Zinc oxide
 - Zinc stearate
- TOPICAL FIRST AID ANTIBIOTIC DRUG PRODUCTS
 - Purpose:
 - 15 ○ Help prevent infection in minor cuts, scrapes, and burns
 - Potential forms:
 - Cream
 - Ointment
 - Potential active ingredients to be combined with organosilane quaternary ammonium compound such as (3-(Trimethoxysil)Propyl)OctadecyDimethylAmmonium Chloride:
 - 20 ○ Bacitracin ointment
 - Bacitracin zinc
 - Chlortetracycline hydrochloride
 - 25 ○ Neomycin sulfate
 - Tetracycline hydrochloride
 - Oxytetracycline hydrochloride
- TOPICAL ANTIFUNGAL DRUG PRODUCTS
 - Purpose:
 - 30 ○ Inhibits the growth and reproduction of fungal cells and decreases the number of fungi present
 - To treat athletes foot, jock itch ringworm
 - Potential forms:

- Cream
 - Gel
 - Aerosol
- 5
 - Potential active ingredients that can be combined with organosilane quaternary ammonium compound such as (3-(Trimethoxysil)Propyl)OctadecyDimethylAmmonium Chloride:
 - Clioquinol
 - Haloprogin
 - Miconazole nitrate
 - 10
 - Povidone-iodine
 - Tolnaftate
 - Undecylenic acid
 - Calcium undecylenate
 - Copper undecylenate
 - 15
 - Zinc undecylenate
- TOPICAL ACNE DUG PRODUCTS
 - Purpose:
 - Acne medication, acne treatment
 - Formulation form:
 - 20
 - Lotion
 - Cream
 - Ointment
 - Gel
 - Potential active ingredients to be combined with organosilane quaternary ammonium compound such as (3-(Trimethoxysil)Propyl)OctadecyDimethylAmmonium Chloride:
 - 25
 - Resorcinol
 - Resorcinol monoacetate
 - Salicylic acid
 - 30
 - Sulfur
- TOPICAL SKIN PROTECTANT: DEODORANT
 - Purpose:
 - antiseptic, antiperspirant

- Formulation form:
 - Solid
 - Gel
 - Liquid
- 5 • Potential active ingredients to be combined with organosilane quaternary ammonium compound such as (3-(Trimethoxysil)Propyl)OctadecyDimethylAmmonium Chloride:
 - Sodium stearate
 - Sodium chloride
 - 10 • Stearyl alcohol
 - Potassium alum
 - Aluminum Zirconium
 - Aluminum Chlorohydrate
 - Aluminum chloride
- 15 • TOPICAL: DENTAL
 - Purpose:
 - Antiseptic, Anti-gingivitis, anti-plaque, anti-cavity
 - Formulation form:
 - Liquid
 - 20 • Spray
 - Paste
 - Gel
 - Potential active ingredients to be combined with organosilane quaternary ammonium compound such as (3-
 - 25 (Trimethoxysil)Propyl)OctadecyDimethylAmmonium Chloride:
 - Sodium fluoride
 - Sodium monofluorophosphate
 - Hydrogen peroxide
 - Stannous fluoride
 - 30 • Cetylpyridinium chloride
 - Thymol
 - Menthol

- Eucalyptol
- Methyl salicylate

[0007] MEDICAL DEVICE COATINGS

- 5 ▪ The application of organosilane compound alone or in combination with other coatings for enhanced, long lasting, non-leaching antimicrobial properties polymeric nano-barriers formed, thus enhancing binding, antimicrobial efficacy and decreasing domain formation on the surface.
- 10 ▪ Length of antimicrobial protection depends on application, exposure to living system parameters (heat, chemistry, flow), surface cleaning agents and overall exposure to abrasion
- Organosilane can be embedded during manufacturing of devices, coated post production or applied in clinical setting
- 15 ▪ Additional favorable biological interfacing properties also possible including reduced inflammation and immune response after implantation

- DISPOSABLE DEVICE PACKAGING

- NON-SURGICAL/NON-IMPLANTABLE DEVICES

- 20 ○ Personal Protective Equipment
- Gloves
- Personnel hair, nose and mouth protectors
- Scrubs and gowns
- Goggles
- 25 ○ Wound care
- Bandages/ wraps
- Orthopedic
- Braces/casting
- Exam room equipment
- 30 ○ Laboratory equipment
- Diagnostic modality components
- EMS/patient transport equipment

- SURGICAL EQUIPMENT

- Surgical tools
 - Surgical tool packaging
 - Surgical furniture
 - **IMPLANTABLE DEVICES**
- 5
- Stents
 - Pacemakers
 - Bladder catheters
 - Central venous catheters
 - Fracture fixation devices
- 10
- Dental implants
 - Joint prostheses
 - Vascular grafts
 - Cardiac pacemakers
 - Mammary implants
- 15
- Mechanical heart valves

CLAIMS

What is claimed is:

1. A method of using an organosilane quaternary ammonium comprising:
combining the organosilane quaternary ammonium with ethanol and/or isopropyl alcohol into a solution; and
applying the combined solution on skin and/or surfaces.

2. A method of using a quaternary ammonium solution as a hand wash and disinfectant rub comprising:
combining a quaternary ammonium in a solution to be used as the hand wash and disinfectant rub.

3. A method of using an organosilane quaternary ammonium in a topical application comprising:
using the organosilane quaternary ammonium in one or more of the following:
 - Consumer hand rub
 - Consumer hand wash
 - First aid hand rub
 - First aid hand wash
 - Patient preoperative skin preparation
 - Healthcare professional hand rub
 - Healthcare professional hand wash
 - Surgical hand scrub
 - Surgical hand rub

4. The method of using an organosilane quaternary ammonium in a topical application of claim 3, wherein the topical application is in the form of one of the following:

- Liquid
- Gel
- Spray
- Foam

5. The method of using an organosilane quaternary ammonium in a topical application of claim 3, wherein the topical application is combined with one of the following:

- a. Alcohol, ethanol, ethyl alcohol
- b. Benzalkonium chloride
- c. Benzethonium chloride
- d. Chlorhexidine gluconate
- e. Chloroxylenol
- f. Iodine tincture USP
- g. Iodine topical solution USP
- h. Isopropyl alcohol
- i. Mercufenol chloride
- j. Combinations:
 - i. Calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative
 - ii. Mercufenol chloride and secondary amyltricsols in 50 percent alcohol

6. A method for using an organosilane quaternary ammonium comprising:
applying the organosilane quaternary ammonium in a topical solution to prevent diaper rash and seal out moisture

7. The method of claim 6, wherein the topical solution is in the form of a spray, cream, ointment, or powder.

8. The method of claim 6, wherein the topical solution is combined with one of the following:

- Alkyldimethyl Benzylammonium chloride
- Allantoin (5-ureidohydantoin)
- Aluminum acetate
- Aluminum hydroxide
- Amylum
- Balsam peru
- Benzethonium chloride
- Benzocaine
- Bicarbonate of soda
- Bismuth subnitrate
- Boric acid
- Calamine
- Calcium carbonate
- Camphor
- Casein
- Cod liver oil
- Cysteine hydrochloride
- Dibucaine
- Dipiperdon hydrochlorid
- Glycerin
- Hexachlorophene
- 8-hydroxyquinoline
- Iron oxide
- Lanolin
- Menthol
- Methapyrilene
- Methionine
- Methylbenzethonium chloride
- Oil of eucalyptus
- Oil of lavenrder
- Oil of peppermint
- Oil of white thyme

- Panthenol
- Para-chloromercuriphenol
- Petrolatum
- Phenol
- Pramoxine hydrochloride
- Salicylic acid
- Silicone
- Sorbitan monosterate
- Talc
- Tetracaine
- Vitamin A
- Vitamin A palmitate
- Vitamin D
- Vitamin D2
- Vitamin E
- White petrolatum
- Zinc oxide
- Zinc stearate

9. A method for using an organosilane quaternary ammonium comprising:
applying the organosilane quaternary ammonium as a topical first aid antibiotic.

10. The method of claim 9, wherein the topical first aid antibiotic is in the form of
a cream or ointment.

11. The method of claim 9, wherein the topical first aid antibiotic includes one of
the following:

Bacitracin ointment
Bacitracin zinc
Chlortetracycline hydrochloride
Neomycin sulfate
Tetracycline hydrochloride
Oxytetracycline hydrochloride

12. A method for using an organosilane quaternary ammonium comprising:
applying the organosilane quaternary ammonium as an antifungal.

13. The method of claim 12, wherein the topical first aid antibiotic is in the form
of a cream, gel or aerosol.

14. The method of claim 12, wherein the topical first aid antibiotic includes one
of the following:

Clioquinol
Haloprogin
Miconazole nitrate
Povidone-iodine
Tolnaftate
Undecylenic acid
Calcium undecylenate
Copper undecylenate
Zinc undecylenate

15. A method for using an organosilane quaternary ammonium comprising:
applying the organosilane quaternary ammonium as a treatment for acne.

16. The method of claim 14, wherein the topical first aid antibiotic is in the form
of a lotion, cream, ointment or gel.

17. The method of claim 14, wherein the topical first aid antibiotic includes one
of the following:

Resorcinol
Resorcinol monoacetate
Salicylic acid
Sulfur

18. A method for using an organosilane quaternary ammonium comprising:
applying the organosilane quaternary ammonium as a skin deodorant.

19. The method of claim 18, wherein the topical first aid antibiotic is in the form of a solid, gel, or liquid.

20. The method of claim 18, wherein the topical first aid antibiotic includes one of the following:

Sodium stearate
Sodium chloride
Stearyl alcohol
Potassium alum
Aluminum Zirconium
Aluminum Chlorohydrate
Aluminum chloride

21. A method for using an organosilane quaternary ammonium comprising:
applying the organosilane quaternary ammonium as a dental product.

22. The method of claim 21, wherein the topical first aid antibiotic is in the form of a liquid, spray, paste or gel

23. The method of claim 21, wherein the topical first aid antibiotic includes one of the following:

Sodium fluoride
Sodium monofluorophosphate
Hydrogen peroxide
Stannous fluoride
Cetylpyridinium chloride
Thymol
Menthol
Eucalyptol
Methyl salicylate

24. A method for using an organosilane quaternary ammonium comprising:
applying to medical device coatings.

25. A method for using an organosilane quaternary ammonium comprising:
applying to disposable device packaging.
26. A method for using an organosilane quaternary ammonium comprising:
applying to non surgical/non implantable devices.
27. The method of claim 26, wherein the non-surgical/non-implantable devices include one or more of the following:
- Personal Protective Equipment
 - Gloves
 - Personnel hair, nose and mouth protectors
 - Scrubs and gowns
 - Goggles
 - Wound care
 - Bandages/ wraps
 - Orthopedic
 - Braces/casting
 - Exam room equipment
 - Laboratory equipment
 - Diagnostic modality components
 - EMS/patient transport equipment
28. A method for using an organosilane quaternary ammonium comprising:
applying to surgical equipment.
29. The method of claim 28, wherein the surgical equipment includes one or more of the following:
- Surgical tools
 - Surgical tool packaging
 - Surgical furniture
30. A method for using an organosilane quaternary ammonium comprising:
applying to implantable devices.

31. The method of claim 30, wherein the surgical equipment includes one or more of the following:

- Stents
- Pacemakers
- Bladder catheters
- Central venous catheters
- Fracture fixation devices
- Dental implants
- Joint prostheses
- Vascular grafts
- Cardiac pacemakers
- Mammary implants
- Mechanical heart valves

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US18/44651

A. CLASSIFICATION OF SUBJECT MATTER
 IPC - A01N 25/08; A61K 31/695 (2018.01)
 CPC - A01N 25/08; A61K 31/695

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)
 See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
 See Search History document

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0141959 A1 (PETERSON, WR et al.) 03 October 2002; abstract; paragraphs [0093]-[0094], [0096], [0157], [0164], [0167]	1-5
A	US 4,797,420 A (BRYANT, JA) 10 January 1989; entire document	1-5
A	US 2016/0128333 A1 (COATING SYSTEMS LABORATORIES, INC., et al.) 12 May 2016; entire document	1-5

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
 10 September 2018 (10.09.2018)

Date of mailing of the international search report

26 NOV 2018

Name and mailing address of the ISA/
 Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
 P.O. Box 1450, Alexandria, Virginia 22313-1450
 Facsimile No. 571-273-8300

Authorized officer
 Shane Thomas

PCT Helpdesk: 571-272-4300
 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US18/44651

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

- 1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

- 2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

- 3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

-***-Please See Within the Next Supplemental Box-***-

- 1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
- 2. As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
- 3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
- 4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

-***-Continued from Box No. III Observations where unity of invention is lacking -***-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-5 are directed towards a method of using a quaternary ammonium solution as a hand wash and disinfectant rub comprising: combining a quaternary ammonium in a solution to be used as the hand wash and disinfectant rub. Group II: Claims 6-8 are directed towards a method for using an organosilane quaternary ammonium comprising: applying the organosilane quaternary ammonium in a topical solution to prevent diaper rash and seal out moisture. Group III: Claims 9-11 are directed towards a method for using an organosilane quaternary ammonium comprising: applying the organosilane quaternary ammonium as a topical first aid antibiotic. Group IV: Claims 12-14 are directed towards a method for using an organosilane quaternary ammonium comprising: applying the organosilane quaternary ammonium as an antifungal. Group V: Claims 15-17 are directed towards a method for using an organosilane quaternary ammonium comprising: applying the organosilane quaternary ammonium as a treatment for acne.

Group VI: Claims 18-20 are directed towards a method for using an organosilane quaternary ammonium comprising: applying the organosilane quaternary ammonium as a skin deodorant. Group VII: Claims 21-23 are directed towards a method for using an organosilane quaternary ammonium comprising: applying the organosilane quaternary ammonium as a dental product.

Group VIII: Claim 24 is directed towards a method for using an organosilane quaternary ammonium comprising: applying to medical device coatings. Group IX: Claim 25 is directed towards a method for using an organosilane quaternary ammonium comprising:

applying to disposable device packaging. Group X: Claims 26-27 are directed towards a method for using an organosilane quaternary ammonium comprising: applying to non surgical/non implantable devices. Group XI: Claims 28-29 are directed towards a method for using an organosilane quaternary ammonium comprising: applying to surgical equipment. Group XII: Claims 30-31 are directed towards a method for using an organosilane quaternary ammonium comprising: applying to implantable devices.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include a method of using a quaternary ammonium solution as a hand wash and disinfectant rub, which are not present in Groups II-XII; the special technical features of Group II include applying the organosilane quaternary ammonium in a topical solution to prevent diaper rash and seal out moisture, which are not present in Groups I and III-XII; the special technical features of Group III include applying the organosilane quaternary ammonium as a topical first aid antibiotic, which are not present in Groups I-II and IV-XII; the special technical features of Group IV include applying the organosilane quaternary ammonium as an antifungal, which are not present in Groups I-III and V-XII; the special technical features of Group V include applying the organosilane quaternary ammonium as a treatment for acne, which are not present in Groups I-IV and VI-XII; the special technical features of Group VI include applying the organosilane quaternary ammonium as a skin deodorant, which are not present in Groups I-V and VII-XII; the special technical features of Group VII include applying the organosilane quaternary ammonium as a dental product, which are not present in Groups I-VI and VIII-XII; the special technical features of Group VIII include applying to medical device coatings, which are not present in Groups I-VII and IX-XII; the special technical features of Group IX include applying to disposable device packaging, which are not present in Groups I-VIII and X-XII; the special technical features of Group X include applying to non surgical/non implantable devices, which are not present in Groups I-IX and XI-XII; the special technical features of Group XI include applying to surgical equipment, which are not present in Groups I-X and XII; and the special technical features of Group XII include applying to implantable devices, which are not present in Groups I-XI.

The common technical features of Groups I-XII are a method of using an organosilane quaternary ammonium comprising applying to skin and/or surfaces.

These common technical features are disclosed by US 2002/0141959 A1 to Peterson, et al. (hereinafter 'Peterson').

Peterson discloses a method of using an organosilane quaternary ammonium comprising applying to skin and/or surfaces (formulation comprising an organosilicon quaternary ammonium compound, wherein the compound is topically applied to the skin; abstract; paragraphs [0093]-[0094]).

Since the common technical features are previously disclosed by the Peterson reference, these common features are not special and so Groups I-XII lack unity.