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**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCION DE NUEVAS CREACIONES**

2020
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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Abogado: JIMENA ESCOBAR URIBE

ASUNTO: Radicación No. 07-033303
Trámite 002
Evento 001
Actuación 430
Oficio
Folios

13185

Como resultado del Examen de Fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

Documentos estudiados:

Descripción: Folios 10 a 34 como se radicó inicialmente.
Reivindicaciones: Folios 35 a 38 como se radicó inicialmente.
Dibujos: Folios 39 a 45 como se radicó inicialmente.
Prioridad: US 2006 11396187 (2006-03-31)

Objeto de la Invención

Título de la invención: Composición para un pretratamiento de espuma para instrumentos médicos.

Problema Técnico Planteado: Necesidad de una composición espumable que desinfeste las superficies de instrumentos antes de un procedimiento de esterilización.

Solución: Composición espumable a base de peróxido de hidrogeno, un agente de superficie y un agente estimulante de espuma para el pretratamiento de instrumentos.

IPC: A61

Análisis de la Solicitud de Patente

Reivindicaciones (Art 30 D 486, Art 22 PCT)

Claridad:

Las reivindicaciones 14 y 15 reivindican una composición espumable caracterizada porque esta empacada en un contenedor ya sea de tipo presurizado o de bombeo manual. Esta característica que involucra el empaque en el cual esta contenida la composición no define dicha composición pues las composiciones deben definirse ya sea por sus componentes o sus proporciones, por tal razón las reivindicaciones deben eliminarse del capítulo reivindicatorio.

Las reivindicaciones 2 a 7 reivindican una composición espumable caracterizada por que contiene un peróxido de hidrogeno, un agente de superficie y un agente

estimulante de espuma en unas proporciones determinadas, sin embargo los términos "hasta cerca de" son imprecisos y la reivindicación deja de ser clara y no permite una comparación con el estado de la técnica, por lo cual debe definirse claramente los rangos o la proporción exacta de estos componentes en la formulación.

Concisión:

La reivindicación 1 establece una composición espumable que contiene un agente de superficie en proporciones entre 0.5 al 20% en peso, sin embargo no se establece claramente a que se refiere el solicitante en cuanto a la naturaleza y tipo de agente de superficie que compone el objeto a reivindicar por lo cual la reivindicación no es concisa. Es necesario que el solicitante establezca claramente y de manera precisa a que tipo de agente de superficie se refiere.

La reivindicación 16 establece una composición espumable caracterizada por la presencia de ácido peracético sin embargo no es clara la proporción, concentración dentro de la composición por lo cual se solicita que el solicitante establezca de forma precisa la proporción de este componente dentro de la composición.

Soporte en la Descripción:

Las reivindicaciones 16 a 21 establecen una composición espumable caracterizada por la presencia de ácido peracético y un inhibidor de corrosión seleccionado entre el grupo de alcanolamina, silicato de sodio y triazolas, sin embargo no se establece en la descripción una formulación en la cual estén presentes estos componentes, no se muestran ejemplos que determinen la presencia de estos componentes. Así mismo, cabe aclarar que dentro de la formulación preferida dentro de la descripción no se muestran estos componentes, por lo cual no hay soporte en la descripción para la adición de estos componentes dentro de la formulación.

Descripción (Art 28 D 486)

Claridad:

La descripción establece que la composición espumable objeto de solicitud contienen silicona (SILSENSE copolyol-1) como componente estimulante de espuma y reductor de pegado (folio 23 a 25), sin embargo en el folio 22 líneas 18 a 20, el solicitante establece que un agente antiespumante apropiado es la silicona SILSENSE copolyol-1 por lo cual hay una contradicción.

Debido a lo anterior la descripción no es clara en cuanto que no se establece si la silicona tiene acción estimulante o anti espumante dentro de la composición.

Determinación del Estado de la Técnica

El Estado de la Técnica se determinó con base en la fecha de solicitud prioritaria 2006-03-31 y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Item	Documento	Título	Fecha de Publicación
D1	US20050019421	<i>Disinfecting Compositions and Methods Of Making And Using Same</i>	2005-01-27
D2	US2003099717	<i>Disinfectant and antiseptic composition</i>	2003-05-29

Análisis de Patentabilidad (Art 14 D486)

Nivel Inventivo (Art18 D486)

La reivindicación 1 dice: "Una composición espumable para el pretratamiento de instrumentos, que comprende: **peróxido de hidrógeno** en una proporción de desde 0.1% hasta 15% por peso; un **agente de superficie** en una proporción de desde 0.5 hasta 20% por peso; y un **agente estimulante de la espuma** que comprende una silicona de desde 0.1% hasta 10% por peso"

D1 es el estado de la técnica más cercano, porque describe una composición tipo **espuma para la limpieza y desinfección de instrumentos médicos** (Párrafos 0002, 0004) que incluye una combinación de sustancias activas como peróxido de hidrogeno en una proporción de 1 al 7% en peso (Párrafos 0004, 0018, 0028, reivindicación 5) y ácidos aromáticos que reemplazan moléculas de tipo ácido como por ejemplo el ácido peracético (Párrafo 0007), así mismo, la composición contiene **surfactantes no iónicos** (Párrafos 0012, 0038, 0028, reivindicación 9) y componentes adicionales que involucran **estimulante de formación de espuma**, inhibidores de corrosión, agentes estabilizantes de peróxido y agentes ajustadores de pH (Párrafo 0040, reivindicación 15).

La composición objeto de esta reivindicación, se diferencia de la composición de D1, en que el agente estimulante de formación de espuma es específicamente una silicona.

Los efectos logrados por esta diferencia es que debido a la presencia del agente estimulante de espuma (silicona), la composición espumable se mantiene en la superficie a tratar y presenta mayor actividad contra microorganismos específicos.

Así, el problema técnico objetivo a resolver es la necesidad de composiciones limpiadoras y desinfectantes de instrumentación médica con permanencia en la superficie y una buena actividad contra microorganismos.

Teniendo en cuenta el problema técnico a resolver, D1 ya había resuelto dicho problema técnico con composiciones de peróxido de hidrogeno las cuales han sido probadas en bacterias (incluidos mycobacterias), esporas, virus y hongos y por tiempos entre 0.5 y 5 min obteniendo mejor actividad germicida (99.9%); Así mismo, D1 establece que las composiciones descritas permanecen en la superficie del instrumento debido la utilización de agentes dentro de la composición tales como polímeros y surfactantes.

Por lo tanto, el experto medio en la materia era obvio resolver el problema técnico a la luz del estado de la técnica, donde además de dar a conocer una composición con espuma que se mantiene en la superficie, también presenta una mayor actividad contra microorganismos lo cual afecta el nivel inventivo.

Conclusión

Los requisitos de Patentabilidad de la presente Solicitud se encuentran afectados así:

N°	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	US20050019421	1-21	Nivel Inventivo

estimulante de espuma en unas proporciones determinadas, sin embargo los términos "hasta cerca de" son imprecisos y la reivindicación deja de ser clara y no permite una comparación con el estado de la técnica, por lo cual debe definirse claramente los rangos o la proporción exacta de estos componentes en la formulación.

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D1	US20050019421	1-21	Nivel Inventivo

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de 60 días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha

08 OCT. 2010

CONCEPTO TECNICO NUMERO: 2660	EXAMINADOR TÉCNICO Código: 202093
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US 20050019421A1

(19) **United States**(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0019421 A1****Hobbs et al.**(43) **Pub. Date:****Jan. 27, 2005**(54) **DISINFECTING COMPOSITIONS AND METHODS OF MAKING AND USING SAME**(75) **Inventors:** Terry R. Hobbs, St. Paul, MN (US); Jeffrey F. Andrews, Stillwater, MN (US); Sophia M. Czechowicz, Woodbury, MN (US); Luke E. Schallinger, Woodbury, MN (US)

Correspondence Address:

**3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427 (US)**(73) **Assignee:** 3M Innovative Properties Company(21) **Appl. No.:** 10/625,271(22) **Filed:** Jul. 23, 2003**Publication Classification**(51) **Int. Cl.⁷** A61K 33/40; A61K 31/19(52) **U.S. Cl.** 424/616; 514/568(57) **ABSTRACT**

The present invention provides a composition, comprising: greater than about 0.1% by weight hydrogen peroxide; an

aromatic acid component; surfactant; optionally, a solvent; and a carrier. The composition of the invention is useful as a disinfecting composition for killing microorganisms such as bacterium (including Mycobacterium), spores and fungi. The composition provides a pathogenic bacteria kill rate of 99.9% in about 30 seconds when bacteria are exposed to the composition and is effective in providing a *Mycobacterium* kill of 10⁶ with two minutes or less. Moreover, the compositions of the invention are generally more resistant to catalase deactivation than, for example, an aqueous solution of hydrogen peroxide. The concentration of hydrogen peroxide within the composition may range from about 1% by weight to about 7% by weight and the concentration of aromatic acid component may range from about 0.1% by weight to about 5% by weight. The invention also provides a method for disinfection of a substrate utilizing the composition. The composition of the invention may be used in the foregoing method on a medical instrument, such as an endoscope or the like. Applying the compositions to a substrate may be accomplished in any of a variety of application methods such as by roll coating, dipping, spraying, or rotational tumbling. The composition may be applied to the substrate for a period of time ranging from about 30 seconds to about ten minutes. In this aspect, the invention can further comprise drying the substrate after removing the composition.

DISINFECTING COMPOSITIONS AND METHODS OF MAKING AND USING SAME

[0001] The present invention relates to a composition that is useful in high level disinfection, methods of making the composition and methods of use.

BACKGROUND OF THE INVENTION

[0002] A disinfecting agent is a composition that, when applied to a surface or the like will kill a wide spectrum of microorganisms such as bacteria, fungi and viruses. The term "high level disinfectant" ("HLD") designates a class of disinfecting agents that can kill 10^6 mycobacteria and have the ability to kill bacterial endospores, the most difficult of all microorganisms to kill. A high level disinfectant can reduce spore populations and at the same time destroy less hardy pathogens such as mycobacteria, fungi, bacteria, and viruses. A "sterilant" is an agent capable of killing 10^6 bacterial endospores.

[0003] Cleaning, disinfection and/or sterilization of medical instruments and devices is a common practice in the health care industry, and improvements to this practice are desired for the further enhancement of hygiene and patient safety. Effective disinfection must act against a wide spectrum of microorganisms including those resistant to common antibacterial agents while not damaging the instruments and devices upon which they are used and without posing significant health or environmental issues of their own.

[0004] Chemical compounds capable of disinfecting or sterilizing an instrument or a surface thereof include peroxy compounds, hydrogen peroxide, chlorine compounds, aldehydes, and phenolics. These compounds and the compositions containing them have been used for disinfecting surfaces and heat sensitive medical devices such as endoscopes, for example. Mycobacteria are generally much more difficult to kill in comparison to fungi, other bacteria, and viruses. Microorganisms from the *Mycobacterium* genus have been identified by the United States Food and Drug Agency ("FDA") as the key organism to be used in establishing the disinfection time of a high level disinfectant. Tuberculosis, caused by *Mycobacterium tuberculosis*, is a key pathogenic organism of concern especially with the rise of antibiotic resistant strains. Approved non-pathogenic surrogates include *Mycobacterium terrae* and *Mycobacterium bovis*.

[0005] Although several commercial products are now available for high level disinfection, these products are often slow in achieving a desired level of disinfection and may suffer from one or more other disadvantages. For example, glutaraldehyde has been used in high level disinfection at a 2% level in an aqueous solution. But, disinfection times are typically as long as 20 to 45 minutes. Although the disinfection times can be reduced with heating (e.g., to 35° C.), material compatibility and health issues have complicated the safety and efficacy picture for this compound. Likewise, peracetic acid and orthophthalaldehyde have also been used in high level disinfection, often with undesired disinfection times and/or with undesired material compatibility and concentration related health or safety issues.

[0006] Hydrogen peroxide is known to possess broad germicidal properties with an ability to kill organisms through oxidative action. At lower concentrations (e.g., <6%), it is safe to handle and is considered environmentally friendly because it readily decomposes into oxygen and water. One disadvantage in the use of hydrogen peroxide is

its rate of disinfection or its kill rate can be rather slow, even when used to eliminate common bacteria such as *Staphylococcus aureus*. Although the disinfection rate or kill rate can be increased simply by increasing the hydrogen peroxide concentration, the increase in the kill rate is frequently obtained at the expense of safety because the more concentrated peroxide solutions are also strong oxidizing agents.

[0007] A water-soluble acid such as peracetic or acetic acid can be combined with hydrogen peroxide to improve its efficacy, and this approach has been used by some manufacturers of disinfectants who have added a second active such as phosphoric, peracetic, or a food grade acid. However, these combinations of peroxide and acid still require longer times to achieve high level disinfection (e.g., more than 5 minutes) and have generally been relatively poor performers. They also have poor materials compatibility because of their low pH (typically <3) and oxidizing ability. Reports of shorter disinfection times may utilize formulations that combine an acid such as succinic acid with a higher level of peroxide, (e.g., 13.4%), thus negating the attractive safety feature of a more dilute hydrogen peroxide solution. Hydrogen peroxide concentrations of 8% or more are classified by the United States Department of Transportation as strong oxidizers that require special shipping conditions.

[0008] There is a need for a disinfectant capable of high level disinfection and exhibiting an improved rate of high level disinfection. It is desirable to provide such a disinfectant in a safe and fast acting form capable of killing a broad range of microorganisms including mycobacteria, fungi, and bacteria while also having improved materials compatibility.

SUMMARY OF THE INVENTION

[0009] The present invention provides a composition, comprising:

[0010] Greater than about 0.1% by weight hydrogen peroxide;

[0011] Aromatic acid component;

[0012] Surfactant;

[0013] Optionally, a solvent; and

[0014] A carrier.

[0015] As used herein, "aromatic acid" refers to a carboxylic acid functionality directly attached to a benzene ring.

[0016] The composition of the invention is useful as a disinfecting composition for killing microorganisms such as bacterium (including *Mycobacterium*), spores and fungi. The composition provides a pathogenic bacteria kill rate of 99.9% in about 30 seconds when bacteria are exposed to the composition and is effective in providing a mycobacteria kill of 10^6 in two minutes or less. The compositions of the invention are generally much more resistant to catalase deactivation than, for example, an aqueous solution of hydrogen peroxide. In achieving a composition having these qualities, the aromatic acid, surfactant, and the hydrogen peroxide are present within the composition in synergistic amounts to provide improved kill rates of microorganisms (e.g., bacteria, fungi and viruses) when applied to a substrate. In addition to the foregoing components, the compositions of the invention may further comprise one or more acidulant such as phosphoric acid, sulfuric acid, caprylic acid, capric acid, lauric acid, or citric acid or combinations of the foregoing.

[0017] The aromatic acid component may be selected from benzoic acid, alkyl derivatives of benzoic acid, hydroxybenzoic acids, halogenated benzoic acids, phthalic acid, terephthalic acid, derivatives of hydroxybenzoic acids such as acetylsalicylic acid, naphthoic acid and combinations of the foregoing. Suitable surfactants may be anionic or nonionic, and the solvent may be glycols, alcohols, aprotic amides, esters, polyethers or combinations of the foregoing. The compositions of the invention may further comprise one or more optional constituents such as corrosion inhibitors, antifoaming agents, foaming agents, pH adjusting agents, coloring agents, peroxide stabilizing agents, fragrances, and chelating agents.

[0018] In another aspect of the invention, the concentration of hydrogen peroxide may range from about 1% by weight to about 7% by weight and the concentration of aromatic acid component may range from about 0.1% by weight to about 5% by weight.

[0019] In still another aspect, the invention provides a method for disinfecting, the method comprising:

[0020] Applying the foregoing composition to a substrate;

[0021] Allowing the composition to remain in contact with the substrate for a period of time to kill microorganisms thereon; and

[0022] Removing the composition from the substrate.

[0023] The compositions of the invention may be used in the foregoing method on a medical instrument, such as an endoscope or the like. Applying the compositions to a substrate may be accomplished in any of a variety of application methods such as by roll coating, dipping, spraying, or rotational tumbling. The composition may be applied to the substrate for a period of time ranging from about 30 seconds to about ten minutes. In this aspect, the invention can further comprise drying the substrate after removing the composition.

[0024] In still another aspect, the invention provides a method for making the foregoing composition, the method comprising combining greater than about 0.1% by weight hydrogen peroxide; aromatic acid component; surfactant; an optional solvent; and a carrier such as water.

[0025] Those skilled in the art will further appreciate the foregoing aspects of the invention upon consideration of the remainder of the disclosure. It is also contemplated that equivalents to the described components and to the composition of the invention are possible but are as yet unforeseen. Nonetheless, such equivalents are within the scope of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0026] The invention provides compositions capable of high level disinfection. The compositions of the invention comprise hydrogen peroxide, an aromatic acid component, a surfactant and a carrier. Because aromatic acids are substantially insoluble in water, an appropriate solvent and/or surfactant system is typically included to create a stable, aqueous based disinfectant. The compositions of the invention provide a rapid disinfection capability in the presence of organic soil and against organisms that produce catalase. Moreover, the compositions of the invention provide an improved rate of kill and an improved spectrum of activity

against microorganisms while also exhibiting an improved efficacy against catalase producing organisms such as *S. aureus*.

[0027] The compositions of the invention are useful for disinfecting medical devices because they are easy to handle, generally compatible with other materials, and require a short contact time to achieve high level disinfection. The compositions of this invention superior to previously described disinfectant chemistries. Compared to known hydrogen peroxide formulations, the compositions of this invention provide a shorter time to achieve disinfection, improved efficacy, improved safety, and improved compatibility with other materials.

[0028] The compositions of the invention comprise hydrogen peroxide and will normally comprise greater than about 0.1% hydrogen peroxide and typically from 0.1 to 7.0 wt % hydrogen peroxide in a ready to use formulation. Typically, the amount of peroxide is from 1 to 6 wt %, and often will range between 3 and 5 wt %. The compositions of the invention may be provided in concentrated form wherein the peroxide concentration will typically range from about 5% to about 25%. The actual concentration of peroxide in a composition will depend on the particular application. Higher concentrations of peroxide may be desired if rapid disinfection is required while lower concentrations are typically used in compositions that may come in contact with human skin. For example, hydrogen peroxide at a weight percentage of 3% is a typical level in over the counter antiseptics. The low levels of hydrogen peroxide (typically 3-5%) required for the ready to use compositions of the invention are sufficient to provide high level disinfection in a relatively short time.

[0029] While hydrogen peroxide is most commonly used in the inventive compositions described herein, other peroxides are also suitable such as perborates, percarbonates, and perorganic acids. Moreover, the compositions of the invention are typically aqueous based micro-emulsions, so that water insoluble peroxides can be used as well including perbenzoic acid or benzoyl peroxide.

[0030] Another component of the invention is an aromatic acid. The aromatic acid component may comprise one or more aromatic acids in combination, each aromatic acid may comprise one or more acid groups. Suitable organic acids for use in the compositions of the invention include but are not limited to: benzoic acid and its alkyl derivatives, hydroxybenzoic acids (e.g., salicylic acid), halogenated benzoic acids, phthalic acid, terephthalic acid, orthophthalic acid, acetylsalicylic acid, and naphthoic acid. Typically, the aromatic acid is used in the composition in conjunction with one of its salts to provide buffering capacity to the composition. The compositions of the invention often comprise benzoic acid in conjunction with an alkali metal salt thereof such as sodium benzoate because these compounds have low toxicity and are widely used as food preservatives. Additionally, benzoic acid has a pKa of 4.2, making it a suitable buffer for the typical pH range of 3.5 to 5.0. Alternatively, the compositions of this invention may utilize a salt of an aromatic acid used in conjunction with one or more acidulants such as phosphoric acid, sulfuric acid, caprylic acid, capric acid, lauric acid, or citric acid. One such composition comprises sodium benzoate and phosphoric acid. As mentioned, the pH of the composition is typically in the range from about 3.5 to about 5.0 and can be controlled by altering the relative concentration of aromatic acid and salt or by altering the pH with acidulants or traditional bases such as

[0038] Nonionic surfactants can be used either alone or in combination with anionic surfactants such as when long term stability of the composition may be a concern. Non-ionic surfactants may also be used alone (e.g., without anionic surfactant) in formulations comprising an acidulant and a salt of an aromatic acid such as, for example, the combination of phosphoric acid and sodium benzoate, mentioned above, which generally has good water solubility.

[0039] The compositions of the invention also include a carrier for the ready to use formulations. Although any of a variety of carriers may be useful, typically, the compositions of the invention include water as the carrier. As such, the compositions of the invention are formulated as ready to use compositions having the above described components in concentrations that fall mainly within the described concentration ranges. The balance of the formulation is then comprised of the carrier (e.g., water) in an amount typically from about 50% to about 99% by weight. Most typically, the carrier is treated in some way to remove contaminants, especially particulates, potentially interfering ions or other chemicals and the like. Filtration, distillation and/or deionization are typical treatments for the carrier in order to render it relatively free of contaminants, undesired materials and the like.

[0040] Optional additional components may be included in the compositions of the invention such as: antifoaming agents, foaming agents, corrosion inhibitors, peroxide stabilizing agents, hydrotropes, fragrances, and colorants. Suitable corrosion inhibitors include nitrates, azoles such as benzotriazole, and imidazoles. Tin compounds and pyrophosphates are examples of suitable peroxide stabilizers. These optional components may be included in the compositions of the invention at a concentration level in the ready to use compositions of up to about 10% by weight. Exact amounts of the individual optional components is within the ordinary skill of those working in the art. Other components known to those skilled in the art may also be included in the composition to alter or tailor the basic composition to a particular need.

[0041] In the compositions of the invention, the combination of an aromatic acid, hydrogen peroxide, and surfactant has shown an improved mycobactericidal activity and a faster kill rate against pathogenic organisms when compared with known hydrogen peroxide formulations. Such known formulations include those based on aliphatic or phosphoric acids combined with hydrogen peroxide or combinations of peracetic acid and hydrogen peroxide. Furthermore, the compositions of this invention are active at higher pH values and generally have a buffering capacity when the solution pH is close to the pKa of the aromatic acid. The aromatic acids used in this invention are also inherently more stable toward oxidation compared to aliphatic acids used in the prior art providing a further advantage for their use with hydrogen peroxide. However, it will be appreciated that the inclusion of the aromatic acid(s) in the compositions of the invention does not preclude the inclusion of other acids such as the aforementioned acidulants including, for example, phosphoric acid, sulfuric acid, caprylic, lauric acid, citric acid and combinations thereof.

[0042] Many known disinfectants are often used improperly both in an industrial and hospital setting. For example, they may be applied to a surface and prematurely removed prior to allowing for the necessary contact or disinfection time. As a result, some pathogens may be reduced in number and not completely eliminated while other, more difficult

pathogens, may not be killed at all. As a result, the surface that has been treated with these disinfectants is not disinfected, and the opportunistic transmission of the pathogen may be facilitated. The compositions of the invention typically provide faster kill rates against *Mycobacteria*, fungi, and other bacteria compared to known hydrogen peroxide based formulations. Consequently, shorter exposure times are more appropriate for the compositions of the invention.

[0043] The contact time for the compositions of this invention when used for high level disinfection tends to be a function of the aromatic acid and peroxide concentrations. Typical contact times for destroying/killing 10^6 *Mycobacterium* species is two minutes or less. In sterilization applications, the time required is substantially longer than that required to achieve high level disinfection. Without being bound to a particular theory, it is believed that the improved activity for the compositions herein is related to the ability of the aromatic acid to penetrate the fatty outer lipid layer of the *Mycobacterium*. This fatty lipid layer normally protects the cell from the action of chemicals interacting with the layer such as traditional aqueous disinfectants (e.g., 7% H_2O_2). The fat soluble nature of the aromatic acids used herein is believed to permit the penetration of the organic acid which is enhanced by the inclusion of anionic surfactants and/or wetting agents in the composition. At lower hydrogen peroxide concentrations (e.g., 5% or less), the peraromatic acid is generally not formed at appreciable levels and does not contribute to the antimicrobial activity of the composition.

[0044] The non-corrosive properties of disinfectant compositions according to the invention may be further enhanced by the addition of certain corrosion inhibitors. The non-corrosive properties may be especially important in applications where the composition is to be applied to any of a variety of metal surfaces such as brass, aluminum, anodized aluminum, carbon steel and the like. Benzotriazole has been shown to have a beneficial effect in the compositions of the invention. Disinfectant compositions formulated with benzotriazole and having a pH of 4.0-4.4 have been known to demonstrate a delay of about 2 weeks before the onset of corrosion on a brass surface following continuous exposure to the disinfectant composition. Benzotriazole is not generally needed to protect aluminum or ferrous metals, but it is useful with copper and its alloys. The compositions generally will not degrade or discolor engineering thermoplastics, o-rings, elastomers, or common household plastics. In addition, the compositions are non-corrosive and mild to the skin.

[0045] The compositions of the invention have a broad spectrum of activity and are capable of accomplishing high level disinfection on any of a variety of surfaces. Exemplary surfaces include the surfaces of delicate medical instruments, devices such as, for example, endoscopes, food contact surfaces, surfaces within ventilation ducts, on cruise ships, in hospitals, under and within carpeting, and the like. The compositions may also be used as disinfectant cleaners and as skin antiseptics. The compositions of the invention can be used for disinfecting dental, medical, and veterinary equipment and devices as well as disinfecting inanimate surfaces such as floors, furniture, ceilings, door knobs, toilet seats, building vents, and surfaces of sinks. In addition, the compositions are useful for treating and disinfecting agricultural goods, produce, and raw materials. Furthermore, because the compositions of this invention contain lower levels of peroxide (<6%), they may be used for antimicrobial skin cleaners (e.g., hand cleaners), washes and scrubs.

first four components were mixed with stirring followed by the addition of 51.15 grams of distilled water. The remainder of the components were added in the order listed followed by stirring and with more water added as the last component

liver catalase was added to each composition and the catalase reacted with the hydrogen peroxide to generate oxygen, causing the protein to foam. After two minutes, the volume of foam was recorded. The results are shown in Table 8.

TABLE 7

Components (Comparative Example A and Examples 5-8)								
Components (weight percent)								
Example Number	Hydrogen peroxide	Propylene glycol	Benzoic acid	Sodium benzoate	Silicone antifoam	Ethanol	Sodium dioctyl sulfosuccinate (GEMTEX SC-40)	Water
Comp. Ex. A	3.00	0.00	0.00	0.00	0.00	0.00	0.00	97.00
5	5.10	6.80	0.31	0.35	0.00	0.00	0.00	87.44
6	5.10	6.10	0.25	0.25	0.02	0.00	0.00	88.28
7	5.00	6.20	0.26	0.27	0.01	3.50	1.50	83.26
8	5.00	6.20	0.25	0.25	0.00	6.90	3.22	78.18

to provide the concentrations shown in the Table. The composition used a higher alcohol and surfactant concentration because of the poor solubility of polytriazole (corrosion inhibitor for copper alloys). The final concentration of salicylic acid was 1.02% and hydrogen peroxide was 4.22%.

TABLE 6

Example 4		
Components	Mass (g)	Concentration (wt. %)
Isopropanol	9.00	9.00
Sodium dioctyl sulfosuccinate (GEMTEX SC-40)	10.48	4.19
Salicylic acid (2-hydroxybenzoic acid)	1.02	1.02
Polytriazole	2.04	2.04
Hydrogen peroxide	12.06	4.22
Sodium hydroxide	0.66	0.04
Distilled water	64.74	79.49

[0082] The composition was tested using Procedure II (Quantitative Tuberculocidal Suspension) for activity against *Mycobacterium terrae* in the presence of 5% bovine serum with an exposure time of 5 minutes. In a kill rate assay, the composition provided a complete kill (≥ 7.69 log reduction) against *Mycobacterium terrae*.

Comparative Example A and Examples 5-8

[0083] To examine the ability of compositions of the invention to significantly reduce the activity of catalase by denaturing it, catalase activity was measured in a foaming experiment. Catalase is a known catalytic enzyme which decomposes hydrogen peroxide into oxygen and water. Consequently, bacteria containing a large amount of catalase (e.g., *S. Aureus*) have a built in defense mechanism against hydrogen peroxide disinfectants. Comparative Example A was a 3% hydrogen peroxide solution (no additives). Examples 5-8 were formulated as set forth in Table 7.

[0084] 1 ml of bovine calf serum was added to 19 ml of hydrogen peroxide disinfectant composition in a graduated cylinder while stirring with a magnetic stir bar. The solution was stirred slowly on a stir bar plate. 0.1 ml of active bovine

[0085]

TABLE 8

Foam Volume (Comparative Example A and Examples 5-8)	
Example	Foam Volume (ml)
Comp. Ex. A	100
5	10
6	10
7	0
8	1

[0086] Similar results were obtained when the bovine catalase was replaced with a 10^8 /mL inoculum of *Staphylococcus aureus*, which was grown in an open plate to maximize catalase content.

Example 9

[0087] A composition was prepared with 0.45% benzoic acid, 0.50% sodium benzoate, 2.30% benzotriazole, 0.48% sodium dioctyl sulfosuccinate, 5.03% hydrogen peroxide, 5.87% propylene glycol, and 3.84% isopropanol. The composition was tested against *Staphylococcus aureus* (ATCC 6538), an organism containing a large amount of catalase, using Procedure I (Microbial Kill Rate Assay) with 5% calf serum. The composition provided complete kill at 2 minutes with ≥ 6.82 log reduction.

Comparative Example B

[0088] A composition was prepared with the components listed and in the amounts given in Table 9. The first five components were added together and stirred in a glass vessel at room temperature for 30 minutes. Thereafter, each additional component was added individually followed by stirring to dissolution. The composition of Comparative Example B was formulated with lauric acid, a C_{12} aliphatic acid, and included no aromatic acid component and no salt of an aromatic acid.

Jan. 27, 2005

4. Composition of claim 1 further comprising an acidulant selected from the group consisting of phosphoric acid, sulfuric acid, caprylic acid, capric acid, lauric acid, or citric acid and combinations of the foregoing.

5. Composition of claim 1 wherein the hydrogen peroxide is present in the composition at a concentration from about 0.1% to about 7% by weight.

6. Composition of claim 1 wherein the aromatic acid component is present in a concentration sufficient to provide a disinfecting action when used to kill microorganisms such as bacteria, fungi and viruses.

7. Composition of claim 1 wherein the aromatic acid component is present in a concentration sufficient to provide a synergy when combined in the composition with the hydrogen peroxide as a disinfecting composition to kill microorganisms such as bacteria, fungi and viruses.

8. Composition of claim 1 wherein the aromatic acid component is selected from the group consisting of benzoic acid, alkyl derivatives of benzoic acid, hydroxybenzoic acids, halogenated benzoic acids, phthalic acid, terephthalic acid, orthophthalic acid, acetylsalicylic acid, naphthoic acid and combinations of the foregoing, the aromatic acid component present in a concentration from 0.1% by weight to 5% by weight.

9. Composition of claim 1 wherein the surfactant is anionic.

10. Composition of claim 9 wherein the surfactant is selected from the group consisting of alkyl sulfates, alkyl arylsulfates, alkyl sulfosuccinates, dialkyl sulfosuccinates, and xylene sulfonates, salts thereof and combinations of the foregoing.

11. Composition of claim 9 wherein the surfactant is the sodium salt of dioctyl sulfosuccinate.

12. Composition of claim 1 wherein the surfactant is selected from the group consisting of amine oxides, phenol ethoxylates, fatty acid amides, sorbitan esters, fatty alcohol ethoxylates, block copolymers of ethylene oxide and propylene oxide and combinations of the foregoing.

13. Composition of claim 1 wherein the solvent is selected from the group consisting of glycols, alcohols, aprotic amides, esters, polyethers and combinations of the foregoing.

14. Composition of claim 1 wherein the carrier is water and the composition is an emulsion.

15. Composition of claim 1 further comprising one or more optional constituents selected from corrosion inhibitors, antifoaming agents, foaming agents, pH adjusting agents, coloring agents, peroxide stabilizing agents, fragrances, and chelating agents.

16. Composition of claim 1 having a pH in the range from about 3.5 to about 5.0.

17. Composition of claim 1 wherein:

The concentration of hydrogen peroxide is from about 1% by weight to about 7% by weight; and

The concentration of aromatic acid component is from about 0.1% by weight to about 5% by weight.

18. Composition of claim 17 further comprising a salt of the aromatic acid in a concentration less than about 2% by weight.

19. Composition of claim 18 wherein the aromatic acid is benzoic acid and the salt is sodium benzoate.

20. Composition of claim 19 wherein the surfactant comprises salts of compounds selected from the group consisting of alkyl sulfates, alkyl arylsulfates, alkyl sulfosuccinates, dialkyl sulfosuccinates, alkyl lactates, alkyl alkoxyated sulfates, xylene sulfonates and combinations of the foregoing.

21. Composition of claim 19 wherein the surfactant is selected from the group consisting of the sodium salt of dioctyl sulfosuccinate, sodium capryl sulfate and combinations of the foregoing.

22. Composition of claim 12 further comprising an anti-foaming agent.

23. Composition of claim 22 further comprising acidulant selected from the group consisting of phosphoric acid, sulfuric acid, caprylic acid, capric acid, lauric acid, citric acid and combinations of the foregoing.

24. Composition of claim 17 wherein the solvent is selected from the group consisting of propylene glycol, ethanol, n-propanol, isopropanol, hexylene glycol, polyethylene glycol, glycerol, phenoxyethanol, butylene glycol and combinations of the foregoing.

25. Composition of claim 24 wherein the solvent concentration is from about 1% to about 40% by weight.

26. Composition of claim 17 wherein the composition is more resistant to catalase deactivation than an aqueous solution of hydrogen peroxide.

27. Composition of claim 17 having a pH in the range from about 3.5 to about 5.0.

28. A method for disinfecting, the method comprising:

Applying the composition of claim 1 to a substrate;

Allowing the composition to remain in contact with the substrate for a period of time to kill microorganisms thereon; and

Removing the composition from the substrate.

29. Method according to claim 28 wherein the substrate is a surface on a medical instrument.

30. Method according to claim 28 wherein the medical instrument is an endoscope.

31. Method according to claim 28 wherein applying the composition of claim 1 to the substrate is accomplished by roll coating, dipping, spraying, or rotational tumbling.

32. Method according to claim 28 wherein the period of time ranges from 30 seconds to ten minutes.

33. Method according to claim 28 wherein the period of time is no longer than about two minutes and the microorganisms comprise *Mycobacterium*, the method providing a kill of 10^6 *Mycobacteria* within the period of time.

34. Method according to claim 28 wherein removing the composition from the substrate is accomplished by rinsing with water, alcohol, or aqueous alcohol solution.

35. Method according to claim 28 further comprising drying the substrate after removing the composition.

36. Method according to claim 28 where the substrate is a hard surface or a textile.

37. A method for making a composition, the method comprising combining the initial components of claim 1 to provide the composition.

38. Composition according to claim 1 formulated for application to skin.

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REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Folio 127

2020
Bogotá D.C.,

Doctor(a)
ESCOBAR URIBE JIMENA
Apoderado(a) y/o Representante de
ETHICON, INC

REFERENCIA	Radicación No. 07 33303
	Trámite 2
	Evento 1
	Actuación 416
	Oficio No. 4294
	Folios 1

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en la referencia, reúne los requisitos de forma establecidos en los artículos 26 y 27 de la Decisión 486 de la Comisión de la Comunidad Andina, y en las demás disposiciones vigentes sobre la materia, se envía el extracto de la solicitud a la Oficina de Comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial, conforme lo establece el artículo 40 de la misma Decisión.

Siendo manifestación expresa del interesado de efectuar la publicación "inmediato", está se realizará en la próxima gaceta de Propiedad Industrial.

Cúmplase
Dado en Bogotá DC,

71 OCT 2007

ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la división de Nuevas Creaciones

adpal