Title: COMPOSITIONS HAVING A HIGH ANTIVIRAL AND ANTIBACTERIAL EFFICACY

Abstract: Antimicrobial compositions having a rapid antiviral and antibacterial effectiveness, and a persistent antiviral effectiveness, are disclosed. The antimicrobial compositions contain a phenolic antimicrobial agent, a disinfecting alcohol, a gelling agent, and an organic acid, wherein the phenolic antimicrobial agent is present in a continuous aqueous phase in an amount of at least 50% of saturation concentration and the composition has a pH of about (5) or less.
COMPOSITIONS HAVING A HIGH ANTIVIRAL AND ANTIBACTERIAL EFFICACY

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application Serial No. 60/634,482, filed December 9, 2004.

FIELD OF THE INVENTION

The present invention relates to antimicrobial compositions having a rapid antiviral and antibacterial effectiveness, and a persistent antiviral effectiveness. More particularly, the present invention relates to antimicrobial compositions, such as hand sanitizer gels, comprising a phenolic antimicrobial agent, a gelling agent, and an organic acid. The composition has a pH of about 5 or less, and provides a substantial reduction, e.g., greater than 99%, in Gram positive and Gram negative bacterial populations, and in viral populations, within one minute.

BACKGROUND OF THE INVENTION

Human health is impacted by a variety of microbes encountered on a daily basis. In particular, contact with various microbes in the environment can lead to an illness, possibly severe, in mammals. For example, microbial contamination can lead to a variety of illnesses, including, but not limited to, food poisoning, a streptococcal infection, anthrax (cutaneous), athlete's foot, cold sores, conjunctivitis ("pink eye"), coxsackievirus (hand-foot-mouth disease), croup, diphtheria (cutaneous), ebolic hemorrhagic fever, and impetigo.
It is known that washing body parts (e.g., hand washing) and hard surfaces (e.g., countertops and sinks) can significantly decrease the population of microorganisms, including pathogens. Therefore, cleaning skin and other animate and inanimate surfaces to reduce microbial populations is a first defense in removing such pathogens from these surfaces, and thereby minimizing the risk of infection.

Viruses are one category of pathogens that are of primary concern. Viral infections are among the greatest causes of human morbidity, with an estimated 60% or more of all episodes of human illness in developed countries resulting from a viral infection. In addition, viruses infect virtually every organism in nature, with high virus infection rates occurring among all mammals, including humans, pets, livestock, and zoo specimens.


Simply stated, virus particles are intrinsic obligate parasites, and have evolved to transfer genetic material between cells and encode sufficient information to ensure their own propagation. In a most basic form, a virus consists of a small segment of nucleic acid encased in a simple protein shell. The broadest distinction between viruses is the enveloped and nonenveloped viruses, i.e., those that do or do not contain, respectively, a lipid-bilayer membrane.

Viruses propagate only within living cells. The principal obstacle encountered by a virus is gaining entry into the cell, which is protected by a cell mem-
brane of thickness comparable to the size of the virus. In order to penetrate a cell, a virus first must become attached to the cell surface. Much of the specificity of a virus for a certain type of cell lies in its ability to attach to the surface of that specific cell. Durable contact is important for the virus to infect the host cell, and the ability of the virus and the cell surface to interact is a property of both the virus and the host cell. The fusion of viral and host-cell membranes allows the intact viral particle, or, in certain cases, only its infectious nucleic acid to enter the cell. Therefore, in order to control a viral infection, it is important to rapidly kill a virus that contacts the skin, and ideally to provide a persistent antiviral activity on the skin, or a hard surface, in order to control viral infections.

For example, rhinoviruses, influenza viruses, and adenoviruses are known to cause respiratory infections. Rhinoviruses are members of the picornavirus family, which is a family of "naked viruses" that lack an outer envelope. The human rhinoviruses are so termed because of their special adaptation to the nasopharyngeal region, and are the most important etiological agents of the common cold in adults and children. Officially there are 102 rhinovirus serotypes. Most of the picornaviruses isolated from the human respiratory system are acid labile, and this lability has become a defining characteristic of rhinoviruses.

Rhinovirus infections are spread from person to person by direct contact with virus-contaminated respiratory secretions. Typically, this contact is in the form of physical contact with a contaminated surface, rather than via inhalation of airborne viral particles.

Rhinovirus can survive on environmental surfaces for hours after initial contamination, and infec-
tion is readily transmitted by finger-to-finger contact, and by contaminated environmental surface-to-finger contact, if the newly contaminated finger then is used to rub an eye or touch the nasal mucosa. Therefore, virus contamination of skin and environmental surfaces should be minimized to reduce the risk of transmitting the infection to the general population.

Several gastrointestinal infections also are caused by viruses. For example, Norwalk virus causes nausea, vomiting (sometimes accompanied by diarrhea), and stomach cramps. This infection typically is spread from person to person by direct contact. Acute hepatitis A viral infection similarly can be spread by direct contact between one infected person and a nonimmune individual by hand-to-hand, hand-to-mouth, or aerosol droplet transfer, or by indirect contact when an uninfected individual comes into contact with a hepatitis A virus-contaminated solid object. Numerous other viral infections are spread similarly. The risk of transmitting such viral infections can be reduced significantly by inactivating or removing viruses from the hands and other environmental surfaces.

Common household phenol/alcohol disinfectants are effective in disinfecting contaminated environmental surfaces, but lack persistent virucidal activity. Hand washing is highly effective in disinfecting contaminated fingers, but again suffers from a lack of persistent activity. These shortcomings illustrate the need for improved virucidal compositions having a persistent activity against viruses, such as rhinoviruses.

Antimicrobial personal care compositions are known in the art. In particular, antibacterial cleansing compositions, which typically are used to cleanse the skin and to destroy bacteria present on the skin, espe-
cially the hands, arms, and face of the user, are well-known commercial products.

Antibacterial compositions are used, for example, in the health care industry, food service industry, meat processing industry, and in the private sector by individual consumers. The widespread use of antibacterial compositions indicates the importance consumers place on controlling bacteria populations on skin. The paradigm for antibacterial compositions is to provide a substantial and broad spectrum reduction in bacterial populations quickly and without adverse side effects associated with toxicity and skin irritation. Such antibacterial compositions are disclosed in U.S. Patent Nos. 6,107,261 and 6,136,771, each incorporated herein by reference.

One class of antibacterial personal care compositions is the hand sanitizer gels. This class of compositions is used primarily by medical personnel to disinfect the hands and fingers. The hand sanitizer gel is applied to, and rubbed into, the hands and fingers, and the composition is allowed to evaporate from the skin.

Hand sanitizer gels contain a high percentage of an alcohol, like ethanol. At the high percent of alcohol present in the gel, the alcohol itself acts as a disinfectant. In addition, the alcohol quickly evaporates to obviate wiping or rinsing skin treated with the sanitizer gel. Hand sanitizer gels containing a high percentage of an alcohol, i.e., about 40% or greater by weight of the composition, however, have a tendency to dry and irritate the skin.

Antibacterial cleansing compositions typically contain an active antibacterial agent, a surfactant, and various other ingredients, for example, dyes, fragrances,
pH adjusters, thickeners, skin conditioners, and the like, in an aqueous and/or alcoholic carrier. Several different classes of antibacterial agents have been used in antibacterial cleansing compositions. Examples of antibacterial agents include bisguanidines (e.g., chlorhexidine digluconate), diphenyl compounds, benzyl alcohols, trihalocarbanilides, quaternary ammonium compounds, ethoxylated phenols, and phenolic compounds, such as halo-substituted phenolic compounds, like PCMX (i.e., p-chloro-m-xylanol) and triclosan (i.e., 2,4,4'-trichloro-2'hydroxydiphenylether). Antimicrobial compositions based on such antibacterial agents exhibit a wide range of antibacterial activity, ranging from low to high, depending on the microorganism to be controlled and the particular antibacterial composition.

Most commercial antibacterial compositions generally offer a low to moderate antibacterial activity, and no reported antiviral activity. Antibacterial activity is assessed against a broad spectrum of microorganisms, including both Gram positive and Gram negative microorganisms. The log reduction, or alternatively the percent reduction, in bacterial populations provided by the antibacterial composition correlates to antibacterial activity. A 1-3 log reduction is preferred, a log reduction of 3-5 is most preferred, whereas a log reduction of less than 1 is least preferred, for a particular contact time, generally ranging from 15 seconds to 5 minutes. Thus, a highly preferred antibacterial composition exhibits a 3-5 log reduction against a broad spectrum of microorganisms in a short contact time.

Virus control poses a more difficult problem, however. By sufficiently reducing bacterial populations, the risk of bacterial infection is reduced to acceptable levels. Therefore, a rapid antibacterial kill is de-
sired. With respect to viruses, however, not only is a rapid kill desired, but a persistent antiviral activity also is required. This difference is because merely reducing a virus population is insufficient to reduce infection. In theory, a single virus can cause infection. Therefore, an essentially total, and persistent, antiviral activity is required, or at least desired, for an effective antiviral cleansing composition.

WO 98/01110 discloses compositions comprising triclosan, surfactants, solvents, chelating agents, thickeners, buffering agents, and water. WO 98/01110 is directed to reducing skin irritation by employing a reduced amount of surfactant.

U.S. Patent No. 5,635,462 discloses compositions comprising PCMIX and selected surfactants. The compositions disclosed therein are devoid of anionic surfactants and nonionic surfactants.

EP 0 505 935 discloses compositions containing PCMIX in combination with nonionic and anionic surfactants, particularly nonionic block copolymer surfactants.

WO 95/32705 discloses a mild surfactant combination that can be combined with antibacterial compounds, like triclosan.

WO 95/09605 discloses antibacterial compositions containing anionic surfactants and alkylpolyglycoside surfactants.

WO 98/55096 discloses antimicrobial wipes having a porous sheet impregnated with an antibacterial composition containing an active antimicrobial agent, an anionic surfactant, an acid, and water, wherein the composition has a pH of about 3.0 to about 6.0.

the antibacterial activity of active antibacterial agents in combination with surfactants.


With respect to hand sanitizer gels, U.S. Patent No. 5,776,430 discloses a topical antimicrobial cleaner containing chlorhexidine and an alcohol. The compositions contain about 50% to 60%, by weight, de-natured alcohol and about 0.65% to 0.85%, by weight, chlorhexidine. The composition is applied to the skin, scrubbed into the skin, then rinsed from the skin.

European Patent Application 0 604 848 discloses a gel-type hand disinfectant containing an antimicrobial agent, 40% to 90% by weight of an alcohol, and a polymer and a thickening agent in a combined weight of not more than 3% by weight. The gel is rubbed into the hands and allowed to evaporate to provide disinfected hands. As illustrated in EP 0 604 848, the amount and identity of the antibacterial agent is not considered important because the hand sanitizer gels contain a high percentage of an alcohol to provide antibacterial activity. The disclosed compositions often do not provide immediate sanitization and do not provide a persistent antimicrobial efficacy.

In general, hand sanitizer gels typically contain: (a) at least 60% by weight ethanol or a combination of lower alcohols, such as ethanol and isopropanol, (b) water, (c) a gelling polymer, such as a crosslinked polyacrylate material, and (d) other ingredients, such as skin conditioners, fragrances, and the like. Hand sanitizer gels are used by consumers to effectively sanitize the hands, without, or after, washing with soap and
water, by rubbing the hand sanitizer gel on the surface of the hands. Current commercial hand sanitizer gels rely on high levels of alcohol for disinfection and evaporation, and thus suffer from disadvantages. Specifically, current hand sanitizer gels have a tendency to dry and irritate the skin because of the high levels of alcohol employed in the compositions. Also, because of the volatility of ethanol, the primary active disinfec tant does not remain on the skin after use, thus failing to provide a persistent antimicrobial effect.

At alcohol concentrations below 60%, ethanol is not recognized as an antiseptic. Thus, in compositions containing less than 60% alcohol, an additional antimicrobial compound must be present to provide antimicrobial activity. Prior disclosures, however, have not addressed the issue of which composition ingredient in such an antimicrobial composition provides microbe control. Therefore, for formulations containing a reduced alcohol concentration, the selection of an antimicrobial agent that provides both a rapid antimicrobial effect and a persistent antimicrobial benefit is difficult.

U.S. Patent Nos. 6,107,261 and 6,136,771 disclose highly effective antibacterial compositions. These patents disclose compositions that solve the problem of controlling bacteria on skin and hard surfaces, but are silent with respect to controlling viruses. Applicants are aware of no reference that provides a solution for combating bacteria in a highly effective way, while simultaneously controlling viruses, in the form of a single composition.

Antiviral compositions that inactivate or destroy pathogenic viruses, including rhinovirus, rotavirus, influenza virus, parainfluenza virus, respiratory syncytial virus, and Norwalk virus, also are known. For
example, U.S. Patent No. 4,767,788 discloses the use of glutaric acid to inactivate or destroy viruses, including rhinovirus. U.S. Patent No. 4,975,217 discloses compositions containing an organic acid and an anionic surfactant, for formulation on a soap or lotion, to control viruses. U.S. Patent Publication 2002/0098159 discloses the use of a proton donating agent and a surfactant, including an antibacterial surfactant, to effect antiviral and antibacterial properties.

U.S. Patent No. 6,034,133 discloses a virucidal hand lotion containing malic acid, citric acid, and a C<sub>1-6</sub> alcohol. U.S. Patent No. 6,294,186 discloses combinations of a benzoic acid analog, such as salicylic acid, and selected metal salts as being effective against viruses, including rhinovirus. U.S. Patent No. 6,436,885 discloses a combination of known antibacterial agents with 2-pyrrolidone-5-carboxylic acid, at a pH of 2 to 5.5, to provide antibacterial and antiviral properties.

Organic acids in personal washing compositions also have been disclosed. For example, WO 97/46218 and WO 96/06152 disclose the use of organic acids or salts, hydrotropes, triclosan, and hydric solvents in a surfactant base for antimicrobial cleansing compositions. These publications are silent with respect to antiviral properties.

Hayden et al., *Antimicrobial Agents and Chemotherapy*, 26:928-929 (1984), discloses interrupting the hand-to-hand transmission of rhinovirus colds through the use of a hand lotion having residual virucidal activity. The hand lotions, containing 2% glutaric acid, were more effective than a placebo in inactivating certain types of rhinovirus. However, the publication discloses that the glutaric acid-containing lotions were not effective against a wide spectrum of rhinovirus serotypes.
A virucidal tissue designed for use by persons infected with the common cold, and including citric acid, malic acid, and sodium lauryl sulfate, is known. Hayden et al., Journal of Infectious Diseases, 152:493-497 (1985), however, reported that use of paper tissues, either treated with virus-killing substances or untreated, can interrupt the hand-to-hand transmission of viruses. Hence, no distinct advantage in preventing the spread of rhinovirus colds can be attributed to the compositions incorporated into the virucidal tissues.

An efficacious antimicrobial composition effective against both bacteria and viruses has been difficult to achieve because of the fundamental differences between a bacteria and a virus, and because of the properties of the antimicrobial agents and the effects of a surfactant on an antimicrobial agent. For example, several antimicrobial agents, like phenols, have an exceedingly low solubility in water, e.g., triclosan solubility in water is about 5 to 10 ppm (parts per million). The solubility of the antimicrobial agent is increased by adding surfactants to the composition. However, an increase in solubility of the antimicrobial agent, and, in turn, the amount of antimicrobial agent in the composition, does not necessarily lead to an increased efficacy.

Although a number of antimicrobial cleansing products currently exist, taking a variety of product forms (e.g., deodorant soaps, hard surface cleaners, and surgical disinfectants), such antimicrobial products typically incorporate high levels of alcohol and/or harsh surfactants, which can dry out and irritate skin tissues. Ideally, personal cleansing products gently cleanse the skin, cause little or no irritation, and do not leave the skin overly dry after frequent use.
Accordingly, a need exists for an antimicrobial composition that is highly efficacious against a broad spectrum of microbes, including viruses and Gram positive and Gram negative bacteria, in a short time period, and wherein the composition can provide a persistent antiviral activity, and is mild to the skin. Cleansing products demonstrating improved mildness and a heightened level of viral and bacterial reduction are provided by the antimicrobial compositions of the present invention.

**SUMMARY OF THE INVENTION**

The present invention is directed to antimicrobial compositions that provide a rapid antiviral and antibacterial effectiveness, and a persistent antiviral effectiveness. The compositions provide a substantial viral control and a substantial reduction in Gram positive and Gram negative bacteria in less than about one minute.

More particularly, the present invention relates to antimicrobial compositions containing an active antimicrobial agent, a disinfecting alcohol, a gelling agent, an organic acid, and water, wherein the antimicrobial agent is present in the continuous aqueous phase (in contrast to being present in micelles) in an amount of at least 50% of saturation, when measured at room temperature.

Accordingly, one aspect of the present invention is to provide an antimicrobial composition that is highly effective at killing a broad spectrum of bacteria, including Gram positive and Gram negative bacteria such as *S. aureus*, *Salmonella choleraesuis*, *E. coli*, and *K. pneumoniae*, while simultaneously inactivating or destroying viruses harmful to human health, particularly acid-
labile viruses, and especially rhinoviruses and other acid-labile picornaviruses.

Another aspect of the present invention is to provide a liquid, antimicrobial composition comprising:

(a) about 0.001% to about 5%, by weight, of a phenolic antimicrobial agent;

(b) about 1% to about 40%, by weight, of a disinfecting alcohol, like a C₁₋₅ alcohol;

(c) about 0.1% to about 5%, by weight, of a gelling agent, like a colloidal or a polymeric gelling agent;

(d) a virucidally effective amount of an organic acid; and

(e) water,

wherein the antimicrobial agent is present in the composition in an amount of at least 50% of saturation concentration, when measured at room temperature, and wherein the composition has a pH of about 5 or less. In preferred embodiments, the composition is free of a surfactant.

Another aspect of the present invention is to provide an antimicrobial composition having antibacterial and antiviral activity comprising a phenolic antimicrobial agent, a disinfecting alcohol, a gelling agent, and an organic acid selected from the group consisting of a monocarboxylic acid, a polycarboxylic acid, a polymeric acid having a plurality of carboxylic, phosphate, sulfonate, and/or sulfate moieties, and mixtures thereof.

Another aspect of the present invention is to provide an antimicrobial composition that exhibits a substantial, wide spectrum, and persistent viral control, and has a pH of about 2 to about 5.

Yet another aspect of the present invention is to provide an antimicrobial composition that exhibits a
log reduction against Gram positive bacteria (i.e., *S. aureus*) of at least 2 after 30 seconds of contact.

Still another aspect of the present invention is to provide an antimicrobial composition that exhibits a log reduction against Gram negative bacteria (i.e., *E. coli*) of at least 2.5 after 30 seconds of contact.

Another aspect of the present invention is to provide an antimicrobial composition that exhibits a log reduction against acid-labile viruses, including rhinovirus serotypes, such as Rhinovirus 14, Rhinovirus 1a, Rhinovirus 2, and Rhinovirus 4, of at least 4 after 30 seconds of contact. The antimicrobial composition also provides a log reduction against acid-labile viruses of at least 3 for at least about five hours, and at least 2 for at least about six hours, after application with a 30 second contact time. In some embodiments, the antimicrobial composition provides a log reduction against nonenveloped virus of about 2 for up to about eight hours.

Another aspect of the present invention is to provide consumer products based on an antimicrobial composition of the present invention, for example, a skin cleanser, a body splash, a surgical scrub, a wound care agent, a hand sanitizer gel, a disinfectant, a mouth wash, a pet shampoo, a hard surface sanitizer, a lotion, an ointment, a cream, and the like. A composition of the present invention can be a rinse-off product or, preferably, a leave-on product. The compositions are esthetically pleasing and nonirritating to the skin.

A further aspect of the present invention is to provide a method of quickly controlling a wide spectrum of viruses and the Gram positive and/or Gram negative bacteria populations on animal tissue, including human tissue, by contacting the tissue, like the dermis, with a composition of the present invention for a suffi-
cient time, for example, about 15 seconds to 5 minutes or
longer, to reduce bacterial and viral population levels
to a desired level. A further aspect of the present in-
vvention is to provide a composition that exhibits a per-
sistent control of viruses on animal tissue.

Yet another aspect of the present invention is
5 to provide a composition and method of interrupting
transmission of a virus from animate and inanimate sur-
faces to an animate surface, especially human skin. Es-
10 pecially provided is a method and composition for con-
trolling the transmission of rhinovirus by effectively
controlling rhinoviruses present on human skin and con-
tinuing to control rhinoviruses for a period of about
four hours or more after application of the composition
to the skin.

These and other novel aspects and advantages
of the present invention are set forth in the following,
nonlimiting detailed description of the preferred embodi-
ments.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Personal care products incorporating an active
antimicrobial agent have been known for many years.
Since the introduction of antimicrobial personal care
products, many claims have been made that such products
20 provide antimicrobial properties. To be most effective,
an antimicrobial composition should provide a high log
reduction against a broad spectrum of organisms in as
short a contact time as possible. Ideally, the composi-
tion also should inactivate viruses.

As presently formulated, most commercial
liquid antibacterial soap compositions provide a poor to
marginal time kill efficacy, i.e., rate of killing bac-
teria. These compositions do not effectively control viruses.

Antimicrobial hand sanitizer compositions typically do not contain a surfactant and rely upon a high concentration of an alcohol to control bacteria. The alcohols evaporate and, therefore, cannot provide a persistent bacterial control. The alcohols also can dry and irritate the skin.

Most current products especially lack efficacy against Gram negative bacteria, such as *E. coli*, which are of particular concern to human health. Compositions do exist, however, that have an exceptionally high broad spectrum antibacterial efficacy, as measured by a rapid kill of bacteria (i.e., time kill), which is to be distinguished from persistent kill. These products also lack a sufficient antiviral activity.

The present antimicrobial compositions provide excellent broad spectrum antibacterial efficacy and significantly improve antiviral efficacy compared to prior compositions that incorporate a high percentage of an alcohol, i.e., greater than 40%, by weight. The basis of this improved efficacy is the discovery that the antimicrobial efficacy of an active agent can be correlated to the rate at which the agent has access to an active site on the microbe and to the pH of the surface after application of the composition to the surface.

The driving force that determines the rate of antimicrobial agent transport to the site of action is the difference in chemical potential between the site at which the agent acts and the external aqueous phase. Alternatively stated, the microbicidal activity of an active agent is proportional to its thermodynamic activity in the external phase. Accordingly, thermodynamic activity, as opposed to concentration, is the more im-
Important variable with respect to antimicrobial efficacy. As discussed more fully hereafter, thermodynamic activity is conveniently correlated to the percent saturation of the active antibacterial agent in the continuous aqueous phase of the composition.

Many compounds have a solubility limit in aqueous solutions termed the "saturation concentration," which varies with temperature. Above the saturation concentration, the compound precipitates from solution.

Percent saturation is the measured concentration in solution divided by the saturation concentration. The concentration of a compound in aqueous solution can be increased over the saturation concentration in water by the addition of compounds like surfactants. Surfactants not only increase the solubility of compounds in the continuous aqueous phase of the composition, but also form micelles, and can solubilize compounds in the micelles.

The % saturation of an active antimicrobial agent in any composition, including a surfactant-containing composition, ideally can be expressed as:

\[ \text{% saturation} = \left( \frac{C}{C_s} \right) \times 100\% \]

wherein \( C \) is the concentration of antimicrobial agent in solution in the composition and \( C_s \) is the saturation concentration of the antimicrobial agent in the composition at room temperature. While not wishing to be bound by any theory, applicants believe that the continuous aqueous phase of a surfactant-containing composition is in equilibrium with the micellar pseudophase of said composition, and further that any dissolved species, such as an antimicrobial active agent, is distributed between the aqueous continuous phase and the micellar pseudophase according to a partition law. Accordingly, the percent saturation, or alternatively the relative thermodynamic
activity or relative chemical potential, of an antimicrobial active agent dissolved in a surfactant-containing composition is the same everywhere within the composition. Thus, the terms percent saturation of the antimicrobial agent "in a composition," "in the aqueous continuous phase of a composition," and "in the micellar pseudophase of a composition" are interchangeable, and are used as such throughout this disclosure.

Maximum antimicrobial efficacy is achieved when the difference in thermodynamic activities of the active antimicrobial agent between the composition and the target organism is maximized (i.e., when the composition is more "saturated" with the active ingredient). A second factor affecting antimicrobial activity is the total amount of available antimicrobial agent present in the composition, which can be thought of as the "critical dose." It has been found that the total amount of active agent in the continuous aqueous phase of a composition greatly influences the time in which a desired level of antimicrobial efficacy is achieved, given equal thermodynamic activities. Thus, the two key factors affecting the antimicrobial efficacy of an active agent in a composition are: (1) its availability, as dictated by its thermodynamic activity, i.e., percent saturation in the continuous aqueous phase of a composition, and (2) the total amount of available active agent in the solution.

An ingredient in many antimicrobial cleansing compositions is a surfactant, which acts as a solubilizer, cleanser, and foaming agent. Surfactants affect the percent saturation of an antimicrobial agent in solution, or more importantly, affect the percent saturation of the active agent in the continuous aqueous phase of the composition. This effect can be explained in the case of a sparingly water-soluble antimicrobial agent in an aqueous
surfactant solution, where the active agent is distributed between the aqueous (i.e., continuous) phase and the micellar pseudophase. For antimicrobial agents of exceedingly low solubility in water, such as triclosan, the distribution is shifted strongly toward the micelles (i.e., a vast majority of the triclosan molecules are present in surfactant micelles, as opposed to the aqueous phase).

The ratio of surfactant to antimicrobial agent directly determines the amount of active agent present in the surfactant micelles, which in turn affects the percent saturation of the active agent in the continuous aqueous phase. It has been found that as the surfactant:active agent ratio increases, the number of micelles relative to active molecules also increases, with the micelles being proportionately less saturated with active agent as the ratio increases. Because active agent in the continuous phase is in equilibrium with active agent in the micellar pseudophase, as the saturation of antibacterial agent in the micellar phase decreases, so does the saturation of the antimicrobial agent in the continuous phase. The converse also is true. Active agent solubilized in the micellar pseudophase is not immediately available to contact the microorganisms, and it is the percent saturation of active agent in the continuous aqueous phase that determines the antimicrobial activity of the composition. The active agent present in the surfactant micelles, however, can serve as a reservoir of active agent to replenish the continuous aqueous phase as the active agent is depleted.

To summarize, the thermodynamic activity, or percent saturation, of an antimicrobial agent in the continuous aqueous phase of a composition drives antimicrobial activity. Further, the total amount of available
active agent determines the ultimate extent of efficacy. In compositions wherein the active agent is solubilized by a surfactant, the active agent present in surfactant micelles is not directly available for antimicrobial activity. For such compositions, the percent saturation of the active agent in the composition, or alternatively the percent saturation of the active agent in the continuous aqueous phase of the composition, determines antimicrobial efficacy.

Although compositions having a high percent saturation of an antimicrobial agent have demonstrated a rapid and effective antibacterial activity against Gram positive and Gram negative bacteria, control of viruses has been inadequate. Virus control on skin and inanimate surfaces is very important in controlling the transmission of numerous diseases.

For example, rhinoviruses are the most significant microorganisms associated with the acute respiratory illness referred to as the "common cold." Other viruses, such as parainfluenza viruses, respiratory syncytial viruses (RSV), enteroviruses, and coronaviruses, also are known to cause symptoms of the "common cold," but rhinoviruses are theorized to cause the greatest number of common colds. Rhinoviruses also are among the most difficult of the cold-causing viruses to control, and have an ability to survive on a hard dry surface for more than four days. Although the molecular biology of rhinoviruses is now understood, finding effective methods for preventing colds caused by rhinoviruses, and for preventing the spread of the virus to noninfected subjects, has been fruitless.

It is known that iodine is an effective antiviral agent, and provides a persistent antirhinoviral activity on skin. In experimentally induced and natural
cold transmission studies, subjects who used iodine products had significantly fewer colds than placebo users. This indicates that iodine is effective for prolonged periods at blocking the transmission of rhinoviral infections. Thus, the development of products that deliver both immediate and persistent antiviral activity would be effective in reducing the incidents of colds. Likewise, a topically applied composition that exhibits antiviral activity would be effective in preventing and/or treating diseases caused by other acid-labile viruses.

Virucidal means capable of inactivating or destroying a virus. As used herein, the term "persistent antiviral efficacy" or "persistent antiviral activity" means leaving a residue or imparting a condition on animate (e.g., skin) or inanimate surfaces that provides significant antiviral activity for an extended time after application. A composition of the present invention provides a persistent antiviral efficacy, i.e., preferably a log reduction of at least 2, and more preferably a log reduction of at least a log 3, against pathogenic acid-labile viruses, such as rhinovirus serotypes, within 30 seconds of contact with the composition. Antiviral activity is maintained for at least about 0.5 hour, preferably at least about 1 hour, and more preferably for at least about 2 hours, at least about 3 hours, and at least about 4 hours after contact with the composition. In some preferred embodiments, antiviral activity is maintained for about six to about eight hours after contact with the composition. The methodology utilized to determine persistent antiviral efficacy is discussed below.

The antimicrobial compositions of the present invention are highly effective in providing a rapid and broad spectrum control of bacteria, and a rapid, broad spectrum, and persistent control of viruses. The highly
effective compositions comprise a high percent saturation concentration of a phenolic antimicrobial agent, and a virucidally effective amount of an organic acid, in a phase stable formulation. The compositions are surprisingly mild to the skin, and noncorrosive to inanimate surfaces. Thus, mild and effective compositions that solve the problem of bacterial and viral control are provided to consumers.

The antimicrobial compositions of the present invention are highly efficacious in household cleaning applications (e.g., hard surfaces, like floors, countertops, tubs, dishes, and softer cloth materials, like clothing), personal care applications (e.g., lotions, shower gels, soaps, shampoos, and wipes), and industrial and hospital applications (e.g., sterilization of instruments, medical devices, and gloves). The present compositions efficaciously and rapidly clean and disinfect surfaces that are infected or contaminated with Gram negative bacteria, Gram positive bacteria, and acid-labile viruses (e.g., rhinoviruses). The present compositions also provide a persistent antiviral effectiveness.

The present compositions can be used in vitro and in vivo. In vitro means in or on nonliving things, especially on inanimate objects having hard or soft surfaces located or used where preventing viral transmission is desired, most especially on objects that are touched by human hands. In vivo means in or on animate objects, especially on mammal skin, and particularly on hands.

As illustrated in the following nonlimiting embodiments, an antimicrobial composition of the present invention comprises: (a) about 0.001% to about 5%, by weight, of a phenolic antimicrobial agent; (b) about 1% to about 40%, by weight, of a disinfecting alcohol; (c)
about 0.1% to about 5%, by weight, of a gelling agent; 
(d) a virucidally effective amount of an organic acid; 
and (e) water. The compositions have a percent satu- 
ration of antimicrobial agent in the continuous aqueous 
phase of at least about 50%, when measured at room tem- 
temperature, and a pH of less than about 5 at 25°C. 
The compositions can further include an option- 
tional hydro trope and/or polyhydric solvent, and addi- 
tional optional ingredients disclosed hereafter, like pH 
adjusters, dyes, skin conditioners, vitamins, and per- 
fumes. The present compositions are free of surfactants, 
i.e., contain 0% to about 0.5%, by weight, of compounds 
that exhibit surface activity. 
The compositions exhibit a log reduction 
against Gram positive bacteria of about 2 after 30 sec- 
onds contact. The compositions also exhibit a log reduc- 
tion against Gram negative bacteria of about 2.5 after 30 
seconds contact. The compositions further exhibit a log 
reduction against acid-labile viruses, including rhino- 
virus serotypes of about 4 after 30 seconds contact, and 
a log reduction against these acid-labile viruses of at 
least 3 about five hours, and at least 2 about six to 
about eight hours, after contact. The compositions also 
are mild, and it is not necessary to rinse or wipe the 
compositions from the skin. 
The following ingredients are present in an 
antimicrobial composition of the present invention. 

A. Antimicrobial Agent 

An antimicrobial agent is present in a com- 
position of the present invention in an amount of about 
0.001% to about 5%, and preferably about 0.01% to about 
2%, by weight of the composition. To achieve the full 
advantage of the present invention, the antimicrobial
agent is present in an amount of about 0.05% to about 1%, by weight of the composition.

The antimicrobial compositions can be ready to use compositions, which typically contain 0.001% to about 2%, preferably 0.01% to about 1.5%, and most preferably about 0.05% to about 1%, of an antimicrobial agent, by weight of the composition. The antimicrobial compositions also can be formulated as concentrates that are diluted before use with one to about 100 parts water to provide an end use composition. The concentrated compositions typically contain greater than about 0.1% and up to about 5%, by weight, of the antimicrobial agent. Applications also are envisioned wherein the end use composition contains greater than 2%, by weight, of the antimicrobial agent.

As discussed above, the absolute amount of antimicrobial agent present in the composition is not as important as the amount of available antimicrobial agent in the composition. The amount of available antimicrobial agent in the composition is related to the identity of the disinfecting alcohol in the composition, the amount of antimicrobial agent in the composition, and the presence and amount of gelling agent optional ingredients in the composition.

To achieve the desired bacteria kill in a short contact time, like 15 to 60 seconds, the continuous aqueous phase of the composition contains an amount of antimicrobial agent that is at least about 50%, preferably at least about 60%, and more preferably at least about 75%, of the saturation concentration of the antimicrobial agent in water, when measured at room temperature. To achieve the full advantage of the present invention, the continuous aqueous phase is about 95% to 100% saturated with the antimicrobial agent. The method
of determining percent saturation of antibacterial agent in the composition is disclosed hereafter.

The antimicrobial agents useful in the present invention are phenolic compounds exemplified by the following classes of compounds:

(a) 2-Hydroxydiphenyl compounds

\[
\begin{align*}
&\text{wherein } Y \text{ is chlorine or bromine, } Z \text{ is } \text{SO}_2\text{H, NO}_2, \text{ or } \text{C}_1-\text{C}_4 \text{ alkyl, } r \text{ is } 0 \text{ to } 3, \ o \text{ is } 0 \text{ to } 3, \ p \text{ is } 0 \text{ or } 1, \ m \text{ is } 0 \text{ or } 1, \text{ and } n \text{ is } 0 \text{ or } 1. \\
&\text{In preferred embodiments, } Y \text{ is chlorine or bromine, } m \text{ is } 0, \ n \text{ is } 0 \text{ or } 1, \ o \text{ is } 1 \text{ or } 2, \ r \text{ is } 1 \text{ or } 2, \text{ and } p \text{ is } 0.
\end{align*}
\]

In especially preferred embodiments, Y is chlorine, m is 0, n is 0, o is 1, r is 2, and p is 0.

A particularly useful 2-hydroxydiphenyl compound has a structure:

\[
\begin{align*}
\text{Cl} &\quad \text{O} &\quad \text{Cl} \\
\text{OH} &\quad \text{Cl}
\end{align*}
\]

having the adopted name, triclosan, and available commercially under the tradename IRGASAN DP300, from Ciba Specialty Chemicals Corp., Greensboro, NC. Another useful 2-hydroxydiphenyl compound is 2,2'-dihydroxy-5,5'-dibromo-diphenyl ether.
(b) Phenol derivatives

wherein R₁ is hydro, hydroxy, C₁-C₄ alkyl, chloro, nitro, phenyl, or benzyl; R₂ is hydro, hydroxy, C₁-C₄ alkyl, or halo; R₃ is hydro, C₁-C₄ alkyl, hydroxy, chloro, nitro, or a sulfur in the form of an alkali metal salt or ammonium salt; R₄ is hydro or methyl; and R₅ is hydro or nitro. Halo is bromo or, preferably, chloro.

Specific examples of phenol derivatives include, but are not limited to, chlorophenols (o-, m-, p-), 2,4-dichlorophenol, p-nitrophenol, picric acid, xylenol, p-chloro-m-xylenol, cresols (o-, m-, p-), p-chloro-m-cresol, pyrocatechol, resorcinol, 4-n-hexyl-resorcinol, pyrogallol, phloroglucin, carvacrol, thymol, p-chlorothymol, o-phenylphenol, o-benzylphenol, p-chloro-o-benzylphenol, phenol, 4-ethylphenol, and 4-phenolsulfonic acid. Other phenol derivatives are listed in U.S. Patent No. 6,436,885, incorporated herein by reference.

(c) Diphenyl Compounds

wherein X is sulfur or a methylene group; R₆ and R₇ are hydroxy, and R₈, R₉, R₁₀, and
R'_{10}, independent of one another, are hydro or halo. Specific, nonlimiting examples of diphenyl compounds are hexachlorophene, tetrachlorophene, dichlorophene, 2,3-dihydroxy-5,5'-dichlorodiphenyl sulfide, 2,2'-dihydroxy-3,3',5,5'-tetrachlorodiphenyl sulfide, 2,2'-dihydroxy-3,5',5',6,6'-hexachlorodiphenyl sulfide, and 3,3'-dibromo-5,5'-dichloro-2,2'-dihydroxydiphenylamine. Other diphenyl compounds are listed in U.S. Patent No. 6,436,885, incorporated herein by reference.

10 B. Disinfecting Alcohol

An antimicrobial composition of the present invention contains about 1% to about 40%, by weight, of a disinfecting alcohol. Preferred embodiments contain about 2% to about 38%, by weight, of a disinfecting alcohol. Most preferred embodiments contain about 5% to about 30%, by weight, of a disinfecting alcohol.

As used herein, the term "disinfecting alcohol" is a water-soluble alcohol containing one to six carbon atoms, i.e., a C_{1-6} alcohol. Disinfecting alcohols include, but are not limited to, methanol, ethanol, propanol, and isopropyl alcohol.

C. Gelling Agent

The present antimicrobial compositions also contain about 0.01% to about 5%, by weight, and preferably 0.10% to about 3%, by weight, of a gelling agent. To achieve the full advantage of the present invention, the antimicrobial compositions contain about 0.25% to about 2.5%, by weight, of a gelling agent. The antimicrobial compositions typically contain a sufficient amount of gelling agent such that the composition is a viscous liquid, gel, or semisolid that can be easily
applied to, and rubbed on, the skin or other surface. Persons skilled in the art are aware of the type and amount of gelling agent to include in the composition to provide the desired composition viscosity or consistency.

The term "gelling agent" as used here and hereafter refers to a compound capable of increasing the viscosity of a water-based composition, or capable of converting a water-based composition to a gel or semisolid. The gelling agent, therefore, can be organic in nature, for example, a natural gum or a synthetic polymer, or can be inorganic in nature.

As previously stated, the present compositions are free of a surfactant. A surfactant is not intentionally added to a present antimicrobial composition, but may be present in an amount of 0% to about 0.5%, by weight, because a surfactant may be present in a commercial form of a gelling agent to help disperse the gelling agent in water. A surfactant also may be present as an additive or by-product in other composition ingredients.

Surfactants are omitted from the present compositions to help avoid micelle formation, which in turn solubilize the active antimicrobial compound and reduce its effectiveness. Similarly, preferred gelling agents are those that do not form micelles, and do not complex or bind with the active antimicrobial agents, or otherwise adversely effect the antimicrobial properties of the antimicrobial agent. Regardless of the identity of the gelling agent, the amount of gelling agent and other composition ingredients is selected such that the antimicrobial agent is present in an amount of at least 50% of saturation, when measured at room temperature.

The following are nonlimiting examples of gelling agents that can be used in the present invention. In particular, the following compounds, both organic and
inorganic, act primarily by thickening or gelling the aqueous portion of the composition:

acacia, agar, algin, alginic acid, ammonium alginate, ammonium chloride, ammonium sulfate, amylopectin, attapulgite, bentonite, C₃₅ alcohols, calcium acetate, calcium alginate, calcium carrageenan, calcium chloride, caprylic alcohol, carboxymethyl hydroxyethylcellulose, carboxymethyl hydroxypropyl guar, carrageenan, cellulose, cellulose gum, cetearyl alcohol, cetyl alcohol, corn starch, damar, dextrin, dibenzylidene sorbitol, ethylene dihydrogenated tallowamide, ethylene dioleamide, ethylene distearamide, gelatin, guar gum, guar hydroxypropyltrimonium chloride, hectorite, hyaluronic acid, hydrated silica, hydroxybutyl methylcellulose, hydroxyethylcellulose, hydroxyethyl ethylcellulose, hydroxyethyl stearamide-MIPA, hydroxypropylcellulose, hydroxypropyl guar, hydroxypropyl methylcellulose, isocetyl alcohol, isostearyl alcohol, karaya gum, kelp, lauryl alcohol, locust bean gum, magnesium aluminum silicate, magnesium silicate, magnesium trisilicate, methoxy PBG-22/dodecyl glycol copolymer, methylcellulose, microcrystalline cellulose, montmorillonite, myristyl alcohol, oat flour, oleyl alcohol, palm kernel alcohol, pectin, PBG-2M, PBG-5M, polyvinyl alcohol, potassium alginate, potassium carrageenan, potassium chloride, potassium sulfate, potato starch, propylene glycol alginate, sodium carboxymethyl dextran, sodium carrageenan, sodium cellulose sulfate, sodium chloride, sodium silicoaluminate, sodium sulfate, stearalkonium bentonite, stearalkonium hectorite, stearyl alcohol, tallow alcohol, TEA-hydrochloride, tragacanth gum, tridecyl alcohol, tromethamine magnesium aluminum silicate, wheat flour, wheat starch, xanthan gum, and mixtures thereof.
The following additional nonlimiting examples of gelling agents act primarily by thickening the non-aqueous portion of the composition:
abietyl alcohol, acrylinoleic acid, aluminum behenate, aluminum caprylate, aluminum dilinoleate, aluminum distearate, aluminum isostearates/laurates/palmitates or stearates, aluminum isostearates/myristates, aluminum isostearates/palmitates, aluminum isostearates/stearates, aluminum lanolate, aluminum myristates/palmitates, aluminum stearate, aluminum stearates, aluminum tristearate, beeswax, behenamide, behenyl alcohol, butadiene/acrylonitrile copolymer, a C23-70 acid, calcium behenate, calcium stearate, candelilla wax, carnauba, cerasin, cholesterol, cholesteryl hydroxystearate, coconut alcohol, copal, diglyceryl stearate malate, dihydroabietyl alcohol, dimethyl lauramine olate, dodecanedioic acid/cetearyl alcohol/glycol copolymer, erucamide, ethylcellulose, glyceryl triacetyl hydroxy-stearate, glyceryl triacetyl ricinoleate, glycol diolehenate, glycol dioctanoate, glycol distearate, hexanediol distearate, hydrogenated C5-14 olefin polymers, hydrogenated castor oil, hydrogenated cottonseed oil, hydrogenated lard, hydrogenated menhaden oil, hydrogenated palm kernel glycerides, hydrogenated palm kernel oil, hydrogenated palm oil, hydrogenated polyisobutene, hydrogenated soybean oil, hydrogenated tallow amide, hydrogenated tallow glyceride, hydrogenated vegetable glyceride, hydrogenated vegetable glycerides, hydrogenated vegetable oil, hydroxypropylcellulose, isobutylene/isoprene copolymer, isocetyl stearoyl stearate, Japan wax, jojoba wax, lanolin alcohol, lauramide, methyl dehydroabietate, methyl hydrogenated rosinate, methyl rosinate, methylstylene/vinyltoluene copolymer, microcrystalline wax, montan acid wax, montan wax, myrist-
yleicosanol, myristyloctadecanol, octadecene/maleic anhydride copolymer, octyldecyl stearoyl stearate, oleamide, oleostearine, oucury wax, oxidized polyethylene, ozokerite, palm kernel alcohol, paraffin, pentaerythritol hydrogenated rosinate, pentaerythrityl rosinate, pentaerythrityl tetraabietate, pentaerythrityl tetrabehenate, pentaerythrityl tetaoctanoate, pentaerythrityl tetraoleate, pentaerythrityl tetrastearate, phthalic anhydride/glycerin/glycidyl decanoate copolymer, phthalic/trimellitic/glycols copolymer, polybutene, polybutylene terephthalate, polydipentene, polyethylene, polyisobutene, polyisoprene, polyvinyl butyral, polyvinyl laurate, propylene glycol dicaprylate, propylene glycol dicocoate, propylene glycol diisononanoate, propylene glycol dilaurate, propylene glycol dipelargonate, propylene glycol distearate, propylene glycol diundecanoate, PVP/eicosene copolymer, PVP/hexadecene copolymer, rice bran wax, stearalkonium bentonite, stearalkonium hectorite, stearamide, stearamide DEA-distearate, stearamide DIBA-stearate, stearamide MEA-stearate, stearone, stearyl alcohol, stearyl erucamide, stearyl stearate, stearyl stearoyl stearate, synthetic beeswax, synthetic wax, trihydroxystearin, triisononanoic acid, triisostearyl trilinoleate, trilaurin, trilinoleic acid, trilinolein, trimyristin, triolein, tripalmitin, tri-stearin, zinc laurate, zinc myristate, zinc neodecanoate, zinc rosinate, zinc stearate, and mixtures thereof.

Exemplary gelling agents useful in the present invention include, but are not limited to,

<p>| Polyethylene Glycol &amp; Propylene Glycol &amp; Water | (ACULYN 44) |
| Ammonium Acrylatedimethyltaurate/VP Copolymer | (ARISTOFLEX AVC) |
| Glyceryl Stearate &amp; PBG 100 Stearate | (ARLACEL 165) |
| Polyethylene(2) Stearyl Ether | (BRIJ 72) |</p>
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Brand Name</th>
<th>Supplier Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyoxyethylene(21)Stearyl Ether</td>
<td>(BRIJ 721)</td>
<td></td>
</tr>
<tr>
<td>Silica</td>
<td>(CAB-O-SIL)</td>
<td></td>
</tr>
<tr>
<td>Polyquaternium 10</td>
<td>(CELQUAT CS230M)</td>
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</tr>
<tr>
<td>Cetyl Alcohol</td>
<td></td>
<td></td>
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<tr>
<td>Cetearyl Alcohol &amp; Cetereth 20</td>
<td>(COSMOWAX P)</td>
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<tr>
<td>Cetearyl Alcohol &amp; Diectyl Phosphate &amp; Ceteth-10 Phosphate</td>
<td>(CRODAPOS CES)</td>
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<tr>
<td>Ceteth-20 Phosphate &amp; Cetearyl Alcohol &amp; Diectyl Phosphate</td>
<td>(CRODAPOS CS-20 Acid)</td>
<td></td>
</tr>
<tr>
<td>Cetearyl Alcohol &amp; Cetereth 20</td>
<td>(EMULGAE NI 1000)</td>
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<tr>
<td>Sodium Magnesium Silicate</td>
<td>(LAPONITE XLG)</td>
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<tr>
<td>Cetyl Alcohol &amp; Stearyl Alcohol &amp; Stearalkonium Chloride &amp; Dimethyl Stearaline &amp; Lactic Acid</td>
<td>(MACKADET CBC)</td>
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<tr>
<td>Cetearyl Alcohol &amp; Stearamidopropylidimethylamine &amp; Stearamidopropylalkonium Chloride</td>
<td>(MACKERNIUM Essential)</td>
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<td>Stearalkonium Chloride</td>
<td>(MACKERNIUM SDC-85)</td>
<td></td>
</tr>
<tr>
<td>Cetearyl Alcohol &amp; Stearamidopropylidimethylamine &amp; Stearamidopropylalkonium Chloride &amp; Silicone Quat 16</td>
<td>(MACKERNIUM Ultra)</td>
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<tr>
<td>Cetearyl Alcohol &amp; Cetearyl Glucoside</td>
<td>(MONTANOV 68EC)</td>
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<tr>
<td>Hydroxyethylcellulose</td>
<td>(NATROSOL 250 HHR CS)</td>
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<td>Polyquaternium-37 &amp; Mineral Oil &amp; Trideceth-6</td>
<td>(SALCARE SC 95)</td>
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<tr>
<td>Polyquaternium-32 &amp; Mineral Oil &amp; Trideceth-6</td>
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<td>Stearic Acid</td>
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<tr>
<td>Cetyl Hydroxyethylcellulose</td>
<td>(NATROSOL Plus 330 CS)</td>
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<tr>
<td>Polynvinyl Alcohol, PVP-K30, Propylene Glycol</td>
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<tr>
<td>Stearic Acid, Behenyl Alcohol, Glyceril Stearate, Lecithin, C12-16 Alcohols, Palmic Acid</td>
<td>(PROLIPID 141)</td>
<td></td>
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<tr>
<td>Beeswax</td>
<td>(saponified beeswax)</td>
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<tr>
<td>Beeswax</td>
<td>(synthetic beeswax)</td>
<td></td>
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<tr>
<td>Water, Beeswax, Sesame Oil, Lecithin, Methyl paraben</td>
<td>(beesmilk)</td>
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<td>Polyquaternium 10</td>
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<tr>
<td>Sodium Acrylate/Sodium Acrylodimethyl Taurate Copolymer &amp; Isolexadecane &amp; Polysorbate 80</td>
<td>(SIMULGEL EG)</td>
<td></td>
</tr>
<tr>
<td>Polyquaternium 44</td>
<td>(LUVIQUAT Care)</td>
<td></td>
</tr>
</tbody>
</table>
D. **Organic Acid**

A present antimicrobial composition contains an organic acid in a sufficient amount to control and inactivate viruses on a surface contacted by the antimicrobial composition. The organic acid helps provide a rapid control of acid-labile viruses, and provides a persistent viral control.

In particular, an organic acid is present in the composition in a sufficient amount such that the pH of the animate or inanimate surface contacted by the composition is lowered to degree wherein a persistent viral control is achieved. This persistent viral control is achieved regardless of whether the composition is rinsed from, or allowed to remain on, the contacted surface. The organic acid remains at least partially undissociated in the composition, and remains so when the composition is diluted, or during application and rinsing.

Upon application to a surface, such as human skin, the pH of the surface is sufficiently lowered such that a persistent viral control is achieved. In preferred embodiments, a residual amount of the organic acid remains on the skin, even after a rinsing step, in order to impart a persistent viral control. However, even if the organic acid is essentially completely rinsed from the surface, the surface pH has been sufficiently lowered to impart a viral control for at least 0.5 hours.

Typically, an organic acid is present in a present composition in an amount of about 0.05% to about 6%, and preferably about 0.1% to about 5%, by weight of the composition. To achieve the full advantage of the present invention, the organic acid is present in an amount of about 0.15% to about 4%, by weight of the composition. The amount of organic acid is related to the
class of organic acid used, and to the identity of the specific acid or acids used.

An organic acid useful in a present antimicrobial composition comprises a monocarboxylic acid, a poly-
carboxylic acid, a polymeric acid having a plurality of carboxylic, phosphate, sulfonate, and/or sulfate moieties, or mixtures thereof. In addition to acid moieties, the organic acid also can contain other moieties, for example, hydroxy groups and/or amino groups. In addi-
tion, an organic acid anhydride can be used in a compos-
iton of the present invention as the organic acid.

In one embodiment, the organic acid comprises a monocarboxylic acid having a structure RCO₂H, wherein R is C₆-alkyl, hydroxyC₆-alkyl, haloC₆-alkyl, phenyl, or substituted phenyl. The monocarboxylic acid preferably has a water solubility of at least about 0.05%, by weight, at 25°C. The alkyl groups can be substituted with phenyl groups and/or phenoxy groups, and these phenyl and phenoxy groups can be substituted or unsub-
stituted.

Nonlimiting examples of monocarboxylic acids useful in the present invention are acetic acid, propi-
onic acid, hydroxyacetic acid, lactic acid, benzoic acid, phenylacetic acid, phenoxyacetic acid, zimanic acid, 2-, 3-, or 4-hydroxybenzoic acid, anilic acid, o-, m-, or p-
chlorophenylacetic acid, o-, m-, or p-chlorophenoxycetic acid, and mixtures thereof. Additional substituted benzoic acids are disclosed in U.S. Patent No. 6,294,186, incorporated herein by reference. Examples of substi-
tuted benzoic acids include, but are not limited to, salicylic acid, 2-nitrobenzoic acid, thiosalicylic acid,
2,6-dihydroxybenzoic acid, 5-nitrosalicylic acid, 5-
bromosalicylic acid, 5-iodosalicylic acid, 5-fluoro-
salicylic acid, 3-chlorosalicylic acid, 4-chlorosalicylic acid, 5-chlorosalicylic acid.

In another embodiment, the organic acid comprises a polycarboxylic acid. The polycarboxylic acid contains at least two, and up to four, carboxylic acid groups. The polycarboxylic acid also can contain hydroxy or amino groups, in addition to substituted and unsubstituted phenyl groups. Preferably, the polycarboxylic acid has a water solubility of at least about 0.05%, by weight, at 25°C.

Nonlimiting examples of polycarboxylic acids useful in the present invention include malonic acid, succinic acid, glutaric acid, adipic acid, pimelic acid, suberic acid, azelaic acid, sebacic acid, fumaric acid, maleic acid, tartaric acid, malic acid, maleic acid, citric acid, aconitic acid, and mixtures thereof.

Anhydrides of polycarboxylic and monocarboxylic acids also are organic acids useful in the present compositions. Preferred anhydrides are anhydrides of polycarboxylic acids. At least a portion of the anhydride is hydrolyzed to a carboxylic acid because of the pH of the composition. It is envisioned that an anhydride can be slowly hydrolyzed on a surface contacted by the composition, and thereby assist in providing a persistent antiviral activity.

In a third embodiment, the organic acid comprises a polymeric carboxylic acid, a polymeric sulfonic acid, a sulfated polymer, a polymeric phosphoric acid, and mixtures thereof. The polymeric acid has a molecular weight of about 500 g/mol to 10,000,000 g/mol, and includes homopolymers, copolymers, and mixtures thereof. The polymeric acid preferably is capable of forming a substantive film on a skin surface, and has a glass transition temperature, Tg, of less than about 25°C,
preferably less than about 20°C, and more preferably less than about 15°C. The glass transition temperature is the temperature at which an amorphous material, such as a polymer, changes from a brittle vitreous state to a plastic state. The $T_g$ of a polymer is readily determined by persons skilled in the art using standard techniques.

The polymeric acids are uncrosslinked or only very minimally crosslinked. The polymeric acids therefore are water soluble or at least water dispersible. The polymeric acids typically are prepared from ethylenically unsaturated monomers having at least one hydrophilic moiety, such as carboxyl, carboxylic acid anhydride, sulfonic acid, and sulfate.

Examples of monomers used to prepare the polymeric organic acid include, but are not limited to:

(a) Carboxyl group-containing monomers, e.g., monoethylenically unsaturated mono- or polycarboxylic acids, such as acrylic acid, methacrylic acid, maleic acid, fumaric acid, crotonic acid, sorbic acid, itaconic acid, ethacrylic acid, $\alpha$-chloroacrylic acid, $\alpha$-cyanoacrylic acid, $\beta$-methylacrylic acid (crotonic acid), $\alpha$-phenylacrylic acid, $\beta$-acryloxypropionic acid, sorbic acid, $\alpha$-chlorosorbic acid, angelic acid, cinnamic acid, p-chlorocinnamic acid, $\beta$-stearylacrylic acid, citraconic acid, mesaconic acid, glutaconic acid, aconitic acid, tricarboxyethylene, and cinnamic acid;

(b) Carboxylic acid anhydride group-containing monomers, e.g., monoethylenically unsaturated polycarboxylic acid anhydrides, such as maleic anhydride; and

(c) Sulfonic acid group-containing monomers, e.g., aliphatic or aromatic vinyl sulfonic acids, such as vinylsulfonic acid, allylsulfonic acid, vinyltoluenesulfonic acid, styrenesulfonic acid, sulfoethyl (meth)acrylate, 2-acrylamido-2-methylpropane sulfonic acid,
sulfopropyl (meth)acrylate, and 2-hydroxy-3-(meth)-
acryloxy propyl sulfonic acid.

The polymeric acid can contain other copoly-
erizable units, i.e., other monoethylenically unsaturated
comonomers, well known in the art, as long as the polymer
is substantially, i.e., at least 10%, and preferably at
least 25%, acid group containing monomer units. To
achieve the full advantage of the present invention, the
polymeric acid contains at least 50%, and more prefer-
ably, at least 75%, and up to 100%, acid group containing
monomer units. The other copolymerizable units, for
example, can be styrene, an alkyl acrylate, or an alkyl
methacrylate.

One preferred polymeric acid is a polyacrylic
acid, either a homopolymer or a copolymer, for example, a
copolymer of acrylic acid and an alkyl acrylate and/or
alkyl methacrylate. Another preferred polymeric acid is
a homopolymer or a copolymer of methacrylic acid.

Exemplary polymeric acids useful in the pres-
ent invention include, but are not limited to:
<table>
<thead>
<tr>
<th>Carbomers</th>
<th>(CARBOPOL 910, 934, 934P, 940, 941, ETD 2050; ULTEZ 10, 21)</th>
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<tr>
<td>Acrylates/C20-30 Alkyl Acrylate Crosspolymer</td>
<td>(ULTREZ 20)</td>
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<td>Acrylates/Beheneth 25 Methacrylate Copolymer</td>
<td>(ACULYN 28)</td>
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<td>Acrylates/Steareth 20 Methacrylate Copolymer</td>
<td>(ACULYN 22)</td>
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<tr>
<td>Acrylates/Steareth 20 Methacrylate Crosspolymer</td>
<td>(ACULYN 88)</td>
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<tr>
<td>Acrylates Copolymer</td>
<td>(CAPIGEL 98)</td>
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<tr>
<td>Acrylates Copolymer</td>
<td>(AVALURE AC)</td>
</tr>
<tr>
<td>Acrylates/Palmeth 25 Acrylate Copolymer</td>
<td>(SYNTHALEN 2000)</td>
</tr>
<tr>
<td>Ammonium Acrylate Copolymers</td>
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<tr>
<td>Sodium Acrylate/Vinyl Alcohol Copolymer</td>
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<tr>
<td>Sodium Polymethacrylate</td>
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<tr>
<td>Acrylamido-propyltrimonium Chloride/Acrylates Copolymer</td>
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<td>Acrylates/Acrylamide Copolymer</td>
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<tr>
<td>Acrylates/Ammonium Methacrylate Copolymer</td>
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</tr>
<tr>
<td>Acrylates/C10-30 Alkyl Acrylate Crosspolymer</td>
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<tr>
<td>Acrylates/Diacetoneacrylamide Copolymer</td>
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<tr>
<td>Acrylates/Octylacrylamide Copolymer</td>
<td></td>
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<tr>
<td>Acrylates/VA Copolymer</td>
<td></td>
</tr>
<tr>
<td>Acrylic Acid/Acrylonitrogens Copolymer</td>
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</tr>
</tbody>
</table>

In a preferred embodiment of the present invention, the organic acid comprises one or more polycarboxylic acid, e.g., citric acid, malic acid, tartaric acid, or a mixture of any two or all three of these acids, and a polymeric acid containing a plurality of carboxyl groups, for example, homopolymers and copolymers of acrylic acid or methacrylic acid.

**E. Carrier**

The carrier of the present antimicrobial composition comprises water.
F. Optional ingredients

An antimicrobial composition of the present invention also can contain optional ingredients well known to persons skilled in the art. The particular optional ingredients and amounts that can be present in the composition are discussed hereafter.

The optional ingredients are present in a sufficient amount to perform their intended function and not adversely affect the antimicrobial efficacy of the composition. Optional ingredients typically are present, individually and collectively, from 0% to about 50%, by weight of the composition.

Classes of optional ingredients include, but are not limited to, hydrotropes, polyhydric solvents, dyes, fragrances, pH adjusters, thickeners, viscosity modifiers, chelating agents, skin conditioners, emollients, preservatives, vitamins, buffering agents, foam stabilizers, antioxidants, foam enhancers, chelating agents, opacifiers, and similar classes of optional ingredients known to persons skilled in the art.

A hydrotrope, if present at all, is present in an amount of about 0.1% to about 30%, and preferably about 1% to about 20%, by weight of the composition. To achieve the full advantage of the present invention, a composition can contain about 2% to about 15%, by weight, of a hydrotrope.

A hydrotrope is a compound that has an ability to enhance the water solubility of other compounds. A hydrotrope utilized in the present invention lacks surfactant properties, and typically is a short-chain alkyl aryl sulfonate. Specific examples of hydrotropes include, but are not limited to, sodium cumene sulfonate, ammonium cumene sulfonate, ammonium xylene sulfonate, potassium toluene sulfonate, sodium toluene sulfonate,
sodium xylene sulfonate, toluene sulfonic acid, and xylene sulfonic acid. Other useful hydrotropes include sodium polynaphthalene sulfonate, sodium polystyrene sulfonate, sodium methyl naphthalene sulfonate, sodium camphor sulfonate, and disodium succinate.

A polyhydric solvent, if present at all, is present in an amount of about 0.1% to about 50%, and preferably about 5% to about 50%, by weight of the composition. To achieve the full advantage of the present invention, the polyhydric solvent is present in an amount of about 10% to about 50% by weight of the composition. In contrast to a disinfecting alcohol, a polyhydric solvent contributes minimally, if at all, to the antimicrobial efficacy of the present composition.

A "polyhydric solvent" is a water-soluble organic compound containing two to six, and typically two or three, hydroxyl groups. The term "water-soluble" means that the polyhydric solvent has a water solubility of at least 0.1 g of polyhydric solvent per 100 g of water at 25°C. There is no upper limit to the water solubility of the polyhydric solvent, e.g., the polyhydric solvent and water can be soluble in all proportions.

The term "polyhydric solvent" therefore encompasses water-soluble diols, triols, and polyols.

Specific examples of hydric solvents include, but are not limited to, ethylene glycol, propylene glycol, glycerol, diethylene glycol, dipropylene glycol, tripropylene glycol, hexylene glycol, butylene glycol, 1,2,6-hexanetriol, sorbitol, PEG-4, and similar polyhydroxy compounds.

Specific classes of optional ingredients include inorganic phosphates, sulfates, and carbonates as buffering agents; EDTA and phosphates as chelating agents; and acids and bases as pH adjusters.
Examples of preferred classes of optional basic pH adjusters are ammonia; mono-, di-, and tri-alkyl amines; mono-, di-, and tri-alkanolamines; alkali metal and alkali earth metal hydroxides; and mixtures thereof. However, the identity of the basic pH adjuster is not limited, and any basic pH adjuster known in the art can be used. Specific, nonlimiting examples of basic pH adjusters are ammonia; sodium, potassium, and lithium hydroxide; monoethanolamine; triethyamine; isopropanol-amine; diethanolamine; and triethanolamine.

Examples of preferred classes of optional acidic pH adjusters are the mineral acids. Nonlimiting examples of mineral acids are hydrochloric acid, nitric acid, phosphoric acid, and sulfuric acid. The identity of the acidic pH adjuster is not limited and any acidic pH adjuster known in the art, alone or in combination, can be used.

G. pH

The pH of a present antimicrobial composition is about 5 or less, and preferably about 4.5 or less, at 25°C. To achieve the full advantage of the present invention, the pH is less than about 4. Typically, the pH of a present composition is about 2 to less than about 5, and preferably about 2.5 to about 4.5.

The pH of the composition is sufficiently low such that at least a portion of the organic acid is in the protonated form. The organic acid then has the capability of lowering skin pH to provide an effective virus control, without irritating the skin. The organic acid also may deposit on the skin, and resist removal by rinsing, to provide a persistent antiviral effect.
To demonstrate the new and unexpected results provided by the antimicrobial compositions of the present invention, the following Examples are prepared, and the ability of the compositions to control Gram positive and Gram negative bacteria, and to control rhinovirus, is determined. The weight percentage listed in the examples represents the actual, or active, weight amount of each ingredient present in the composition. The compositions are prepared by blending the ingredients, as understood by those skilled in the art and as described below.

The following methods are used in the preparation and testing of the examples:

a) Determination of Rapid Germicidal (Time Kill) Activity of Antibacterial Products. The activity of antibacterial compositions is measured by the time kill method, whereby the survival of challenged organisms exposed to an antibacterial test composition is determined as a function of time. In this test, a diluted aliquot of the composition is brought into contact with a known population of test bacteria for a specified time period at a specified temperature. The test composition is neutralized at the end of the time period, which arrests the antibacterial activity of the composition. The percent or, alternatively, log reduction from the original bacteria population is calculated.

In general, the time kill method is known to those skilled in the art.

The composition can be tested at any concentration up to 100%. The choice of which concentration to use is at the discretion of the investigator, and suitable concentrations are readily determined by those skilled in the art. For example, viscous samples usually are tested at 50% dilution, whereas nonviscous samples are not diluted. The test sample is placed in a sterile
250 ml beaker equipped with a magnetic stirring bar and the sample volume is brought to 100 ml, if needed, with sterile deionized water. All testing is performed in triplicate, the results are combined, and the average log reduction is reported.

The choice of contact time period also is at the discretion of the investigator. Any contact time period can be chosen. Typical contact times range from 15 seconds to 5 minutes, with 30 seconds and 1 minute being typical contact times. The contact temperature also can be any temperature, typically room temperature, or about 25 degrees Celsius.

The bacterial suspension, or test inoculum, is prepared by growing a bacterial culture on any appropriate solid media (e.g., agar). The bacterial population then is washed from the agar with sterile physiological saline and the population of the bacterial suspension is adjusted to about $10^8$ colony forming units per ml (cfu/ml).

The table below lists the test bacterial cultures used in the tests and includes the name of the bacteria, the ATCC (American Type Culture Collection) identification number, and the abbreviation for the name of the organism used hereafter. S. aureus is a Gram positive bacteria, whereas E. coli, K. pneum, and S. cholera. are Gram negative bacteria.

<table>
<thead>
<tr>
<th>Organism Name</th>
<th>ATCC #</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>6538</td>
<td>S. aureus</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>11229</td>
<td>E. coli</td>
</tr>
<tr>
<td>Klebsiella pneumoniae</td>
<td>10031</td>
<td>K. pneum.</td>
</tr>
<tr>
<td>Salmonella choleraesuis</td>
<td>10708</td>
<td>S. chol.</td>
</tr>
</tbody>
</table>

The beaker containing the test composition is placed in a water bath (if constant temperature is de-
sired), or placed on a magnetic stirrer (if ambient laboratory temperature is desired). The sample then is inoculated with 1.0 ml of the test bacteria suspension. The inoculum is stirred with the test composition for the predetermined contact time. When the contact time expires, 1.0 ml of the test composition/bacteria mixture is transferred into 9.0 ml of Neutralizer Solution. Decimal dilutions to a countable range then are made. The dilutions can differ for different organisms. Selected dilutions are plated in triplicate on TSA+ plates (TSA+ is Trypticase Soy Agar with Lecithin and Polysorbate 80). The plates then are incubated for 24±2 hours, and the colonies are counted for the number of survivors and the calculation of percent or log reduction. The control count (numbers control) is determined by conducting the procedure as described above with the exception that de-ionized water is used in place of the test composition. The plate counts are converted to cfu/ml for the numbers control and samples, respectively, by standard microbiological methods.

The log reduction is calculated using the formula

\[
\text{Log reduction} = \log_{10}(\text{numbers controlled}) - \log_{10}(\text{test sample survivors}).
\]

The following table correlates percent reduction in bacteria population to log reduction:

<table>
<thead>
<tr>
<th>% Reduction</th>
<th>Log Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>90</td>
<td>1</td>
</tr>
<tr>
<td>99</td>
<td>2</td>
</tr>
<tr>
<td>99.9</td>
<td>3</td>
</tr>
<tr>
<td>99.99</td>
<td>4</td>
</tr>
<tr>
<td>99.999</td>
<td>5</td>
</tr>
</tbody>
</table>
b) Antiviral Residual Efficacy Test


The method used to determine the Antiviral Index of the present invention is a modification of that described in Sattar I, a test for the virucidal activity of liquid hand washes (rinse-off products). The method is modified in this case to provide reliable data for leave-on products.

Modifications of Sattar I include the product being delivered directly to the skin as described below, virus inoculation of the fingerpads as described below, and viral recovery using ten-cycle washing. The inoculated skin site then is completely decontaminated by treating the area with 70% dilution of ethanol in water.

Procedure:

Ten-minute Test:

Subjects (5 per test product) initially wash their hands with a nonmedicated soap, rinse the hands, and allow the hands to dry.

The hands then are treated with 70% ethanol and air dried.

Test product (1.0 ml) is applied to the hands, except for the thumbs, and allowed to dry.
About 10 minutes (±30 seconds) after product application, 10 μl of a Rhinovirus 14 suspension (ATCC VR-284, approximately 1x10⁶ PFU (plaque-forming units)/ml) is topically applied using a micropipette to various sites on the hand within a designated skin surface area known as fingerpads. At this time, a solution of rhinovirus also is applied to the untreated thumb in a similar manner.

After a dry-down period of 7-10 minutes, the virus then is eluted from each of the various skin sites with 1 ml of eluent (Minimal Essential media (MEM)+1% pen-strep-glutamate), washing 10 times per site.

The inoculated skin site then is completely decontaminated by treating the area with a 1:10 dilution of domestic bleach (CLOROX® 5.25% sodium hypochlorite) in tap water, then rinsing with 70% ethanol. Viral titers are determined using standard techniques, i.e., plaque assays or TCID₅₀ (Tissue Culture Infectious Dose).

One-hour test:

Subjects are allowed to resume normal activities (with the exception of washing their hands) between the 1-hour and 3-hour timepoints. After one hour, a rhinovirus suspension is applied to and eluted from designated sites on the fingerpads exactly as described in above for the 10-minute test.

Example 1

A composition of the invention is prepared by admixing the following ingredients at the indicated weight percentages until homogeneous.
The pH of the composition is about 3.5. The composition has a percent saturation of TCS of 50%, and excellent antibacterial properties, exhibiting a greater than 3 log reduction in Gram positive and Gram negative bacteria in 30 seconds by the time kill test. The composition also eliminates human rhinovirus from the skin, and provides a persistent antiviral effect.

**Example 2**

A composition of the invention is prepared by admixing the following ingredients at the indicated weight percentages until homogeneous.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Weight Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triclosan (TCS)</td>
<td>0.15</td>
</tr>
<tr>
<td>PPG-9</td>
<td>11.5</td>
</tr>
<tr>
<td>Ethanol</td>
<td>26</td>
</tr>
<tr>
<td>Carbopol</td>
<td>0.1</td>
</tr>
<tr>
<td>Citric acid</td>
<td>3</td>
</tr>
<tr>
<td>Water</td>
<td>q.s.</td>
</tr>
</tbody>
</table>

The pH of the composition is about 3.5. The composition has a percent saturation of TCS of 50%, and an excellent antibacterial properties, exhibiting a greater than 3 log reduction in Gram positive and Gram negative bacteria in 30 seconds by the time kill test.
The composition also eliminates human rhinovirus from the skin, and provides a persistent antiviral effect.

The antimicrobial compositions of the present invention have several practical end uses, including hand cleansers, mouthwashes, surgical scrubs, body splashes, antiseptics, disinfectants, hand sanitizer gels, deodorants, dental care additives, mouthwashes, and similar personal care products. Additional types of compositions include foamed compositions, such as creams, mousse, and the like, and compositions containing organic and inorganic filler materials, such as emulsions, lotions, creams, pastes, and the like. The compositions further can be used as an antimicrobial cleanser for hard surfaces, for example, sinks and countertops in hospitals, food service areas, and meat processing plants. The present antimicrobial compositions can be manufactured as dilute ready-to-use compositions, or as concentrates that are diluted prior to use.

The present invention, therefore, encompasses applying an effective amount of the antimicrobial cleansing compositions of the present invention onto nonskin surfaces, such as household surfaces, e.g., countertops, kitchen surfaces, food preparing surfaces (cutting boards, dishes, pots and pans, and the like); major household appliances, e.g., refrigerators, freezers, washing machines, automatic dryers, ovens, microwave ovens, and dishwashers; cabinets; walls; floors; bathroom surfaces, shower curtains, garbage cans, and/or recycling bins, and the like.

The compositions also can be incorporated into a web material to provide an antimicrobial wiping article. The wiping article can be used to clean and sanitize animate or inanimate surfaces.
In one embodiment of the present invention, a person suffering from a rhinovirus cold, or who is likely to be exposed to other individuals suffering from a rhinovirus cold, can apply a present antimicrobial composition to his or her hands. This application kills bacteria and inactivates rhinovirus particles present on the hands. The applied composition, either rinsed off or allowed to remain on the hands, provides a persistent antiviral activity. Rhinovirus particles therefore are not transmitted to noninfected individuals via hand-to-hand transmission. The amount of the composition applied, the frequency of application, and the period of use will vary depending upon the level of disinfection and cleansing desired, e.g., the degree of microbial contamination and/or skin soiling.

The present antimicrobial compositions provide the advantages of a broad spectrum kill of Gram positive and Gram negative bacteria, and a broad spectrum viral control, in short contact times. The short contact time for a substantial log reduction of bacteria is important in view of the typical 15 to 60 second time frame used to cleanse and sanitize the skin and inanimate surfaces. The composition also imparts a persistent antiviral activity to the contacted surface.

The present compositions are effective in short contact time because the antimicrobial agent is present in the aqueous continuous phase of the composition, as opposed to surfactant micelles, and because of the reduced pH of the composition. The antimicrobial agent, therefore, is available to immediately begin reducing bacterial populations, and further is available to deposit on the skin to provide persistent antimicrobial efficacy. In addition, because the antimicrobial agent is in solution as opposed to surfactant micelles, the
absolute amount of antimicrobial agent in the composition can be reduced without adversely affecting efficacy, and the antimicrobial agent is not rinsed from the skin with the surfactant prior to performing its antimicrobial function. In addition, the amount of surfactant in the present antimicrobial compositions typically is low, thereby providing additional environmental benefits.

Obviously, many modifications and variations of the invention as hereinbefore set forth can be made without departing from the spirit and scope thereof, and, therefore, only such limitations should be imposed as are indicated by the appended claims.
WHAT IS CLAIMED IS:

1. A method of reducing a bacteria and a virus population on a surface comprising contacting the surface with a composition for 30 seconds to achieve a log reduction of at least 2 against S. aureus, a log reduction of at least 2.5 against E. coli, and a log reduction of at least 4 against an acid-labile virus, said composition comprising
   (a) about 0.001% to about 5%, by weight, of a phenolic antimicrobial agent;
   (b) about 1% to about 40%, by weight, of a disinfecting alcohol;
   (c) about 0.1% to about 5%, by weight, of a gelling agent;
   (d) a virucidally effective amount of an organic acid; and
   (e) water,
   wherein the antimicrobial agent is present in the composition in an amount of at least 50% of saturation concentration, when measured at room temperature, and wherein the composition has a pH of about 5 or less at 25°C.

2. The method of claim 1 wherein the acid-labile virus comprises a rhinovirus serotype.

3. The method of claim 1 further comprising a step of rinsing the composition from the surface.

4. The method of claim 1 wherein the surface is a skin of a mammal.
5. The method of claim 4 wherein the composition lowers a pH of skin to less than 4 after drying on the skin.

6. The method of claim 1 wherein the surface is a hard, inanimate surface.

7. The method of claim 1 wherein the composition imparts a persistent antiviral activity to the surface.

8. The method of claim 1 wherein the composition comprises about 0.01% to about 2%, by weight, of the phenolic antibacterial agent.
9. The method of claim 1 wherein the phenolic antibacterial agent is selected from the group consisting of:

(a) a 2-hydroxydiphenyl compound having the structure

\[ \begin{array}{c}
\text{Z}_p \quad \text{Y}_0 \\
\text{(OH)}_m \\
\text{OH} \\
\text{Y}_r \\
\text{(OH)}_n
\end{array} \]

wherein \( Y \) is chlorine or bromine, \( Z \) is \( \text{SO}_2\text{H}, \text{NO}_2 \), or \( \text{C}_1-\text{C}_4 \) alkyl, \( r \) is 0 to 3, \( o \) is 0 to 3, \( p \) is 0 or 1, \( m \) is 0 or 1, and \( n \) is 0 or 1;

(b) a phenol derivative having the structure

\[ \begin{array}{c}
\text{R}_5 \\
\text{R}_4 \\
\text{R}_3 \\
\text{R}_2 \\
\text{R}_1
\end{array} \]

wherein \( R_1 \) is hydro, hydroxy, \( \text{C}_1-\text{C}_4 \) alkyl, chloro, nitro, phenyl, or benzyl, \( R_3 \) is hydro, hydroxy, \( \text{C}_1-\text{C}_6 \) alkyl, or halo, \( R_5 \) is hydro, \( \text{C}_1-\text{C}_6 \) alkyl, hydroxy, chloro, nitro, or a sulfur in the form of an alkali metal salt or ammonium salt, \( R_4 \) is hydro or methyl, and \( R_5 \) is hydro or nitro;

(c) a diphenyl compound having the structure
wherein X is sulfur or a methylene group, R₆ and R'₆ are hydroxy, and R₇, R'₇, R₈, R'₈, R₉, R'₉, R₁₀, and R'₁₀, independent of one another, are hydro or halo; and
(d) mixtures thereof.

10. The method of claim 9 wherein the antimicrobial agent comprises triclosan, p-chloro-m-xylenol, or a mixture thereof.

11. The method of claim 1 wherein the antimicrobial agent is present in an amount of at least 60% of saturation concentration.

12. The method of claim 1 wherein the antimicrobial agent is present in an amount of at least 75% of saturation concentration.

13. The method of claim 1 wherein the antimicrobial agent is present in an amount of at least 95% of saturation concentration.

14. The method of claim 1 wherein the disinfecting alcohol is present in the composition in an amount of about 2% to about 35%, by weight.

15. The method of claim 1 wherein the disinfecting alcohol is present in the composition in an amount of about 5% to about 30%, by weight.
16. The method of claim 1 wherein the disinfecting alcohol is a C$_1$-6 alcohol or mixtures thereof.

17. The method of claim 1 wherein the disinfecting alcohol is selected from the group consisting of methanol, ethanol, isopropyl alcohol, n-butanol, n-propyl alcohol, and mixtures thereof.

18. The method of claim 1 wherein the gelling agent is present in the composition in an amount of about 0.1% to about 3%, by weight.

19. The method of claim 1 wherein the gelling agent is present in the composition in an amount of about 0.25% to about 2.5%, by weight.

20. The method of claim 1 wherein the gelling agent comprises a natural gum, a synthetic polymer, a clay, an oil, a wax, and mixtures thereof.

21. The method of claim 1 wherein the gelling agent is selected from the group consisting of cellulose, a cellulose derivative, guar, a guar derivative, algin, an algin derivative, a water-insoluble C$_8$-C$_{20}$ alcohol, carrageenan, a smectite clay, a polyquaternium compound, and mixtures thereof.

22. The method of claim 1 wherein the composition is free of a surfactant.

23. The method of claim 1 wherein the composition comprises about 0.05% to about 6%, by weight, of the organic acid.
24. The method of claim 1 wherein the organic acid has a water solubility of at least about 0.05% by weight, at 25°C.

25. The method of claim 1 wherein the organic acid comprises a monocarboxylic acid, a polycarboxylic acid, a polymeric acid having a plurality of carboxylic, phosphate, sulfonate, and/or sulfate moieties, anhydrides thereof, or mixtures thereof.

26. The method of claim 1 wherein the organic acid comprises a monocarboxylic acid having a structure RCO₂H, wherein R is C₃₋₃alkyl, hydroxyC₃₋₃alkyl, haloC₃₋₃alkyl, phenyl, or substituted phenyl.

27. The method of claim 26 wherein the monocarboxylic acid is selected from the group consisting of acetic acid, propionic acid, hydroxyacetic acid, lactic acid, benzoic acid, phenylacetic acid, phenoxyacetic acid, zimanic acid, 2-, 3-, or 4-hydroxybenzoic acid, anilic acid, o-, m-, or p-chlorophenylacetic acid, o-, m-, or p-chlorophenoxyacetic acid, and mixtures thereof.

28. The method of claim 1 wherein the organic acid comprises a polycarboxylic acid containing two to four carboxylic acid groups, and optionally contains one or more hydroxyl group, amino group, or both.
29. The method of claim 28 wherein the polycarboxylic acid is selected from the group consisting of malonic acid, succinic acid, glutaric acid, adipic acid, pimelic acid, suberic acid, azelaic acid, sebacic acid, fumaric acid, maleic acid, tartaric acid, malic acid, maleic acid, citric acid, aconitic acid, and mixtures thereof.

30. The method of claim 1 wherein the organic acid comprises a polymeric acid having a molecular weight of about 500 to about 10,000,000 g/mol.

31. The method of claim 30 wherein the polymeric acid is water soluble or water dispersible.

32. The method of claim 30 wherein the polymeric acid is selected from the group consisting of a polymeric carboxylic acid, a polymeric sulfonic acid, a sulfated polymer, a polymeric phosphoric acid, and mixtures thereof.

33. The method of claim 25 wherein the polymeric acid comprises a homopolymer or a copolymer of acrylic acid.

34. The method of claim 1 wherein the organic acid comprises an anhydride of a polycarboxylic acid.

35. The method of claim 25 wherein the organic acid comprises a polycarboxylic acid and a polymeric carboxylic acid.
36. The method of claim 35 wherein the polycarboxylic acid comprises citric acid, malic acid, tartaric acid, or mixtures thereof, and the polymeric carboxylic acid comprises a homopolymer or a copolymer of acrylic acid, or methacrylic acid.

37. The method of claim 36 wherein the polymeric acid comprises a homopolymer or a copolymer of acrylic acid.

38. The method of claim 1 wherein the composition has a pH of about 2 to less than about 5.

39. The method of claim 1 wherein the composition has a pH of about 2.5 to about 4.5.

40. The method of claim 1 wherein the composition further comprises a hydrotrope in amount of about 0.1% to about 30%, by weight.

41. The method of claim 1 wherein the composition further comprises about 0.1% to about 50% of a polyhydric solvent selected from the group consisting of a diol, a triol, and mixtures thereof.

42. The method of claim 4 wherein the skin has a log reduction against an acid-labile virus of at least 3 about five hours after contact with the composition.

43. The method of claim 4 wherein the skin has a log reduction against an acid-labile virus of at least 2 about eight hours after contact with the composition.
44. A method of inactivating viruses and killing bacteria comprising the step of topically applying a composition to a surface in need of such treatment, said composition comprising
(a) about 0.001% to about 5%, by weight, of a phenolic antimicrobial agent;
(b) about 1% to about 40%, by weight, of a disinfecting alcohol;
(c) about 0.1% to about 5%, by weight, of a gelling agent;
(d) a virucidally effective amount of an organic acid; and
(e) water,
wherein the antimicrobial agent is present in the composition in an amount of at least 50% of saturation concentration, when measured at room temperature, and wherein the composition has a pH of about 5 or less at 25°C.

45. The method of claim 44 wherein a persistent antiviral efficacy is imparted to the surface.

46. The method of claim 43 wherein the viruses are inactivated for up to about six hours.

47. The method of claim 44 wherein the surface is animate.

48. The method of claim 44 wherein the surface is inanimate.

49. The method of claim 44 wherein rhinoviruses are inactivated.
50. A method of improving the overall health of a mammal by reducing exposure to viruses and bacteria comprising the steps of:
   (a) topically applying a composition to a surface which is prone to viral and/or bacterial contamination; and
   (b) allowing the surface to dry,
        said composition comprising:
   (c) about 0.001% to about 5%, by weight, of a phenolic antimicrobial agent;
   (d) about 1% to about 40%, by weight, of a disinfecting alcohol;
   (e) about 0.1% to about 5%, by weight, of a gelling agent;
   (f) a virucidally effective amount of an organic acid; and
   (g) water,

wherein the antimicrobial agent is present in the composition in an amount of at least 50% of saturation concentration, when measured at room temperature, and wherein the composition has a pH of about 5 or less at 25°C.
51. A method of protecting an individual against infection by rhinoviruses comprising the step of applying a composition to hands of the individual in an amount sufficient to eradicate rhinoviruses, said composition comprising

(a) about 0.001% to about 5%, by weight, of a phenolic antimicrobial agent;
(b) about 1% to about 40%, by weight, of a disinfecting alcohol;
(c) about 0.1% to about 5%, by weight, of a gelling agent;
(d) a virucidally effective amount of an organic acid; and
(e) water,

wherein the antimicrobial agent is present in the composition in an amount of at least 50% of saturation concentration, when measured at room temperature, and wherein the composition has a pH of about 5 or less at 25°C.

52. The method of claim 50 wherein the composition is applied prior to the individual being exposed to rhinoviruses.

53. The method of claim 50 wherein the composition is applied multiple times within a twenty-four hour period.

54. The method of claim 50 wherein the composition is rinsed from the hands.

55. The method of claim 51 wherein the composition is allowed to dry and remain on the hands.
56. An antimicrobial composition comprising:
   (a) about 0.001% to about 5%, by weight, of a phenolic antimicrobial agent;
   (b) about 1% to about 40%, by weight, of a disinfecting alcohol;
   (c) about 0.1% to about 5%, by weight, of a gelling agent;
   (d) a virucidally effective amount of an organic acid; and
   (e) water,
   wherein the antimicrobial agent is present in the composition in an amount of at least 50% of saturation concentration, when measured at room temperature, and wherein the composition has a pH of about 5 or less at 25°C.